Patient Care Policy Agenda 3/18/2026

* ***Indicates policy is pending Medical Executive Committee's approval 3/23/2026***

Title	Area	Revised?	Summary of Changes
Policy For Ambulatory Care Organization	Ambulatory Care	Revised	Made changes in document to reflect the partnership between Ambulatory Medical Director and CSMs in clinic leadership.
Policy for Diagnostic Imaging Results for Resource Nurse	Ambulatory Care	New	No Comment Provided
Policy for Health Center Hours	Ambulatory Care	Revised	Looks like went through approvals not picking up new dates
Policy for Quick Response Cart	Ambulatory Care	Revised	No Comment Provided
Policy for Standing Orders: Nursing	Ambulatory Care	Revised	Updates
Procedure For Outpatient Critical and Urgent Test Results	Ambulatory Care	New	No Comment Provided
Policy For Cardiology Department Disaster Plan	Cardiology	New	No Comment Provided
Policy for Adverse Contrast Media Reaction/Non-Contrast Media Occurrances	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for Care of Critical Patients in the MRI Department	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for Declared Pregnant Worker	Diagnostic Imaging	Revised	Edited mSv and combined C&D. Approved by John Stalp, RSO and Angela Womble
Policy for Gadolinium Based Contrast Media (MRI)	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for General Orientation of Newly Appointed Diagnostic Imaging Employees	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for Infection Control Practices in Diagnostic Imaging	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for Lead Apron/ Shielding: Cleaning and Storage	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for Mammography Comparison Images	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for Mammography Records	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for Missed Appointments	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for Physicians Authorized to Perform Diagnostic Fluoroscopy	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for Protocols for General Diagnostic Radiography and Mammography	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for Radiation Physicist Survey	Diagnostic Imaging	Revised	Reviewed and Approved with John Stalp, RSO. updated policy and link

Title	Area	Revised?	Summary of Changes
Policy for Radiologists' Professional Duties and Responsibilities	Diagnostic Imaging	Revised	Radiologist workflow changes were made.
Policy for Release of Medical Imaging Records	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for Staffing Coverage of Diagnostic Imaging Department	Diagnostic Imaging	Unchanged	No Comment Provided
Policy for VRAD Radiology Service	Diagnostic Imaging	Revised	Reviewed by Dr. Usha Murphy and Angela Womble. Changed preliminary to final
Three (3) Strikes Policy for Re-Scheduling Appointments	Diagnostic Imaging	Unchanged	No Comment Provided
CCRMC & HC's EMTALA Policy *	Hospital & Health Centers	Revised	Updates and attachment are from County Counsel.
Community Health Privileges	Hospital & Health Centers	Unchanged	No Comment Provided
Diagnostic Imaging Privileges	Hospital & Health Centers	New	No Comment Provided
Ethics Committee Policy	Hospital & Health Centers	Revised	Verbiage around HEC-C certification for chairperson (encouraged but not mandatory). Also verbiage around "should" have admin membership (we currently don't have anyone)
MyChart Account Governance Policy	Hospital & Health Centers	New	New to PolicyStat. Not a new policy.
Oral and Maxillofacial Surgery Privileges	Hospital & Health Centers	New	No Comment Provided
Policy for Adoption Services	Hospital & Health Centers	Revised	No changes per Perinatal however, requesting for Medical Social Worker review.
Policy for Anesthesia Assessments and Monitoring	Hospital & Health Centers	New	No Comment Provided
Policy for Emergency Airway Support by In-House Anesthesiology	Hospital & Health Centers	Unchanged	No Comment Provided
Policy for Management of Patient with Suspected or Confirmed Pulmonary Tuberculosis	Infection Control	Revised	Editing for clarity
Policy for Pertussis Culture and PCR Specimen Collection	Infection Control	Revised	Change document link. Will add link to procedure instead
Policy for Skin Cleansing with 2% Chlorhexidine Gluconate Impregnated Wipes	Infection Control	Unchanged	No Comment Provided
Policy for Transmission-Based Isolation Precautions	Infection Control	Unchanged	No Comment Provided
Sudden Influx of Infectious Patient Surge Capacity Plan	Infection Control	Unchanged	No Comment Provided

Title	Area	Revised?	Summary of Changes
Policy for Blood and Blood Components, Transfusion	Nursing	Revised	Editing completed
Policy for Medication Administration and Documentation	Nursing	Revised	Updated per policy changes
Policy for Restraints And Seclusion	Nursing	Revised	Updated to reflect policy changes and definitions.
Patient Menu Policy	Nutrition	Revised	Updated diet order names and approval letter.
Medication Error Reduction Plan-Annual MERP Review *	Pharmacy	Revised	Updated signature page date (page 1 of attachment) from 3/2025 to 3/2026.
Policy for 340B Drug Discount Program	Pharmacy	Revised	Removed references to contract pharmacies which have been terminated as of 1/1/25. Updated language as suggested by Spendmend External Consultant Auditor Visit from
Policy for Access to Automated Drug Delivery Systems (ADDS) *	Pharmacy	Revised	Updated review cycle to 365 days (annually) and removed approvals section
Policy for Antineoplastic and Hazardous Drug Handling *	Pharmacy	Revised	Updated references
Policy for Automated Drug Delivery System – Closure of a Patient Care Unit *	Pharmacy	Revised	1) Removed information regarding deactivation of an ADDS if patient unit is closed for >2 weeks' duration. This is not current practice and no regulatory requirement for this. 2) Removed Approvals Section 3) Updated renewal cycle to 365 days (annual) 4) Updated references
Policy for Automated Drug Delivery System – Removing Medications *	Pharmacy	Revised	1) Added text for requirement of the ADDS to record all transactions 2) Added reference to ADDS Policy regarding Override/ER/STAT med orders 3) Clarified section on patient-specific multi-use medications 4) Added text for requirement training on the operation and use to personnel using the ADDS 5) Added related links section 6) Updated Referneces 7) Removed approvals section 8) Changed review cycle to 365 days (annually)

Title	Area	Revised?	Summary of Changes
Policy for Automated Drug Delivery System (ADDS) – Stocking Medications *	Pharmacy	Revised	1) Added related links to P&P for ADDS inspection/inventory and maintenance/monitoring 2) Added statement that training is provided on the use of the ADDS to Pharmacy Personnel prior to installation and annually thereafter 3) Updated references 4) Changed renewal cycle to 365 days (annually)
Policy for Automated Drug Delivery Systems – Inspection and Inventory *	Pharmacy	Revised	1) added text for responsibilities of the pharmacy dept related to ADDS 2) Removed duplicative text referencing monthly inspection 3) Removed erroneous text regarding PCP&E review of ADDS P&P and moved it to the ADDS P&P Policy 4) Added related links to other P&P (LASA and Multidose Vials) 5) Removed Approvals section 6) Updated references 7) changed review cycle to 365 days (annually)
Policy for Automated Drug Delivery Systems - Maintenance & Monitoring *	Pharmacy	Revised	1) Added review of transaction records to verify security and accountability of the ADDS. 2) Deleted text re: reference materials attached regarding maintenance and cleaning, operations, and troubleshooting information. This pertained to the Omnicell Repackager machine that is no longer at CCRMC. 3) Added text re: security and accountability measures conducted by the Pharmacy Dept. 4) Added related links 5) Updated References 6) Removed approvals section 7) Changed review cycle to 365 days (annually)
Policy for Automated Drug Delivery Systems – Malfunction & Failure *	Pharmacy	Revised	Removed approvals section. Updated review cycle to 365 days (annually). Referenced Procedure for turning off medication verification in Omnicell.

Title	Area	Revised?	Summary of Changes
Policy for Automated Drug Delivery Systems - Override and Emergency/STAT Medication Orders *	Pharmacy	Revised	1) Combined this Override policy with the Emergency/STAT orders policy. We will retire the Emergency/STAT orders policy (https://cchealth-ccrmc-hc-detention.policystat.com/policy/16687783/latest) 2) aligned LIP controlled environments list across all pharmacy policies 3) aligned override drug classes across all pharmacy policies - added specific drug classes and removed the overarching statement allowing "any other medication required urgently..." 4) updated language to change "ADDM" to "ADDS" 5) included language that override is reviewed by pharmacist within 48 hours 6) Updated References 7) Removed Approvals section 8) Changed renewal time to 365 days (annually)
Policy for Automated Drug Delivery Systems – Pharmacist Order Verification *	Pharmacy	Revised	1) aligned LIP controlled environments list across all pharmacy policies 2) aligned override drug classes across all pharmacy policies - added specific drug classes and removed the overarching statement allowing "any other medication required urgently..." 3) included language that override is reviewed by pharmacist within 48 hours 4) Updated References 5) Changed renewal time to 365 days (annually)
Policy for Automated Drug Delivery Systems – Policies and Procedures *	Pharmacy	Revised	1) Added information about required annual review of P&P, access to P&P at ADDS location and pharmacy location, and types of P&P required by Board of Pharmacy regulations. 2) Added Related Links to all ADDS P&P 3) Removed Approvals Section 4) Updated review cycle to 365 days (annually)
Policy for CCRMC Drug Formulary	Pharmacy	Revised	Hyperlinked to stub for formulary spreadsheet.

Title	Area	Revised?	Summary of Changes
Policy for Compounding Competency Assessment *	Pharmacy	Revised	1) Rewrote the policy to make information clearer and added additional information as per revised BOP regulations 10/1/2025 Sections 1735, 1736, 1737, 1738 2) Non-sterile compounding competency training program also added 3) Updated related links names to procedures 4) Updated References
Policy for Compounding of Medications *	Pharmacy	Revised	Updated related links' names throughout the policy and related links
Policy for Controlled Substance Diversion Prevention *	Pharmacy	Revised	Changed ADC to ADDS, removed approvals section, changed review cycle to 365 days (annually).
Policy for Controlled Substances, Removal and Wasting: Automated Drug Delivery Systems *	Pharmacy	Revised	1) Fixed formatting of definitions section 2) Added related links to Policies for Theft, Diversion, and Reporting 3) Removed Approvals Section 4) Updated References 5) Changed review cycle to 365 days
Policy for Drug Procurement, Storage & Inventory Control *	Pharmacy	Revised	Removed approvals section
Policy for Drug Shortages *	Pharmacy	Revised	Removed approvals section, added link to actual policy where policy # is listed
Policy for Drug Storage Temperatures – Pharmacy Department Only *	Pharmacy	Revised	Removed incubator temperature as the Pharmacy no longer as incubators in use. Updated link to VFC temperature log. Updated TJC and BOP References. Removed approvals section.
Policy for Emergency Medication Supply – Location & Quantity	Pharmacy	Revised	Removed Antepartum crash cart approved by Code Blue Committee on 12/10/2025
Policy for Expiration Dates *	Pharmacy	Revised	Fixed typo in formatting, updated references, removed approvals section
Policy for Handling of Suspected IV Contamination *	Pharmacy	Revised	removed approvals section and updated references
Policy for Hazardous Materials and Waste Training *	Pharmacy	Revised	Removed approvals section.
Policy for High Risk/High Alert Medication Management	Pharmacy	Revised	Reviewed policy, no changes made to policy. Medication Safeguards poster (related link) had very minor updates.

Title	Area	Revised?	Summary of Changes
Policy for Labeling Standards	Pharmacy	Revised	Changed "syringes of medication" to "medication containers" to match TJC language.
Policy for Licensed Employee – Theft or Impairment *	Pharmacy	Revised	Updated reference to Policy# with a Policy link. Removed approvals section.
Policy for Look-Alike, Sound-Alike Medication Management *	Pharmacy	Revised	Updated reference to TJC MM 14.01.01 to match 2026 numbering system. Also we had stated that the lasa drugs are listed in physician charting areas, but removed this because it is in med rooms, but not charting areas, which is ok since safeguards are also embedded in ccLink, which is noted in the policy.
Policy for Maintenance of Sterile Compounding Facilities and Equipments *	Pharmacy	Revised	Updated references.
Policy for Medication Orders - Pharmacy *	Pharmacy	Revised	Removed LIP list of locations and overridable drug classes and referenced to pertinent Override and ADDS Pharmacist Verification Policies to avoid updating across multiple policies.
Policy for Medication Recall *	Pharmacy	Revised	1) Added language as required by BOP Regulations to review quality control complaints of CSPs and CNSPs within 72 hours and emphasized the reporting requirement to the Board. 2) Removed Approvals section 3) Updated References
Policy for Medication Reconciliation	Pharmacy	Revised	Updated the pharmacy med rec section to include discharge
Policy for Non-Sterile Compounding *	Pharmacy	Revised	1) Updated competency documentation to remove last revised date. Linked to stub 2) Updated references 3) Updated hyperlink names throughout the document
Policy for Outsourced Compounding Pharmacy- Quality Assurance *	Pharmacy	Revised	Added language regarding reporting of compounding contractual relationship as per B&PC 4123. Updated references. Removed approvals section.
Policy for Patient's Own Medication – Storage & Destruction *	Pharmacy	Revised	Removed sections related to COVID and approvals section.

Title	Area	Revised?	Summary of Changes
Policy for Pharmacist Order Verification *	Pharmacy	Revised	Removed LIP list of locations and overridable drug classes and referenced to pertinent Override and ADDS Pharmacist Verification Policies to avoid updating across multiple policies.
Policy for Pharmacy Hazard Communication Program *	Pharmacy	Unchanged	No Comment Provided
Policy for Prescribing & Ordering – General Practices *	Pharmacy	Revised	No material changes. Removed approvals section.
Policy for Procurement of Medications *	Pharmacy	Revised	Removed approvals section
Policy for Quality Assurance in Pharmacy *	Pharmacy	Revised	1) Added language regarding ADDS "medication error" definition 2) Added language regarding Quality Assurance reporting of ADDS related medication errors and duty to report to CA State BOP on cycle as required by ADDS licensure status (licensed vs. unlicensed) 3) updated references 4) removed approvals section 5) changed review cycle to 365 days (annually)
Policy for Reporting Diversion of Controlled Substances *	Pharmacy	Unchanged	No Comment Provided
Policy for Room Temperature Monitoring for Drug Storage Areas *	Pharmacy	Revised	Removed approvals section, updated references
Policy for Standard Administration Times for Medications	Pharmacy	Revised	Removed digoxin from policy so it can be administered at 1000 (standard admin time) rather than 1400. Original request from Dr. Bhandari, approved by cardiology. Removed approvals section
Policy for Standing Orders *	Pharmacy	Revised	approvals removed TJC reference was updated to their new numbering system
Inpatient Psychiatry 2025 Utilization Management Plan	Psychiatry	New	No Comment Provided
Policy for Discharge Planning/After-Care Plan for Inpatient Psychiatry	Psychiatry	Unchanged	No Comment Provided
Policy for Respiratory Care Patient Transport	Respiratory	New	No Comment Provided

Status **Pending** PolicyStat ID **19307646**

Origination	08/2012
Last Approved	N/A
Effective	Upon Approval
Last Revised	01/2026
Next Review	3 years after approval
Owner	Kelley Taylor: Ambulatory Care Clin Supv
Area	Ambulatory Care

Policy For Ambulatory Care Organization

POLICY STATEMENT:

The responsibility of directing and coordinating the activities of Contra Costa Health Centers is assigned to the Medical and Nursing Directors. The development and implementation of health center policies is the responsibility of the Ambulatory Nursing Director, Chief Nursing Officer, Chief Medical Officer, and the Ambulatory Medical Directors. Ambulatory care policies are subject to approval by APC, MEC and JCC. The day-to-day health center operations are the responsibility of Ambulatory Care Clinical Supervisor (ACCS) [AKA Clinical Services Manager (CSM)] with support from ~~a~~the Ambulatory Medical Directors and/or their designee, Clinic Coordinator, ~~Medical Department Chairs, Division Heads~~ and ancillary department managers.

GUIDELINES:

A. **Ambulatory Care Centers**:

1. ~~West County Health Center~~
2. ~~Pittsburg Health Center~~
3. ~~Concord Health Center~~
4. ~~Brentwood Health Center~~
5. ~~Martinez Health Center~~
6. ~~Antioch Health Center~~
7. ~~Bay Point Health Center~~
8. ~~North Richmond Center for Health~~West

1. West County Health Center
2. North Richmond Center for Health

9. ~~George and Cynthia Miller Wellness Center~~Central
    1. Concord Health Center
    2. Martinez Health Center
    3. George and Cynthia Miller Wellness Center
10. East
    1. Pittsburg Health Center
    2. Bay Point Health Center
    3. Antioch Health Center
    4. Brentwood Health Center

B. **Policy Direction**:
All Health Centers are part of one ambulatory care system and, as such, function with one set of overall policies. The implementation of established policy, however, may vary from site to site due to unique variations and staff availability.

C. **On-Site Operational Responsibilities**:
~~The~~In partnership the Medical Directors and Ambulatory Care Clinical Supervisors (ACCS)~~, with the assistance of Clinic Coordinators and DFAM Division Heads,~~ are responsible for the overall day-to-day operations of Health Centers. At regional health centers, this includes leadership responsibilities for on-site ancillary support services.

D. **Ancillary Management Team:**

The ancillary managers who are based at CCRMC are also responsible for their respective services at the health centers. Those services include:

1. Laboratory
2. Pharmacy
3. Diagnostic Imaging
4. Nutrition Services
5. Medical Social Workers
6. Volunteers
7. Financial Counselors
8. Health Information Management
9. Cardiopulmonary
10. Rehabilitation
11. Public Safety
12. Environmental Services

The ancillary manager's responsibility in health centers includes, but is not limited to, supervising and evaluating employee performance, initial orientation and ongoing training for employees and providing coverage, when necessary, for employee absences. In addition, ancillary managers are responsible for all operational and professional aspects of their respective departments and will collaborate, as necessary, with Ambulatory Care Administration.

REFERENCES:

CCRMC and Contra Costa Health Centers Policy #151, "Hospital and Health Centers Organization."

APPROVALS:

Ambulatory Care Policy Committee: 8/2012; 3/2018;5/2013; 5/2021, 8/2025

Ambulatory Policy Committee: 8/2012; 3/2018;5/2013; 5/2021, 8/2025

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Ambulatory Policy Committee	Laura R. Colebourn [LC]	01/2026
Ambulatory Clinical Practice Committee	Helena Martey: Chief Nursing Officer - Interim	12/2025
	Kelley Taylor: Ambulatory Care Clin Supv	12/2025
	Kelley Taylor: Ambulatory Care Clin Supv	11/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19115002**

Origination	N/A	Owner	Kelley Taylor: Ambulatory Care Clin Supv
Last Approved	N/A	Area	Ambulatory Care
Effective	Upon Approval		
Last Revised	N/A		
Next Review	3 years after approval		

Policy for Diagnostic Imaging Results for Resource Nurse

DIAGNOSTIC IMAGING DEPARTMENT DEFINITIONS OF

CRITICAL AND URGENT ABNORMAL RESULTS

Contra Costa Regional Medical Center Policy 4083 Contra Costa Health Centers March 2007

Diagnostic Imaging Department Definitions of Critical and Urgent Abnormal Results

The following results are considered critical results when they are new, active and unresolved.

A. Critical Results:

1. Ectopic gestation
2. CNS bleed or imminent herniation
3. Oligohydramnios > 20 weeks gestation
4. Pneumothorax, Pneumomediastinum or Pneumopericardium
5. Bowel obstruction or perforation
6. Malposition of endotracheal tube
7. NG or feeding tube in the respiratory tract
8. Fetal demise
9. Suspected IUGR
10. Misdirected catheters
11. Other results as determined by the radiologist

B. Urgent Abnormal Results:

1. OB/GYN

a. Unexpected multiple gestations

b. Congenital anomaly

c. Persistent placenta previa in the third trimester

2.Chest

a. Possible TB (active)
b. New Mass (suspected cancer)
c. Pleural effusion
d. Pneumonias

3.GI Tract

a. Suspected Cancer
b. New ulcer

4. Any suspected cancer in any organ

5. Fractures unless noted on a prior X-ray

6. Any case where biopsy or other follow-up is recommended.

7. Abnormal Head CT or MRI

8. Other significant abnormal results as determined by radiologist

RELATED LINKS:

Policy for Resource Nurse for Critical and Urgent Test Value Notifications

Procedure for Outpatient Critical and Urgent Test Results

Standardized Procedure for the Resource Nurse

REFERENCES:

A. 2019 TJC Standard PC.02.02.01: "The hospital coordinates the patient's care, treatment and services based on the patient's needs."
B. Department of Public Health STD Control Branch. (2021). Retrieved from cdph.ca.gov: https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/California-STI-Treatment-Guidelines-for-Adults-and-Adolescents.pdf
C. Michael E Pichichero, M. (2021, August 24). Retrieved from uptodate.com: https://www.uptodate.com/contents/treatment-and-prevention-of-streptococcal-pharyngitis-in-adults-and-children?search=Treatment%20and%20Prevention%20of%20Streptococcal%20Tonsillopharyngitis&source=search_result&selectedTitle=1~150&usage_type=default&displ
D. Miriam Baron Barshak, M. L. (2021, October 26). Retrieved from uptodate.com: https://www.uptodate.com/contents/group-b-streptococcal-infections-in-nonpregnant-adults?search=Group%20B%20streptococcal%20infections%20in%20nonpregnant%20adults&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1
E. Scott Moses, M. (2021, January 15). *fpnotebook.com*. Retrieved from https://fpnotebook.com/Uro/ID/UrnryTrctInfctn.htm
F. Thomas M Hooton, M. G. (2021, March 15). Retrieved from uptodate.com: https://www.uptodate.com/contents/acute-simple-cystitis-in-women?search=Acute%20Cystitis%20in%20Women&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1
G. U.S. Department of Health and Human Services. (2021, july). *cdc.gov*. Retrieved from https://www.cdc.gov/std/treatment-guidelines/pocket-guide.pdf

APPROVALS:

Ambulatory Policy Committee: 5/2019

Medical Executive Committee: 5/2019, 12/2021

Revised and Approved by ACPC: 11/2021

Revised and Approved by APC: 12/2021

Joint Conference:

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Ambulatory Policy Committee	Laura R. Colebourn [LC]	01/2026
Ambulatory Clinical Practice Committee	Helena Martey: Chief Nursing Officer-Exempt	10/2025
	Kelley Taylor: Ambulatory Care Clin Supv	10/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19694131**

Origination	05/2015
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	3 years after approval
Owner	Kelley Taylor: Ambulatory Care Clin Supv
Area	Ambulatory Care

Policy for Health Center Hours

POLICY STATEMENT:

The health center building hours will be prominently posted at the main door of all health centers. The main entrance door(s) will be unlocked during the posted hours. If, for any reason, the health center will not be open during the regularly posted hours, a special sign will be posted next to the hours sign.

GUIDELINES:

Health Center	Day(s)	Hours
Antioch	Mon – Friday	7:45 am – 11:45 am; 12:45 pm – 8:30 pm
Antioch Women's Health	Wednesday Thursday	8:00 am – 12:00 pm 1:00pm – 5:00pm
Bay Point	Monday	7:45 am –11:45 am, 12:45 pm – 4:45 pm; 5:15 pm - 8:30 pm
	Tue, Wed, Thurs, Fri	7:45 am – 11:45 am, 12:45 pm - 4:45 pm
Bay Point WH	Tuesday & Friday	1:00 pm- 5:00 pm
Brentwood WH	Monday & Tuesday	8:00 am- 12:00 pm & 1:00 pm -5:00 pm
Brentwood	Mon, Tues, Wed	7:45 am – 11:45 am; 12:45 pm – 8:30 pm
	Thurs, Fri	7:45 am – 11:45 am; 12:45 pm – 4:45

		pm
Community Practice Clinic- Antioch	Mon, Tues	8:30 am – 7:00 pm
	Wed, Thurs, Fri	8:30 am – 5:00 pm
Community Practice Clinic- Concord	Mon, Wed, Fri	8:30 am – 5:00 pm
	Tues, Thurs	8:30 am – 7:00 pm
	1st and 3rd Saturday	8:30 am – 2:00 pm
Community Practice Clinic - Richmond	Mon, Tues, Thurs	8:30 am – 8:00 pm
	Wed, Fri	8:30 am – 5:00 pm
	1st and 3rd Saturday	8:30 am – 2:00 pm
Concord Health Center 1	Monday - Friday	7:45 am – 11:45 am; 12:45 pm – 4:45 pm
Concord Health Center 2	Monday - Thursday	7:45 am – 11:45 am; 12:45 pm – 4:45 pm; 5:00-8:45pm
	Friday	7:45 am – 11:45 am; 12:45 pm – 4:45 pm
Concord WH	Monday & Wednesday	8:00 am – 12:00 pm
	Thursday	1:00 pm -5:00 pm
Concord Sexual Health Clinic	Tuesday's	5:30 pm – 9:00 pm
El Cerrito High SBC	Monday, Wednesday, Thursday	8:00am – 12:00pm
Martinez Health Center Bldg. 1	Monday – Friday	7:45 am – 8:45 pm
Contra Costa Regional Medical Center Emergency	Monday – Sunday	24 Hours
Contra Costa Regional Medical Center Psych Emergency	Monday – Friday	24 Hours
George & Cynthia Miller Wellness Center -Ambulatory Clinic	Mon, Fri, Sat	7:45 am – 11:45 am; 12:45 pm – 4:45 pm
Miller Wellness - Behavioral Health	Monday – Friday Saturday	12:00 pm – 8:15 pm 8 am – 4:15 pm
Mobile Clinics	Monday - Friday	8:00 am – 8:00pm
Mobile Unit #6878	Monday - Friday	8:00 am – 5:00pm
Mobile Unit #6879	Monday – Friday	8:00 am – 5:00 pm
North Richmond	Monday – Friday,	7:45 am – 4:45 pm

~~Pittsburg~~Pittsburgh	Monday – Friday	7:45 am – 8:30 pm
	Saturday	7:45 am – 11:45 am; 12:45 pm – 4:45 pm
~~Pittsburg~~Pittsburgh Women's Health	Tuesday & Thursday	8:00 am – 12:00 pm
	Monday & Wednesday	1:00 pm – 5:00 pm
Respite	Mon, Tues, Fri	8:00 am – 12: 00 pm
	Thursday	8:00 am – 12: 00 pm, 1:00 pm – 5:00 pm
	4th Wednesday	8:00 am – 12:00 pm
West County	Monday - Thursday,	7:45 am – 8:30 pm
	Friday	7:45 am – 4:45 pm
	Saturday	7:45 am – 11:45 am; 12:45 pm – 4:45 pm
West County Women's Health	Wednesday Thursday	8:00 am – 12:00 pm 1:00 pm – 5:00 pm
West County Sexual Health	Thursday	5:30 pm – 9:00 pm

APPROVALS:

Ambulatory Care Policy Committee: 5/2015, 4/2017, 9/2020, 06/2022 , 10/2025
Ambulatory Policy Committee: 9/2020, 07/2022
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Medical Executive Committee: 9/2020, 08/2022
Joint Conference Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
CCRMC Chiefs	David Culberson: CCRMC Chief Executive Officer	02/2026
	Kelley Taylor: Ambulatory Care Clin Supv	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19102660**

Origination	04/2008	Owner	Kelley Taylor: Ambulatory Care Clin Supv
Last Approved	N/A	Area	Ambulatory Care
Effective	Upon Approval		
Last Revised	01/2026		
Next Review	3 years after approval		

Policy for Quick Response Cart

POLICY STATEMENT:

Trained and qualified health center staff will respond to potentially life-threatening medical emergencies at the Basic Life Support level and call 9-1-1 to activate the county's EMS system. These carts will remain locked at all times except when in use.

To specify the medications and supplies to be kept on hand at each Health Center except the Infusion Clinic* located on the CCRMC Campus in Martinez.

The Infusion Clinic located on the CCRMC campus will maintain a crash cart as described in CCRMC Nursing Policy for Crash Cart Readiness.

GUIDELINES:

A. Check Quick Response Cart **DAILY** to make sure locking mechanism is intact and ensure:
   1. All supplies stored on top and outside of the Quick Response Cart are present per **Quick Response Medication and Supply Contents and Expiration List** (See attachment A).
   2. Oxygen cylinder is > 1000 psi and replace if necessary.
   3. Battery operated portable suction is functional.
   4. Battery operated portable suction is plugged into a power source when not in use.
   5. Readiness of AED and resuscitation kit plus extra electrodes with current date. The QUIK-PAK electrode packet should remain connected to the defibrillator and unopened until required for an SCA (sudden cardiac arrest) Quick Response.

6. Expiration date sticker on all drawers is current.
7. One (1) pair of scissors
8. Sign and date the List of Expiration Dates Form.

B. If security seal is broken:
    1. Check the contents immediately.
    2. Replace missing items.
    3. Reseal the Quick Response Cart with appropriate locking mechanism.
    4. Document name, date and seal number on the Quick Response Cart check form.

C. Check the expiration dates of the Quick Response Cart **ONCE A MONTH**.
    1. It will be the monthly responsibility of sterile processing and pharmacy to do monthly checks.
    2. Replace any outdated supplies.
    3. Place date of first drug to ~~outdated~~outdate on front of drawer.
    4. Check and replenish/exchange all necessary items to the Quick Response Cart immediately after using the cart.
    5. Seal the Quick Response Cart with the appropriate locking device if needed.
    6. Nursing will document with name, seal number and date on the Quick Response Cart check form daily.

REFERENCES:

A. ~~2025~~2020 American Heart Association Advanced Cardiac Life Support (ACLS).

B. American Academy of Pediatrics and the American Heart Association Pediatric Advanced Life Advanced Life Support (PALS) 2016 Guidelines.

C. Nursing Policy for Crash Cart Readiness

D. Pharmacy Policy for Ambulatory Care Quick Response Carts

APPROVALS:

Ambulatory Clinical Practice Committee: 4/2016, 9/2019, 10/2022~~, 11/2025~~

Ambulatory Policy Committee: 3/2013, 7/2016, 9/2019, 11/2022

Medical Executive Committee: 8/2016, 10/2017, 12/2022

Joint Conference Committee: 3/2023

Attachments

A_ Quick Response Cart Contents updated old 4064 A.docx

B: Ambulatory Care Quick Response Cart Log

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Ambulatory Policy Committee	Laura R. Colebourn [TT]	01/2026
Ambulatory Clinical Practice Committee	Helena Martey: Chief Nursing Officer-Exempt	10/2025
	Kelley Taylor: Ambulatory Care Clin Supv	10/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **18290803**

Origination	11/2009	Owner	Kelley Taylor: Ambulatory Care Clin Supv
Last Approved	N/A	Area	Ambulatory Care
Effective	Upon Approval		
Last Revised	01/2026		
Next Review	3 years after approval		

Policy for Standing Orders: Nursing

Policy for Standing Orders - Nursing

PURPOSE STATEMENT:

To document nursing standing orders approved by the Ambulatory Policy Committee and provide guidance for ~~RN, LVN~~clinical staff (Immunizations & Section F)

PROCEDURE:

Immunizations: See Current CDC Guidelines. (LVN staff may also administer immunizations using recommendations set for by CDC)

Hemoglobin or Hematocrit:

A. ~~The Treatment or Resource~~ Nurse may order and/or perform a hemoglobin or hematocrit when requested for ~~a WIC appointment in the following situations:~~
    1. ~~First time WIC enrollment for a child 12 months of age or older, if not already done within the previous 60 days.~~
    2. Any child 5 years old or younger or any menstruating female (has had a period before and has not yet hit menopause) AND has not had a screen in the past 12 months or 6 months (if they have anemia).
    3. A child who has restricted their diet to no more than 5 foods, or a child who has pica (is eating non-food items such as dirt for example) AND has not had a screen in the past 1 month.
    4. ~~Re-certification for an anemic child (anemia defined as previous hemoglobin < 11 or~~

~~hematocrit < 34), if not already done within 6 months prior to the re-certification date.~~When requested for a WIC appointment in the following situations:

1. First time WIC enrollment for a child 12 months of age or older, if not already done within the previous 60 days.
2. Re-certification for an anemic child (anemia defined as previous hemoglobin < 11 or hematocrit < 34), if not already done within 6 months prior to the re-certification date.
3. Re-certification for a non-anemic child, if not already done within the previous 12 months prior to the re-certification date.

5. ~~Re-certification for a non-anemic child, if not already done within the previous 12 months prior to the re-certification date.~~

B. ~~During the treatment nurse appointment, the nurse will review the record to see if well-child exams are up-to-date and, if not, schedule a primary care appointment for the patient.~~

Well Child Check

A. During the treatment nurse appointment, the nurse will review the record to see if well-child exams are up-to-date and, if not, schedule a primary care appointment for the patient.

Lead

A. The Nurse may order and/or perform a lead if due or if the most recent lead level was abnormal.

Neonatal Jaundice~~:~~

~~If an infant, seven days or younger, presents with obvious jaundice; after conferring with the provider, a total bilirubin may be performed in clinic with a Bilimeter when available.~~

A. If an infant, one month or younger, presents with obvious jaundice, a transcutaneous total bilirubin may be performed in clinic with a Bilimeter when available. Results of >10mg/dL(AND this is the first bilirubin the patient has on record OR the value is increased from the most recent TcBili) should be reported to a provider verbally before the patient leaves the clinic.

Pregnancy Test. Refer to ~~Procedure~~Policy #4068 for Walk-In patients.

A. Upon patient request, the nurse may order and perform a pregnancy test.
B. If the Pregnancy Test is Positive, and if the patient desires pregnancy, then the nurse can refer the patient ~~is referred~~ to Healthy Start to begin prenatal care or to Ob/GYN and a Medical Social Worker, if patient desires other options.
Point of Care Testing (POCT):
If any point of care testing "Care Gaps" are due, all clinical staff can perform and document. If any POCT test is done that is abnormal and outside of a provider visit, document and send in basket message to the PCP. If result is abnormal and it was part of a provider visit, document in MyCClink and inform provider.
Positive TST test
    A. If symptomatic, document in chart, notify CHIP/DOD, and order Quantiferon-TB.

B. If asymptomatic, order Quantiferon-TB.

~~Point of Care Testing:~~

~~If any point of care testing due to Gaps of Care, all licensed staff can perform and document. If any POCT test is done that is abnormal and outside of a provider visit, document and send in basket message to the provider. If result is abnormal and it was part of a provider visit, document in MyCClink.~~

Positive ~~TST or~~ IGRA (QUANTIFERON)

~~Patients that screen for TB disease, may have a IGRA (Quantiferon) test ordered by nursing. For RN staff place order, for LVN/ CMA pend order for PCP to approve~~

~~If positive test, referral should be placed. For RN staff- place referral for LTBI nurse either at WCHC, MHC or PHC. For LVN/CMA staff send to PCP to place referral or Care Team RN to place referral for LTBI nurse.~~

A. Contact patient to discuss positive Quantiferon results
    a. Ask about history of positive TB test and/or treatment for TB. If patient has been treated previously, document and route to PCP with details of treatment.
    b. Then perform a symptom assessment for TB and document. Symptoms of active TB are prolonged cough (often productive and sometimes bloody), fever, night sweats, and weight loss.
        i. If symptoms are concerning for active TB, advise patient of respiratory precautions, notify public health, and order urgent chest x-ray.
        ii. If asymptomatic for active TB, order routine chest x-ray with indication "positive Quant."

B. When chest x-ray results are received:
    a. If the chest x-ray comes back negative, place referral to LTBI nurse. In the comments section, please state "+ Quantiferon/negative chest x-ray. PCP has been notified." Send pended rifampin 600mg daily for 30 days with message to PCP advising that a referral has been sent. PCP may decide to change or defer treatment if necissary.
    b. If chest x-ray is positive for TB, notify CHIP/DOD so that they can refer to chest clinic.

~~RELATED LINKS:~~RELATED LINKS:

4074-1 – Cautions and Contraindications for Immunizations

4074-2 Acetaminophen Dosage Chart

4074-3 Dilation for Patients in Eye Clinic: Standing Orders

4074-4a Ambulatory Care Hypoglycemia Guidelines

4074-4b Diabetes Standing Orders

4074-5 RN New Adult Patient Pre-Visit Preparation

4074-7 Procedure for Alternative Administration and Education of Estradiol and Testosterone

REFERENCES:

A. ~~Not sure which one of the following applies based on policy, but I would think it is 70706.2~~2024 AAFP Primary Care Health Care Guidelines
B. CCR, Title 22, § 70706.2 Standardized Procedures (b)-(c)
C. CCR, Title 22, § 70263 (h)
D. CFR, Title 42, § 482.23(c)
E. CFR, Title 42 $$ 482.24©(3)
F. Joint Commission, 2024, MM.04.01.01.15
G. CDC Immunization Recommendations for 2014-2015 and any subsequent updates
H. Adult Recommended Immunization Schedule, 2024
I. ~~2025~~2024 AAP Guidelines/ Bright Future guidelines
J. ~~2024 AAFP Primary Care Health Care Guidelines~~
K.

~~APPROVALS:~~

~~ACPC: 1/2013, 7/2014, 9/2016, 03/2023, 8/2025~~
~~APC: 3/21/2013, 11/2014, 12/15/2016, 05/2023~~
~~MEC: 5/20/2013, 1/23/2017, 06/2023~~

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Ambulatory Policy Committee	Laura R. Colebourn [LC]	01/2026
Ambulatory Clinical Practice Committee	Helena Martey: Chief Nursing Officer-Exempt	09/2025
	Kelley Taylor: Ambulatory Care Clin Supv	09/2025

Standards

No standards are associated with this document

Status Pending PolicyStat ID 19115092

Origination	N/A
Last Approved	N/A
Effective	Upon Approval
Last Revised	N/A
Next Review	3 years after approval
Owner	Kelley Taylor: Ambulatory Care Clin Supv
Area	Ambulatory Care

Procedure For Outpatient Critical and Urgent Test Results

AMBULATORY CARE POLICY 4200

PROCEDURE FOR OUTPATIENT CRITICAL AND URGENT ABNORMAL RESULTS

PURPOSE STATEMENT:

To provide instructions pertaining to critical and urgent test results for all outpatients.

PROCEDURE:

A. Read back of test results:
Any licensed provider or RN receiving a critical abnormal test result verbally will write down the patient information and test result and read back the patient's name and test result to the reporting staff member.

B. Documentation of Critical and Urgent test results follow up:

C. When designated clinician receives critical or urgent abnormal test results, they will document their plan in the medical record in ccLink. Notification of critical values:

1. When the health center is open the reporting department will call the following in order of priority:

a. Ordering Provider.

b. CHIP/ or DOD

c. Resource Nurse.

1. The Resource Nurse will report the critical test value with medical record to:

a. The ordering provider. If no response in 20 minutes, then go to b. or c.

b. Call the Specialty Provider on call, if test was ordered by a Specialist. If no response in 20 minutes, then

c. The PCP of the patient if different from the ordering provider. If no response in 20 minutes, then

d. The provider of the day or CHIP. The provider of the day for each site will be listed on Amion.

e. If a critical lab is not addressed by a MD, DO, FNP within one hour, then Resource Nurse will call the ED, speak with the ED physician for a warm hand off and follow ED physician's instructions.

A. Critical and Urgent Labs and Tests:

1. Resource nurses will refer to appendix 1 and 2 for the list of labs and diagnostic imaging tests to be reported and addressed by a provider.
2. The Resource nurse will address significantly abnormal results within 24-hour business hours. Notification will occur in the following order:

a. Ordering provider. If the ordering provider is a specialist, and is unavailable, notify on-call or covering specialist provider.

b. The patient's PCP. If PCP is unavailable.

c. The Doctor of the day as listed on Amion.

E. Outside Lab / Reference Lab Notification of Critical and Urgent Lab results:

to be handled in the same order as listed above.

F. Inbox Routing

All Critical and Urgent lab and DI values, as listed in appendix 1, and in appendix 2, are routed to the ccLink inbox of the ordering provider, PCP and the Resource Nurse at each Health Center.

1. If the provider has reviewed the results they must mark as "reviewed" and/or "done". By marking as "reviewed" and/or "done", it communicates to the Resource Nurse that the provider has seen the result and is assuming responsibility and acting on it.
2. If the result has not been reviewed, then the Resource nurse must initiate the process of notification listed above to ensure that the provider is aware of the critical or urgent abnormal result. Resources nurse must document who they contacted in cclink.
3. Hours of operation: Resource nurses manage and review their inbox Monday through Friday 8am-5:00pm (excluding all holidays).
4. For the following positive culture results: Candidiasis Vulvovaginal, Chlamydia, Gonorrhea, Streptococcal Throat Infection, Trichomonas, and Urinary Tract Infection for the uncomplicated patient, the Resource nurse can initiate treatment as outlined in the attached appendix 3 under a standardized protocol. The Resource nurses will prescribe the appropriate and approved treatment and provide the listed education.
5. If an ambulatory clinic collect specimen is received by the lab and cannot be processed for any reasons, the Resource Nurse at the appropriate health center will be notified by the lab through In-Basket message. The Resource Nurse will contact the provider to find out if the lab needs to be repeated and, if necessary, the Resource Nurse will reorder the lab, contact patient, and facilitate specimen collection.
6. For Urgent abnormal DI results, the Resource Nurse will review diagnosis with ordering provider or designee to see if patient needs to return for an appointment, escalation in ordering further diagnostic imaging studies, or prescription.

ABNORMAL LAB NOTIFICATION VALUES

TEST	CRITICAL VALUES
Absolute Neutrophil Count	< 500 TH/uL
Bilirubin – Total: • 0-24 hrs • 24-48 hrs	• ≥7.0 mg/dL • ≥12.0 mg/dL • ≥17.0 mg/dL

• 2-30 days	
BUN	> 100 mg/dL *within 14-day window - DO NOT CALL if previous result have been called.
Calcium	• < 6 or > 13 mg/dL
Carbon Dioxide: • Newborn to 2 yrs. • > 2 yrs.	• < 12 or > 45 mmol/L • < 10 or > 45 mmol/L
Chloride	< 70 mmol/L
CK (CPK)	> 10, 000 U/L
Creatinine: • Newborn to < 2 yrs. • 2 to 13 yrs. • > 13 yrs.	• > 1.2 mg/dL • > 2.0 mg/dL • > 6.5 mg/dL
Culture	Positive Body Fluid Culture - CSF - Peritoneal - Blood - Pleural - Pericardial - Joint
Digoxin	> 3.0 ng/ mL
Dilantin, adjusted	> 35 ug/mL
Fibrinogen	< 80 mg/dL
Gentamicin Trough	> 2 UG/mL
Glucose: • 0 – 3 yrs • 4 – 21yrs • >21 yrs	• 0-3 yrs. < 40 or > 300 mg/dL • 4 to 21 yrs. < 50 or > 300 mg/dL • >21 yrs. < 54 or > 500 mg/dL
Hematocrit – Manual: • Newborn to 1 month • > 1 month	< 27 % or > 70 % < 20 %

TEST	**CRITICAL VALUES**
Hemoglobin: • Newborn to 1 month • > 1 month • > 12 yrs.	• < 9 g/dL • < 7 g/dL • < 6 g/dL
Lactic Acid	≥ 4.0 mmol/L
Lead	.5mcg/dl

Lithium	> 1.5 mmol/L
Lipase	> 5000 U/L
Magnesium	< 0.5 or > 8.0 mg/dL
Phenobarbital	> 60 UG/mL
Phosphorus	< 1.0 mg/dL
Platelets: • Newborn to 30 days. • 1 month – 13 yrs • > 13 yrs.	• ≤ 40,000 TH/uL • < 50,000 TH/uL • <20,000 TH/uL
Potassium	< 2.6 to > 6.5 mmol/L
Protein, Total (< to 1 yr)	< 3.0 g/dL
INR (from PT)	> 6
PTT	> 120 seconds
Salicylate	> 50 mg/mL
Sodium	< 120 to > 155 mmol/L
Tegretol	> 15 UG/mL
Theophylline	> 30 UG/mL
Troponin	Positive
WBC: • Newborn to 6 days • 6 days to 3 years	• < 5000 TH/Ul • < 2000 or > 25,000 TH/uL

RELATED LINKS:

Policy for Resource Nurse for Critical and Urgent Test Value Notifications

Diagnostic Imaging Department Definitions of Critical and Urgent Abnormal Results

Standardized Procedures for the Resource Nurse

REFERENCES:

A. 2019 TJC Standard PC.02.02.01: "The hospital coordinates the patient's care, treatment and services based on the patient's needs."

B. Department of Public Health STD Control Branch. (2021). Retrieved from cdph.ca.gov: https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/California-STI-Treatment-Guidelines-for-Adults-and-Adolescents.pdf

C. Michael E Pichichero, M. (2021, August 24). Retrieved from uptodate.com: https://www.uptodate.com/contents/treatment-and-prevention-of-streptococcal-pharyngitis-in-adults-and-children?search=Treatment%20and%20Prevention%20of%20Streptococcal%20Tonsillopharyngitis&source=search_result&selectedTitle=1~150&usage_type=default&displ

D. Miriam Baron Barshak, M. L. (2021, October 26). Retrieved from uptodate.com: https://www.uptodate.com/contents/group-b-streptococcal-infections-in-nonpregnant-adults?search=Group%20B%20streptococcal%20infections%20in%20nonpregnant%20adults&source=se

arch_result&selectedTitle=1~150&usage_type=default&display_rank=1

E. Scott Moses, M. (2021, January 15). *fpnotebook.com*. Retrieved from https://fpnotebook.com/Uro/ID/UrnryTrctInfctn.htm

F. Thomas M Hooton, M. G. (2021, March 15). Retrieved from uptodate.com: https://www.uptodate.com/contents/acute-simple-cystitis-in-women?search=Acute%20Cystitis%20in%20Women&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

G. U.S. Department of Health and Human Services. (2021, july). *cdc.gov*. Retrieved from https://www.cdc.gov/std/treatment-guidelines/pocket-guide.pdf

APPROVALS:

Ambulatory Policy Committee: 5/2019

Medical Executive Committee: 5/2019, 12/2021

Revised and Approved by ACPC: 11/2021

Revised and Approved by APC: 12/2021

Joint Conference:

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Ambulatory Policy Committee	Laura R. Colebourn [LC]	01/2026
Ambulatory Clinical Practice Committee	Helena Martey: Chief Nursing Officer-Exempt	10/2025
	Kelley Taylor: Ambulatory Care Clin Supv	10/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19618643**

Origination	N/A	Owner	Carmen Gatmaitan: Cardiology Technician I
Last Approved	N/A	Area	Cardiology
Effective	Upon Approval		
Last Revised	N/A		
Next Review	3 years after approval		

Policy For Cardiology Department Disaster Plan

POLICY STATEMENT:

In the event of an emergency/disaster Cardiology Services will provide will provide emergent EKGs and ECHOs where power sources allow.

GUIDELINES:

Immediate Actions

Upon Notification, The Cardiology Services Manager, Supervisor, or designee will activate the department's disaster preparedness plan.

A. **Staff Assembly**
All in-house Cardiology Technicians and Cardiac Ultrasonographers will report to the CCRMC third floor Stress Room for briefing and assignment.

B. **Command Center Representation**
The Cardiology Services Manager, Supervisor, or designee will report to the Hospital Command Center for situational updates, instructions, and assignment coordination.

C. **Equipment & Supply Deployment**
The Manager, Supervisor, or designee will immediately locate, secure, and position essential EKG and echocardiography equipment, including portable units, throughout the hospital as needed.

D. **Operational Capability Assessment**
The Manager, Supervisor, or designee will evaluate the department's ability to provide cardiac diagnostic services, including:

1. Availability of power sources for EKG and ECHO machines.
2. Functionality of portable devices and battery-powered equipment.
3. Assessment of imaging and diagnostic systems for operational integrity.
4. Coordination with Facilities regarding electrical or equipment-related concerns.

E. Additional Equipment Needs
Evaluate the need for additional cardiac diagnostic equipment and notify Materials Management to anticipate increased demand.

F. Staffing Assessment
Assess current staffing levels and assign in-house personnel to ensure the most effective coverage for emergent cardiac diagnostics.

G. **Disaster Call-Back Plan**
Initiate the Cardiology Services disaster call-back plan to bring in additional staff as needed.

H. Status Reporting
Provide ongoing updates to the Command Center, including service capability, staffing, and equipment status.

I. Essential Supply Access
Ensure essential supplies for EKGs and ECHOs are available and accessible in the designated Cardiology Services workroom.

J. Equipment Monitoring
Monitor the operational status of all cardiac diagnostic equipment, including battery levels, power availability, and machine readiness.

K. Command Center Compliance
Respond promptly to directives issued by the Hospital Command Center.

L. **Service Prioritization & Resource Management**
Continuously assess:

1. Available inventory and supplies
2. Diagnostic services the department can safely provide
3. Prioritization of all cardiac diagnostic requests
4. Immediate and projected needs

M. Reporting Needs
Communicate equipment, staffing, or supply needs to the Medical Center Command and provide updates as requested.

N. Staff Well-Being
Observe staff for signs of stress, fatigue, or distress, and adjust assignments or provide relief as appropriate.

REFERENCES:

A. CCRMC Disaster Preparedness and Evacuation Plan

B. Hospital Emergency Incident Command System (HEICS), P&P Manual

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [GS]	02/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [AL]	02/2026
	Carmen Gatmaitan: Cardiology Technician I	01/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19390838**

Origination	06/2006
Last Approved	N/A
Effective	Upon Approval
Last Revised	08/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for Adverse Contrast Media Reaction/Non-Contrast Media Occurrances

POLICY STATEMENT:

To establish guidelines for the prevention and treatment of allergic reactions to intravascular contrast media used for Diagnostic Imaging (DI) studies and to establish guidelines for non-contrast media occurrences. Licensed personnel will monitor all patients receiving intravenous contrast media to immediately and effectively treat contrast reactions.

GUIDELINES:

A. Risk Factors for Contrast Reaction:
    1. Patients with history of allergies, especially previous reaction to contrast media (risk of reaction is two times greater than in the general population).
    2. History of asthma (risk of reaction is five times greater than in the general population).
    3. Marked anxiety.

B. Contrast Reaction Prevention:
    1. Obtain a complete health history on all patients.
    2. Patients with a history of asthma or allergy to IV contrast, iodine can be pre-medicated with 40 mg of Prednisone the night prior to and the morning of the injection. For urgent studies, an equivalent dose of IV Solumedrol may be utilized on the day of the examination. Any such patient not receiving proper pre-medication will be given contrast only at the discretion of the Radiologist.

3. Minimize patient anxiety by clearly explaining the procedure and forewarning them of the possible side effects (e.g., heat sensation and metallic taste).
4. Secure IV access.
5. Low-Osmolar contrast media (LOCM) will be injected.
6. IV access will be maintained until the potential for an acute reaction has passed (approximately 15 minutes).

C. Preparation for Hospital:
   1. Emergency drug box will be available in each exam room.
   2. Emergency equipment will be set up and for use.
   3. Radiologist and/or ED Physician will be contracted and determine patient's treatment plan.

D. Preparation for Computerized Tomography (CT) Mobile-Non-Contrast Media Reaction/Non-Life Threatening:
   1. DI CT Mobile Medication Box will be available.
   2. Emergency equipment.
   3. Technologist will call/page the Medical Officer of the Day (925) 346-4785/555-785 or Cell (925) 787-3082.
   4. Technologist will Contact on-call Radiologist listed on AMION.
   5. Physician and/or Nurse will determine patients' treatment plan as directed by attending physician.

RELATED LINKS:

Microsoft Word - Contrast_Manual_2023_Calculating eGFR_Gadopiclenol_Corrections Ellis (acr.org)

REFERENCES:

TJC 2024 Standard MM .07.01.03. "The hospital responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors."

APPROVALS:

Diagnostic Imaging Leadership: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date

Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19391011**

Origination	06/2008
Last Approved	N/A
Effective	Upon Approval
Last Revised	08/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for Care of Critical Patients in the MRI Department

POLICY STATEMENT:

To assure inpatient safety during MRI exams. The level of care for every patient shall be maintained in the MRI department as it is elsewhere in the hospital.

GUIDELINES:

A. Any patient whose condition required life support or physiologic monitoring must be accompanied by whatever qualified personnel and equipment needed to maintain the appropriate level of care.

B. MRI staff shall be responsible for screening personnel and equipment prior to entry into the MRI scan room.

C. The MRI Medical Director shall be notified any time there is a critical patient in the MRI unit.

D. If appropriate personnel are not available to accompany the patient, the exam shall be postponed, and the reason documented in the patient's chart.

APPROVALS:

Diagnostic Imaging Leadership: 8/2022

Patient Care Policy & Evaluation Committee: 9/2022

Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19427194**

Origination	06/2006	Owner	Angela Womble: Chief Radiologic Technologist
Last Approved	N/A	Area	Diagnostic Imaging
Effective	Upon Approval		
Last Revised	12/2025		
Next Review	1 year after approval		

Policy for Declared Pregnant Worker

POLICY STATEMENT:

To minimize the radiation exposure to the embryo/fetus of the declared pregnant worker. The dose should not exceed 0.5 rems (5~~m/Sv~~ mSv) over the entire pregnancy. The declaration of pregnancy must be in writing and is voluntary. That is, the pregnant worker need not declare her pregnancy if she so chooses. Further, the licensee is not required to restrict the dose to the embryo/fetus to 0.5 rems until a written declaration of pregnancy is made. The written declaration of pregnancy must include an estimated date of conception (Month/Year).

GUIDELINES:

A. The declared pregnant worker must meet with the ~~RSO~~Radiation Safety Officer or department manager to discuss precautions.

B. The declared pregnant worker must **wear a second monthly monitor** under their lead apron at waist level. In this way, the most representative exposure to the embryo/fetus can be recorded while maintaining a consistency with previous exposure records.

C. ~~Generally, reassignment or restrictions in work assignment is not necessary.~~

Generally, reassignment or restrictions in work assignment is not necessary. Consideration ***may*** be given to reassignment of the declared pregnant worker or to placing certain duty restrictions on the individual to limit the exposure to the embryo/fetus.

D. ~~Consideration ***may*** be given to reassignment of the declared pregnant worker or to placing certain duty restrictions on the individual to limit the exposure to the embryo/fetus.~~

E. Documentation of the employee's review of this policy will be indicated on the employee's

declaration.

F. Exposure records and the written declaration of pregnancy will be maintained in the employee's personnel file.

REFERENCES:

A. § 20.1208 Dose Equivalent To An Embryo/fetus. | NRC.gov (Accessed 2.24.24 PC)

B. Radiation and Pregnancy: Information for Clinicians | CDC Radiation Emergencies (Accessed 2.24.24 PC)

APPROVALS:

Diagnostic Imaging Leadership: 8/2022, 8/2023, 4/2024, 4/2025
Patient Care Policy & Evaluation Committee: 9/2022, 6/2024
Medical Executive Committee: 9/2022, 6/2024
Joint Conference Committee: 11/14/2024

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	01/2026
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19390834**

Origination	06/2006
Last Approved	N/A
Effective	Upon Approval
Last Revised	08/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for Gadolinium Based Contrast Media (MRI)

POLICY STATEMENT:

To provide guidelines for the use of Gadolinium-Based Contrast Media in patients with kidney dysfunction.

GUIDELINES:

A. Diagnostic Imaging staff will pre-screen and obtain health and allergy history on all patients prior to contrast media administration for MRI exams.

B. Patients with acute kidney injury (AKI) or chronic, severe kidney disease and that currently undergoing dialysis will be evaluated on a case-by-case basis by the Radiologist performing the MRI.

C. The Radiologist on the final Diagnostic Imaging Report will dictate the type and amount of contrast media injected.

RELATED LINKS:

ccLink (EPIC)

REFERENCES:

Information on Gadolinium-Based Contrast Agents | FDA (accessed 2.23.24 PC)

APPROVALS:

Diagnostic Imaging Department Leadership: 8/22

Patient Care Policy and Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19390841**

Origination	06/2006
Last Approved	N/A
Effective	Upon Approval
Last Revised	08/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for General Orientation of Newly Appointed Diagnostic Imaging Employees

POLICY STATEMENT:

The orientation program for the Diagnostic Imaging Department is designed to prepare the staff for performance of duties in the Imaging Departments of Contra Costa Regional Medical Center and Health Centers.

GUIDELINES:

A. Each new employee will complete the organization's new employee and department orientation programs.

B. Documentation of orientation will be maintained in the employee's personnel folder located in the Diagnostic Imaging Department.

C. Upon completion of the orientation, the new employee will receive organizational and departmental information regarding the following:

1. A Guide to Location of Services
2. Universal Blood and Body-Fluid Precautions
3. Fire Procedure
4. Department Emergency Exits
5. Execution of Emergency Procedures (i.e., code blue, redstone, STAT team, paging system)
6. Patient Confidentiality

7. Radiation Safety
8. Emergency Drug Carts
9. DI Clerical Workroom
10. Department Policies and Procedures
11. General Safety Responsibility
12. Job Description and Performance Expectations
13. Continuous Quality Improvement (CQI)
14. Use and Maintenance of Equipment (as necessary)
15. Disaster Preparedness

RELATED LINKS:

Diagnostic Imaging Personnel File

REFERENCES:

CCRMC Hospital Policy #247, "Orientation, Continuing Education and In-Service Training for Employees."

APPROVALS:

Diagnostic Imaging Leadership: 8/2022

Patient Care Policy & Evaluation Committee: 9/2022

Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19391150**

Origination	05/2001
Last Approved	N/A
Effective	Upon Approval
Last Revised	08/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for Infection Control Practices in Diagnostic Imaging

POLICY STATEMENT:

Policy provides guidelines for infection prevention and control practices within the Diagnostic Imaging Department. Staff must always follow proper infection prevention and control practices.

GUIDELINES:

A. Standard Precautions:

1. All patients should be handled using standard precautions.
2. If a patient has a contagious respiratory disease, respiratory isolation precautions will be used in addition to standard precautions.
3. X-ray procedures will be scheduled in sequence so there is minimal patient waiting time in the department.
    a. If possible, defer the examination until the patient is out of respiratory isolation.
    b. If this is not possible and the patient must have X-rays performed, schedule the examination to be done late in the morning or afternoon to minimize contact with others.
    c. If patient is brought to the department, he/she will be wearing a mask.
4. Radiological technologists will adhere to all policies and procedures for isolation.
5. Personnel from the floor will mark the requisition with respiratory isolation when appropriate. All other patients will be under standard precautions.
6. Any sterile procedures shall be performed using strict sterile technique.

B. Sterile Procedure in Diagnostic Imaging Department

1. Angiography:
    a. Sterile techniques such as practiced in the Operating Room will be used.
    b. Shave the area involved only if necessary. The skin surface is scrubbed for three minutes with Septo Dyne solution (providine iodine).
    c. The area is painted with E-Z Prep point sticks with Iodophor.
    d. Drape the area with sterile drapes before beginning the procedure. Have sterile gloves, gowns, as well as eye protection and mask available for the physician.
    e. Check all injectable material for sterility and expiration date.
2. Intravenous Pyelogram:
    a. Sterile technique will be practiced.
    b. Gloves will be worn by the physician, nurse or IV certified technologist starting the IV.
3. Barium Studies:
    a. Disposable enemas bags are used.
    b. Barium suspension should be freshly prepared.
    c. Personnel should wear gloves and gowns if appropriate.
    d. Any spills from patient should be wiped up immediately by the technologist or environmental services using a phenolic cleaner.
4. Equipment:
    a. Portable X-ray equipment should be wiped once daily with germicide solution.
    b. Lead aprons and other protective shielding (i.e., gonad, thyroid, etc.) contaminated with blood or other body fluids will be removed from department circulation immediately and cleaned and deodorized by scrubbing with an approved germicide wipe and rinsed thoroughly with water to remove residue of cleaner.
    c. If portable X-ray equipment is used in respiratory isolation rooms, it must be decontaminated as it leaves the room. Every surface must be wiped or sprayed with germicidal solution.
    d. Place all disposable enema bag IV's, foley catheters, etc., in the appropriate disposal area.
    e. Return all non-disposable sterile trays and instruments to Central Supply for processing and re-sterilization.
    f. Wipe tables with disinfectant after any procedure in which body secretions, excretions, or fluids are handled.
    g. Disposable items will be used when possible. Disposables should be

handled in accordance with the manufacturer's instructions and should be considered contaminated when open and not re-sterilized.

h. Sharps should be carefully handled and disposed of in designated sharp containers.

REFERENCES:

A. Healthcare - Standards | Occupational Safety and Health Administration (osha.gov) (Accessed 2.24.24 PC)

APPROVALS:

Diagnostic Imaging Leadership: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19408033**

Origination	05/2017
Last Approved	N/A
Effective	Upon Approval
Last Revised	08/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for Lead Apron/ Shielding: Cleaning and Storage

POLICY STATEMENT:

To provide guidelines for lead apron/shielding cleaning and storage.

GUIDELINES:

Radiologic Technologist will follow the standard procedure when cleaning and storing lead apron/ shielding.

A. General Guidelines:
   1. When wearing a thyroid shield, always wear a thyroid shield cover.
   2. Prior to use, inspect apron thoroughly for general cleanliness and integrity (no rips, holes, cracks, or frayed seams).
   3. Never throw aprons on the floor or fold. Always hang apron on heavy-duty lead apron hangers.

B. Routine Care of Aprons:
   1. Apron and thyroid shields should be wiped down with Sani-Wipes (purple top) as soon as possible after each use.
   2. Heavily soiled apron/shields can be washed in a sink with mild detergent and laid flat to dry. Generally, takes 24 hours to dry.

C. Annual Care of Aprons:
   After physicist inspection, lead aprons will be cleaned annually. Products used:
   1. Sani-wipes (purple top)

2. Mild detergent.

REFERENCES:

TJC 2024 Standard IC .02.02.01"The hospital reduces the risk of infections associated with medical equipment, devices, and supplies."

APPROVALS:

Diagnostic Imaging Leadership: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19390926**

Origination	02/2006
Last Approved	N/A
Effective	Upon Approval
Last Revised	08/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for Mammography Comparison Images

POLICY STATEMENT:

To outline the process for obtaining outside mammography comparison images for current exam readings. Mammography exams will be dictated within a maximum of 10 working days from the time the exam was performed, if waiting for outside mammography comparison images.

GUIDELINES:

A. At the time of scheduling the patient appointment, Diagnostic Imaging staff will ascertain information from the patient as to when and where their last mammogram was performed. After receiving this information, the DI staff will immediately request outside images as necessary. Diagnostic Imaging staff will review the outside film log to assure films are received. If the images have not been received after two weeks (sooner if necessary), a second request will be made.

B. In cases where the images have not arrived prior to the patient's exam, the radiologist will review the current images; these images will be held for no more than 10 working days, after which a formal reading will be performed. DI staff will again request the outside images.

APPROVALS:

Diagnostic Imaging Leadership: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19408094**

Origination	05/2006
Last Approved	N/A
Effective	Upon Approval
Last Revised	08/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for Mammography Records

POLICY STATEMENT:

To provide guidelines for saving and storing mammography records.

GUIDELINES:

The Diagnostic Imaging Department will preserve all mammography records according to American College of Radiology Recommendation..

REFERENCES:

Record Keeping: Mammography (Revised 12-12-19) : Accreditation Support (acr.org)

APPROVALS:

Diagnostic Imaging Leadership: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date

Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19455216**

Origination	06/2006
Last Approved	N/A
Effective	Upon Approval
Last Revised	08/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for Missed Appointments

POLICY STATEMENT:

To establish a guideline for missed appointments in the Diagnostic Imaging Department.

An appointment is considered "missed" or "broken" if the patient fails to notify the department 24 hours in advance that they cannot keep their appointment.

GUIDELINES:

A. When the patient misses or breaks an appointment:
    1. Use the tracking device to change the status of the appointment by right clicking on the appointment.
    2. Select the "No Show" option and enter. **Note**: If you do not use the "**No** Show" option before you select the "Reschedule" option, it is not possible to go back and change the status to reflect that the patient has missed an appointment.

B. As part of Diagnostic Imaging Department's Three Strikes Policy, if the patient calls to reschedule on the day of the scheduled appointment, before rescheduling, be sure to use the tracking device.
    1. Uncheck the "Cancelled" and "Past Appointment" boxes.
    2. If the Pie Chart shows that the patient has missed an appointment, the missed appointments are flagged red.
    3. The Pie Chart will reflect what appointment(s) were missed and the number of failures to show.
    4. If the patient has missed an appointment, notify them of the Three Strikes Rule.

5. If they miss a second time, want them that failure to keep the 3rd scheduled appointment will be reported to their Provider, and the appointment will not be rescheduled.

C. **Note**: There are extenuating circumstances that may have caused the patient to miss their appointment(s) (i.e., cancer patient ill from the effects of chemotherapy, physically challenged, elderly, etc.)
    1. Use discretion and/or consult a Radiologist as necessary.
    2. Make all attempts to adhere to the policy as appropriate.

RELATED LINKS:

Diagnostic Imaging Requisition in ccLink
Radiant (RIS)

APPROVALS:

Diagnostic Imaging Leadership: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	01/2026
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19390985**

Origination	06/2006
Last Approved	N/A
Effective	Upon Approval
Last Revised	08/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for Physicians Authorized to Perform Diagnostic Fluoroscopy

POLICY STATEMENT:

To establish which physicians are authorized to perform diagnostic fluoroscopy.

GUIDELINES:

A. Diagnostic fluoroscopy can only be performed or supervised by a radiologist or other medical staff member in possession of a California State Radiology X-Ray Supervisor and Operator Permit.

B. Radiologic Technologists or non-physician personnel shall not independently perform diagnostic fluoroscopy.

C. Radiologists and other medical staff members who perform diagnostic fluoroscopy (either within the Diagnostic Imaging Department or outside the department utilizing portable fluoroscopic equipment) must apply for and maintain a California State Radiology X-Ray Supervisor and Operator Permit. The Diagnostic Imaging Department and Medical Staff Office shall maintain a list of all physicians on the Medical Staff who possess a valid permit.

D. Physicians not licensed to perform fluoroscopy must be supported by a licensed Radiologist or other licensed physician.

E. Radiologic Technologists or non-physician personnel shall not independently perform diagnostic fluoroscopy.

F. Patients scheduled for a fluoroscopic examination in the Diagnostic Imaging Department will be brought to a fluoroscopy room by a radiologic technologist. The technologist will prepare the patient according to the appropriate protocol and will notify the Radiologist and/or

physician when ready for fluoroscopy.

RELATED LINKS:

ccLink (EPIC) Diagnostic Imaging Report

Copies of physicians' California State Radiology X-ray Supervisor and Operator Permits are maintained in the Medical Staff Office and the Diagnostic Imaging Department

REFERENCES:

California Code of Regulations, Title 17, Division 1, Chapter 5, Subchapter 4.5 "Radiologic Technology", Group 1, Article 7, Section 30408. "Certificate and Permit Fees" (Confirmed 2.22.24 PC)

APPROVALS:

Diagnostic Imaging Leadership: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19390990**

Origination	06/2006
Last Approved	N/A
Effective	Upon Approval
Last Revised	09/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for Protocols for General Diagnostic Radiography and Mammography

POLICY STATEMENT:

To provide standard protocol when performing radiography, fluoroscopic and contrast studies, and mammography are included on the following pages s for Radiologic Technologists performing general diagnostic radiography, fluoroscopic and contrast studies, and mammography.

GUIDELINES:

Standard protocols for general radiographic examinations, fluoroscopic and contrast studies and mammography are online or in a binder.

APPROVALS:

Diagnostic Imaging Leadership: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date

Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19428076**

Origination	06/2006
Last Approved	N/A
Effective	Upon Approval
Last Revised	12/2025
Next Review	1 year after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for Radiation Physicist Survey

POLICY STATEMENT:

To provide ~~physics~~physicist support ~~services and to ensure~~to certify that all radiographic equipment is operating ~~at an optimal level~~properly and room shielding is adequate.

GUIDELINES:

An inspection by the radiation physicist will be performed annually and upon the installation of any X-ray equipment, or installation of a new X-ray tube/image intensifier~~; and of all lead shielding and accessories (aprons, gloves, thyroid shields, vests, half-aprons)~~.

A. All radiographic equipment that produces ionizing radiation will be inspected by a certified radiation physicist.

B. Adequacy of room shielding will be verified on installation of new fixed imaging equipment.

C. Any areas of concern that do now comply to State and Federal regulations will be reported to the equipment manufacturer or independent contractor for correction.

D. The physicist will review the policy and procedure for radiation safety.

E. The physicist will serve as consultant on all patient care issues that require physics support. The physicist will make recommendations on equipment when called upon to do so.

RELATED LINKS:

~~The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation onc (acr.org)~~

Preparing for Medical Clinic Inspection

APPROVALS:

Diagnostic Imaging Leadership: 8/2022, 8/2023, 4/2024, 4/2025
Patient Care Policy and Evaluation Committee: 9/2022, 6/2024
Medical Executive Committee: 9/2022, 6/2024
Joint Conference Committee: 11/14/2024

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	01/2026
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19419574**

Origination	04/2004	Owner	Angela Womble: Chief Radiologic Technologist
Last Approved	N/A	Area	Diagnostic Imaging
Effective	Upon Approval		
Last Revised	12/2025		
Next Review	3 years after approval		

Policy for Radiologists' Professional Duties and Responsibilities

POLICY STATEMENT:

To outline the radiologists' responsibilities in relation to the delivery of medical care by the Diagnostic Imaging Department.

GUIDELINES:

A. Radiologist members of the department shall collectively perform the professional services and teaching duties of the department.

B. These duties and responsibilities shall be outlined and assigned by the Diagnostic Imaging Department Chief.

C. Professional Services Performed by Radiologists:

1. Formal interpretation of all imaging studies and diagnostic and therapeutic procedures performed by the Diagnostic Imaging Department, with dictation of an official report for inclusion in the medical record.
2. Supervision and direction of all radiologic examinations and procedures performed by radiologic technologists, nursing staff, and other ancillary staff within the department. This includes designation of examination protocols, determination of appropriate patient preparation, review of images, determination of the need for supplementary images/views, and prescription of radiographic contrast media and medications.
3. Performance of imaging procedures or portions thereof which require direct radiologist participation.

4. Establishment of protocols and policies for imaging studies and procedures performed by the Diagnostic Imaging Department.
5. Consultation with referring clinicians regarding the indications and contraindications of imaging studies, optimal utilization of imaging services for patient care, and proper patient preparation for diagnostic imaging examinations.
6. When necessary, performance of targeted history and/or examination of patients undergoing imaging studies and procedures.
7. Efficient communication of the results of imaging studies and procedures and recommendations for treatment and/or additional diagnostic studies to referring clinicians and/or other responsible healthcare providers.

D. Assignment of Diagnostic Imaging Departmental Workload:
    1. Allocation of workload (including performance and interpretation of imaging examinations and procedures) amongst the staff radiologists shall be determined by the radiologists, with consideration of each radiologist's skills, experience and availability.

E. Communication of Results of diagnostic Imaging Studies:
    1. Radiologists will dictate reports for all imaging studies interpreted and procedures performed within the department. Reports will be typed by the Diagnostic Imaging Department transcriptionists or transcription service utilized by CCRMC. Transcribed reports are available to the radiologists for electronic authentication and signature.
    2. When a radiologist is present in the Diagnostic Imaging Department, examinations performed on patients from the Emergency Department will be immediately presented to a radiologist by the technologist. The radiologist will dictate a report promptly.
    3. The radiologists will report medically emergent results verbally to the ordering clinician or other responsible healthcare provider upon completion of an examination. Documentation of such communication should be included in the radiologist's dictated report.
    4. When reviewing or performing urgent imaging studies or procedures "after hours," the on-call radiologist will report the results promptly to the ordering clinician or other responsible healthcare provider.

F. Radiologist Availability:
    1. At least one staff radiologist will be available within the Diagnostic Imaging Department during the hours of 8:30 AM to 5:00 PM, Monday through Friday, excluding holidays.
    2. A staff radiologist will be available "on-call" at all times twenty-four hours daily and during weekends and holidays.
    3. ~~A~~The radiologist will dictate reports on all available examinations and notify the medical and/or nursing staff ~~radiologist will be available in the Diagnostic Imaging Department on all weekends and holidays. The radiologist on-call will arrive in the morning and remain in the department for as long as is necessary, as determined by~~

~~the volume of work and consideration of the needs of the patients and the medical staff. The radiologist will dictate reports on all available examinations and notify the medical and/or nursing staff~~ of pertinent results as necessary.

G. Physician Education:

1. A staff radiologist will be available for presentation and discussion of imaging studies at selected CCRMC medical conferences, including the weekly Cancer Conference.
2. The radiologists will endeavor to educate staff and resident physicians and other health care providers regarding the indications, contraindications, patient preparation, optimal utilization, and proper ordering of diagnostic imaging examinations and procedures, as well as basic image interpretation skills.

RELATED LINKS:

What Is a Radiologist? | American College of Radiology (acr.org)
Scope of Practice | American College of Radiology (acr.org)

APPROVALS:

Diagnostic Imaging Leadership: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [TT]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19455234**

Origination	10/2012
Last Approved	N/A
Effective	Upon Approval
Last Revised	08/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for Release of Medical Imaging Records

POLICY STATEMENT:

To provide a reference to assist Diagnostic Imaging personnel when handling a request for release of medical imaging records.

GUIDELINES:

A. The Contra Costa Health Services Diagnostic Imaging Department will refer patients requesting Diagnostic Imaging reports only to the Health Information Management Department for release of reports.

B. The Contra Costa Health Service Diagnostic Imaging Department will release medical imaging records to the patient, the patient's legal representative or to a medical facility after a "Diagnostic Imaging Department Authorization to Disclose Medical Information" request is completed.

C. The Contra Cost Health Service Diagnostic Imaging Department will not release studies in a "Reported" status. Studies in a "Reported" status have not yet been signed by the dictating radiologist. The Imaging staff will ask a Radiologist to dictate and sign the report prior to publishing the study to CD media.

D. A "Diagnostic Imaging Authorization to Disclose Medical Information" request will be completed prior to releasing the imaging record/CD Media.

E. Diagnostic Imaging Medical Imaging staff will follow the CE Media Guideline for preparing CDs.

F. The Diagnostic Imaging Medical Imaging staff will open the CD and cross-reference it to the request to ensure the correct exam is recorded prior to releasing it to the requestor.

G. The Diagnostic Imaging Medical Imaging Records staff will cross-reference the CD to the request to ensure the patient information imprinted on the front of the CD is correct prior to releasing it to requestor.

APPROVALS:

Diagnostic Imaging Leadership: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	01/2026
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19408090**

Origination	07/2006	Owner	Angela Womble: Chief Radiologic Technologist
Last Approved	N/A	Area	Diagnostic Imaging
Effective	Upon Approval		
Last Revised	08/2022		
Next Review	3 years after approval		

Policy for Staffing Coverage of Diagnostic Imaging Department

POLICY STATEMENT:

To assure department coverage is maintained if assigned staffing personnel is unavailable for his/her shift.

GUIDELINES:

A. Diagnostic Imaging personnel will not leave the department unstaffed.

B. DI personnel are required to stay on duty or call for support using the phone list (by seniority) if the assigned staff person for the next shift is unavailable.

    1. CT on-call technologist can be called to support on-duty technical staff if workload requires additional support.

APPROVALS:

Diagnostic Imaging Department Leadership: 8/22

Patient Care Policy and Evaluation Committee: 9/2022

Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19390906**

Origination	06/2006
Last Approved	N/A
Effective	Upon Approval
Last Revised	12/2025
Next Review	3 years after approval
Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Policy for VRAD Radiology Service

POLICY STATEMENT:

To provide ~~preliminary~~final Radiologic exam interpretations after normal business hours. Any diagnostic imaging exam can be sent via PACS to vRad Radiology Services during the hours of ~~6~~4 PM – ~~8~~7 AM, seven days a week.

GUIDELINES:

A. DI Staff will send urgent/stat exam images to vRad Radiology Services as necessary or as requested for ~~a preliminary~~final interpretation.

B. ~~Every study read by vRad will be re-read by the CCRMC staff radiologist.~~

C. Report discrepancies are reported to the vRad QA on a QA Discrepancy Submission Form.

D. A designated radiologist will present a summary of QA data, along with associated corrective action for discrepancies, in the DI monthly meeting.

APPROVALS:

Diagnostic Imaging Leadership: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19455244**

Origination	06/2006
Last Approved	N/A
Effective	Upon Approval
Last Revised	08/2022
Next Review	3 years after approval

Owner	Angela Womble: Chief Radiologic Technologist
Area	Diagnostic Imaging

Three (3) Strikes Policy for Re-Scheduling Appointments

POLICY STATEMENT:

To establish a guideline for re-scheduling Diagnostic Imaging procedures for the patient who has missed 3 scheduled appointments.

GUIDELINES:

A. An appointment is considered "missed" or "broken" if the patient fails to notify the department 24 hours in advance that they cannot keep their appointment. It is also considered missed if the patient calls to cancel on the day of the appointment.

B. Every patient, after having missed one (1) appointment is notified of the "3 Strikes Policy."

C. Any patient who has failed to show up for a total of three (3) appointments will not be re-scheduled.

    1. Because there are often extenuating circumstances that may cause the patient to miss their appointment(s), it is important to be considerate and use discretion in making this decision.

D. After Three (3) No Shows, DI Clerical Staff will document in "order comments" and notify ordering physician to determine if patient is still to be scheduled for desired exam.

RELATED LINKS:

Diagnostic Imaging Requisition
Diagnostic Imaging Scheduling System (DISS)

APPROVALS:

Diagnostic Imaging Leadership: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	01/2026
DI Policy & Procedure Committee	Angela Womble: Chief Radiologic Technologist	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **18709549**

Origination	01/2025
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	3 years after approval

Owner	David Piccinati: Associate Medical Director
Area	Hospital & Health Centers

CCRMC & HC's EMTALA Policy

POLICY STATEMENT:

~~Contra Costa Regional Medical Center (CCRMC) shall provide for a medical screening examination and necessary stabilizing care for any individual who comes to the hospital and requests[1] the evaluation or treatment for an Emergency Medical Condition[2] or labor without regard to their ability to pay and in accordance with the federal Emergency Medical Treatment and Labor Act ("EMTALA").~~

The purpose of this policy is to ensure that all individuals who come to a Dedicated Emergency Department at Contra Costa Regional Medical Center (hereinafter referred to as "CCRMC" or the "Hospital") seeking care or treatment for a medical condition will receive an appropriate Medical Screening Examination, within the capability of the Hospital, to determine whether an Emergency Medical Condition exists as required by the federal Emergency Medical Treatment and Labor Act ("EMTALA"), codified at 42 U.S.C., Section 1395dd and all federal regulations and interpretive guidelines promulgated thereunder.

Such Medical Screening examinations will be provided without regard to a patient's race, ethnicity, religion, national origin, citizenship, age, gender, sexual orientation, pre-existing medical condition(s), physical or mental disability, insurance status, economic status, or ability to pay for medical services.

If an Emergency Medical Condition exists, the individual must receive treatment within the Hospital's capabilities until the individual is stable for transfer or discharge, regardless of the individual's insurance status or ability to pay.

GUIDELINES:

A. TRIGGER: The following guidelines apply to the evaluation and treatment of:

1. An individual who presents to the hospital's emergency department or labor and delivery unit requesting care for or the evaluation or treatment of any medical or surgical condition; and
2. An individual who presents within 250 yards of the hospital (including parking lots, excluding on-site clinic buildings) and:
    a. requests care for a medical or surgical emergency;
    b. appears to be experiencing a medical or surgical emergency; or
    c. requests care for or appears to be a person in labor.

B. CENTRAL LOG: The below listed data should be collected for any individual who triggers the hospital's EMTALA obligations:

1. the individual's name;
2. the date and time of arrival;
3. the presenting complaint; and
4. the date, time, and nature of disposition (discharged home, admitted, transferred, left before the conclusion of care, expired, etc.)

C. POSTING OF SIGNS: Legible signs advising the public of their rights under EMTALA should be posted in readily visible locations within the emergency department and labor and delivery.

D. MEDICAL SCREENING AND STABILIZATION: A medical screening examination and care within the current capability of the hospital to stabilize any Emergency Medical Condition should be provided to individuals who trigger the hospital's EMTALA obligations as described in section 'A' above.[3] The medical screening examination should be completed by a Qualified Medical Person ("QMP"), as spelled out in the Medical Staff Rules and Regulations. Although the ultimate responsibility for medical screening rests with the QMP conducting or directing medical screening and stabilization, they may rely on information provided by others on the health care team in making their decision about whether an Emergency Medical Condition exists, whether a person is in labor, the need for stabilizing care and treatment, or any indicated continuing plan of care and treatment for the stabilized patient. For example:

1. A QMP may rely on the judgment of a community-based psychiatric evaluation team in making a determination about whether a patient presents a credible danger to themselves or others.
2. A QMP may rely on the assessment of and supportive information provided by a qualified labor and delivery nurse when making the decision as to whether a person is in labor, whether they should be admitted or observed, or whether they may be safely discharged with instructions about when to return to the hospital.
3. A QMP may rely on the advice of on-call specialists when making a determination as to a patient's plan of care and treatment.

E. ON-CALL PHYSICIANS: The hospital should maintain a roster of on-call physicians who agree

to respond as described in the Medical Staff Rules and Regulations.

F. TRANSFERS TO OTHER HOSPITALS

1. STABLE AND ADMITTED PATIENTS: Neither EMTALA nor this guideline applies to the transfer of hospital inpatients or to patients where the QMP finds"... that no material deterioration of the [patient's]condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility ..."
2. UNSTABLE PATIENTS AND PEOPLE IN LABOR: The transfer of an unstable patient or a person in labor should only be carried out:
    a. when the risks of the transfer are outweighed by the benefits of the care available at the receiving institution, or
    b. at the request of the patient or their legal representative after the risks of the transfer have been explained.
3. TRANSFER PROCESS:
    a. Transfers should be carried out after confirming that the receiving hospital has the current capacity and capability to care for the patient and has agreed to accept the patient.
    b. The EMTALA transfer certification and acknowledgement form in the EMR (ccLink) should be used to document the transfer of unstable patients and people in labor.
    c. Transfers should be carried out using appropriate equipment, supplies and qualified accompanying personnel.
    d. A copy of records related to the transferred individual's current Emergency Medical condition should be provided to the receiving hospital at the time of transfer or as soon as the information becomes available thereafter, including:
        i. pertinent history,
        ii. observations of signs or symptoms,
        iii. preliminary diagnosis,
        iv. results of diagnostic studies or tests, and
        v. treatment(s) provided.
    e. The information provided to the receiving hospital should include the name and address of any on-call Practitioner who failed to provide examinations of or care to the patient when obliged to do so by the hospital's Medical Staff Rules and Regulations.

G. REQUESTS FOR TRANSFERS FROM OTHER HOSPITALS: This hospital is obliged to accept the transfer of a patient from another hospital when all of the following conditions are met:

1. the transferring hospital is within the United States, including United States territories; and

2. ~~the transferring hospital represents that it is not currently capable of providing the care necessary to stabilize the patient's Emergency Medical Condition or safely accommodate risks to the person in labor or the fetus; and~~
3. ~~this hospital (the receiving hospital) has the current capability and the capacity to provide the stabilizing care requested by the transferring hospital representative.~~

H. ~~[OPTIONAL: TO BE INCLUDED AS APPLICABLE] TRANSFER CENTER: Requests for transfers to and from other hospitals should be coordinated through the hospital's Transfer Center, which should promptly verify the availability of necessary specialists, personnel, equipment and staffed beds at any hospital that will receive the patient upon transfer. The Administrator on Call should be promptly consulted should Transfer Center personnel conclude that care requested for an unstable patient at another hospital is not currently available at this hospital.~~

I. ~~RECEIPT OF PATIENTS FROM OTHER HOSPITALS IN VIOLATION OF EMTALA: If hospital personnel believe this hospital has received an unstable patient transferred from another hospital in violation of EMTALA, they shall promptly refer the matter via the Safety Event Reporting System (SERS) for investigation and, if verified, report to CMS.~~

~~Guideline for Locations Away from the Main Hospital Campus~~

~~The following applies when an individual presents to a location covered under the hospital's CMS Certification Number (CCN) that is away from the hospital's main campus and when the individual: requests care for a medical or surgical emergency; or appears to a prudent layperson to be experiencing a medical or surgical emergency; or requests care for or appears to be a person in labor:~~

A. ~~First aid and stabilizing care should be provided to the patient within the current capabilities of the off-campus location.~~

B. ~~When indicated by the individual's complaint or condition, hospital personnel should activate the community's pre-hospital-care system (e.g. call 911).~~

C. ~~A record should be made of the event.(Entries into a central log and the maintenance of a medical record are not required.)~~

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1. ~~Requests for care may be made by the patient or any other individual on behalf of the patient.~~
2. ~~An Emergency Medical Condition is defined by EMTALA as a "medical condition manifesting itself by acute symptoms of sufficient severity, which may include severe pain, such that the absence of immediate medical attention would reasonably be expected to result in serious jeopardy to the patient's health."~~
3. ~~The hospital meets its obligation to provide a medical screening examination should the patient voluntarily and without coercion decide the leave before the completion of medical screening or the conclusion of stabilizing care.~~

A. Definitions

1. **Dedicated Emergency Department** refers to all Hospital departments and/or facilities where an individual might present for emergency services or to receive a Medical Screening Examination, including CCRMC's Emergency Department and Labor and Delivery Unit (See **Appendix A** for other definitions, including but not limited to, the definition of an

"Emergency Medical Condition".)

B. SCOPE Of EMTALA

1. EMTALA is applicable to any individual who presents to the Hospital's Emergency Department or Labor and Delivery Unit requesting care for or the evaluation or treatment of any medical condition, or an individual who appears to be experiencing a medical emergency.
2. EMTALA **does not** apply to:
    a. An inpatient (including patients who are "boarded" in the Dedicated Emergency Department waiting for an available bed);
    b. An individual who presents to any off-campus department of the Hospital that is not a Dedicated Emergency Department;
    c. An outpatient during the course of his/her encounter (even if the Outpatient develops an emergency medical condition while receiving outpatient services and is taken to the Dedicated Emergency Department for further examination and treatment);
    d. An individual who presents to a private physician's office or other ambulatory care clinic that participates separately from the Hospital in the Medicare program; and
    e. Restaurants, private residences, shops, or other nonmedical facilities that are not part of the Hospital.
3. Application to Physicians: EMTALA is applicable to any physician who is responsible for the examination, treatment, or transfer of an individual to whom EMTALA applies, including an on-call physician and other members of the Hospital staff who provide for the care of such individual.

C. GENERAL POLICIES

1. CENTRAL LOG. Each dedicated Emergency Department of the Hospital will maintain a central log recording the names of individuals who present to the Dedicated Emergency Department. The below listed data should be collected for any individual who triggers the hospital's EMTALA obligations:
    a. the individual's name;
    b. the date, time, and means of arrival;
    c. the presenting complaint; and
    d. the date, time, and nature of disposition including:
        i. Whether the individual was admitted and treated;
        ii. Whether the individual was discharged;
        iii. Whether the individual was stabilized and transferred;
        iv. Whether the individual refused treatment;
        v. Whether the individual was refused treatment by the hospital;
        vi. Whether the individual was transferred;
        vii. Whether the individual left before the conclusion of care; or

viii. Whether the individual expired.

2. POSTING OF SIGNS: The Hospital must post signs in conspicuous locations likely to be noticed by all individuals entering the Emergency Department, Labor and Delivery Unit, and other areas where examination and treatment occurs, e.g., lobbies, waiting rooms, admitting areas, entrance, and treatment areas, in the form required by CMS that advises the public of their rights under EMTALA with respect to examination and treatment for emergency medical conditions and women in labor, and whether the hospital participates in the States Medi-Cal Program. The signage must be printed in English and other major languages common to the population served by the Hospital.
3. ON-CALL PHYSICIANS: The Hospital will maintain a roster of on-call physicians who are "on-call" for duty to consult or to provide further evaluation and/or treatment necessary to stabilize an individual with an Emergency Medical Condition after the initial Medical Screening Examination. The purpose of the on-call list is to ensure that the Emergency Department is prospectively aware of which physicians, including specialists and sub-specialists, are available to provide necessary treatment to stabilize individuals with Emergency Medical Conditions. An on-call physician's responsibilities to respond to, examine, and treat emergency patients are described in the Medical Staff Rules and Regulations. The notification of an on-call physician shall be documented and any failure or refusal of an on-call physician to timely respond to call will be reported to the Department Chair and the Medical Executive Committee as set forth in Section 2.2.6 of the Medical Staff Rules and Regulations.
4. DISPUTES: In the event of any concern over emergency services to an individual, or a dispute with another facility regarding a transfer or a concern about the Hospital's compliance with EMTALA, Hospital staff or physicians will refer the dispute to [the person designated by the Hospital].
5. NON-RETALIATION: The Hospital will not retaliate, penalize, or take adverse action against any physician or Qualified Medical Person for refusing to transfer an individual with an Emergency Medical Condition that has not been stabilized, or against any Hospital employee for reporting a violation of EMTALA or State laws to a governmental enforcement agency.

D. MEDICAL SCREENING EXAMINATION

1. If an individual comes to the Dedicated Emergency Department and the individual, or someone on the individual's behalf, requests examination or treatment for a medical condition, then the Hospital must provide a Medical Screening Examination within the Hospital's current capability, including ancillary services that are routinely available to the Emergency Department, to determine whether an Emergency Medical Condition exists.
2. The Hospital shall not delay in providing a Medical Screening Examination or necessary stabilizing treatment in order to inquire about an individual's method of payment or insurance status.
3. The Medical Screening Examination must be tailored to the individual's presenting complaint and medical history, and must be the same Medical Screening Examination that the hospital would perform on any individual presenting to the Hospital with similar signs and symptoms, regardless of the individual's ability to pay for medical care.
4. Triage is **not** equivalent to a Medical Screening Examination.
5. The Medical Screening Examination must be completed by a Qualified Medical Person

("QMP"), as set forth in Section 2.2.7 of the Medical Staff Rules and Regulations. Although the ultimate responsibility for medical screening rests with the QMP conducting or directing medical screening and stabilization, they may rely on information provided by others on the health care team in making their decision about whether an Emergency Medical Condition exists, whether a person is in labor, the need for stabilizing care and treatment, or any indicated continuing plan of care and treatment for the stabilized patient. For example:

   a. A QMP may rely on the judgment of a community-based psychiatric evaluation team in making a determination about whether a patient presents a credible danger to themselves or others.

   b. A QMP may rely on the assessment of and supportive information provided by a qualified labor and delivery nurse when making the decision as to whether a person is in labor, whether they should be admitted or observed, or whether they may be safely discharged with instructions about when to return to the hospital.

   c. A QMP may rely on the advice of on-call specialists when making a determination as to a patient's plan of care and treatment.

6. The Medical Screening Examination is a continuous process reflecting ongoing monitoring in accordance with an individual's needs. Monitoring will continue until the individual is stabilized or appropriately transferred. Reevaluation of the individual must occur prior to discharge or transfer.

E. PATIENT REGISTRATION

1. The Hospital must not delay the process of providing a Medical Screening Examination or necessary stabilizing treatment in order to inquire about an individual's method of payment or insurance status.
2. The Hospital may not seek, or direct an individual to seek, authorization from the individual's insurance company or health plan for the Medical Screening Examination or stabilizing treatment until the Hospital has provided the Medical Screening Examination and initiated any further examination and treatment that may be required to stabilize the Emergency Medical Condition.
3. The Hospital may follow reasonable registration processes for individuals for whom examination or treatment is required under EMTALA. If a patient is unwilling to proceed with the Medical Screening Examination or stabilizing treatment for any reason, the situation must be handled the same as any refusal of care and documented as referred in the "Refusal to Consent to Examination, Treatment, or Transfer" section of this Policy.

F. TRANSFERRING INDIVIDUALS WITH EMERGENCY MEDICAL CONDITIONS TO OTHER HOSPITALS

1. STABLE AND ADMITTED PATIENTS: Neither EMTALA nor this Policy applies to the transfer of Hospital inpatients or to patients where the QMP finds that no material deterioration of the patient's condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility.
2. UNSTABLE PATIENTS AND PATIENTS IN LABOR: The transfer of a patient with an unstable medical condition, or a patient in labor, should only be carried out for medical reasons or if the patient makes an informed request for a transfer. The Hospital must provide additional examination and treatment within its capacity as may be required to stabilize the Emergency

Medical Condition until the individual leaves the Hospital:

a. Medical Reasons with Physician Certification: When a physician signs a certification utilizing the "EMTALA Transfer Certification and Acknowledgement Form" in the EMR (ccLink) stating that, upon the information available at the time of the patient's transfer, and based on the reasonable risks and benefits to the patient, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the patient, or, in the case of labor, to the patient's unborn child from effecting the transfer to another medical facility; or

b. Patient's Informed Request: at the written request of the patient, or a legally responsible person acting on the patient's behalf, after the risks of the transfer and the hospital's obligations under EMTALA have been explained; or

c. When a physician is not physically present in the Emergency Department at the time an individual is transferred, a Qualified Medical Person, as defined in Section 2.2.7 of the Medical Staff Rules and Regulations, has signed a certification described in section VII.b.i. above, after a physician, in consultation with the Qualified Medical Person, has made the determination described in section VII.b.i. above, and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.

G. REQUIREMENTS FOR AN APPROPRIATE TRANSFER

Patients with an unstabilized emergency medical condition may be transferred only if the Hospital complies with **all** of the following standards:

1. The Hospital provides medical treatment within its capacity which minimizes the risk(s) to the patient's health and, in the case of a woman in labor, the health of the unborn child;
2. The receiving medical facility has the current capacity, available space, and qualified personnel to provide medical treatment to the patient, and the receiving medical facility has agreed to accept transfer of the patient and to provide appropriate medical treatment;
3. The EMTALA transfer certification and acknowledgement form in the EMR (ccLink) should be used to document the transfer of unstable patients and patients in labor;
4. The Hospital sends the receiving facility all medical records related to the transferred individual's Emergency Medical Condition for which the individual has presented, that are available at the time of the transfer, including records related to:
    a. Pertinent history;
    b. Observations of signs and symptoms;
    c. Preliminary diagnosis;
    d. Results of diagnostic studies or tests;
    e. Treatment(s) provided; and
    f. Other records, such as test results not yet available or historical records not readily available from the Hospital's files, must be sent as soon as practicable after transfer
5. The information provided to the receiving hospital should include the name and address of any

on-call physician who failed or refused to provide examination of or care to the patient when obliged to do so as required by the Hospital's Medical Staff Rules and Regulations; and

6. The transfer is carried out using qualified personnel and equipment, as well as necessary and medically appropriate life-support measures.

H. REFUSAL TO CONSENT TO EXAMINATION, TREATMENT, OR TRANSFER

1. Policy. A patient retains the right to refuse necessary stabilizing treatment and further medical examination, as well as a transfer to another facility.
2. Refusal of Medical Screening Examination. If an individual leaves the Hospital before receiving a Medical Screening Examination, either with or without notice to Hospital staff of his/her departure, Hospital staff should document the circumstances and reasons (if known) for the individual's departure and the time the patient was discovered to have left the premises.
3. Refusal to Consent to Further Examination or Stabilizing Treatment. If an individual who has received a Medical Screening Examination refuses to consent to further examination or stabilizing treatment, the Hospital must offer the examination and treatment to the individual, inform the individual (or a person acting on the individual's behalf) of the risks and benefits of such examination or treatment, and the risks and benefits of withdrawal prior to receiving such examination and treatment, and take all reasonable steps to obtain the patient's (or representative's) informed written consent to refuse such examination and treatment.
4. Refusal to Consent to a Transfer. If an individual has been offered a transfer by the Hospital to another medical facility in accordance with the EMTALA requirements and the Hospital has informed the individual (or a person acting on the individual's behalf) of the risks and benefits of the transfer, the individual (or his/her representative) may refuse the transfer. The hospital must take all reasonable steps to obtain the individual's (or representative's) informed written consent to the refusal of the transfer.

I. ACCEPTANCE OF TRANSFERS

1. The Hospital is obliged to accept an appropriate transfer of an individual with an unstabilized emergency medical condition from another hospital when all of the following conditions are met:
    a. the transferring hospital is within the United States, including United States territories; and
    b. the transferring hospital represents that it is not currently capable of providing the care necessary to stabilize the patient's Emergency Medical Condition or safely accommodate risks to the person in labor or the fetus; and
    c. this Hospital (the receiving hospital) has specialized capabilities that the requesting facility does not have and this Hospital has the capacity to provide the stabilizing care requested by the transferring hospital representative.
2. Acceptance and/or refusal of transfers must be documented on [insert name of appropriate form(s)]

J. RECEIPT OF PATIENTS FROM OTHER FACILITIES IN VIOLATION OF EMTALA

1. If the Hospital has a reason to believe that it may have received an individual who is suffering

from an Emergency Medical Condition which has not been stabilized in compliance with the EMTALA transfer requirements from another medical facility, the Hospital is required by law to report that to the Centers for Medicare & Medicaid Services (CMS) within 72 hours and report to the California Department of Public Health.

2. Any Hospital staff who becomes aware of an inappropriate transfer of an unstable patient with an Emergency Medical Condition shall promptly refer the matter to (_____) via the Safety Event Reporting System (SERS) for investigation and, if verified, report to the Centers for Medicare & Medicaid Services (CMS) and the California Department of Public Health.

RELATED LINKS:

Policy for Medical Screening Exams

Procedure for Triage

Medical Staff Rules and Regulations

REFERENCES:

~~42 CFR § 489.24 - Special responsibilities of Medicare hospitals in emergency ca:~~

~~APPROVALS:~~

~~Joint Conference Committee: 3/2025~~

42 CFR §489.20(l), (m), (q), (r)

42 CFR §489.24

Emergency Medical Treatment and Active Labor Act ("EMTALA"), 42 U.S.C. §1395dd

California Health and Safety Code §§1317 – 1317.9a

Attachments

Appendix A - EMTALA Definitions.docx

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending

Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	01/2026
	Geena Jester: Medical Director	12/2025

Standards

No standards are associated with this document

Community Health
Privileges

Name:
Date Completing this packet:

Instructions to applicant

1. Initial to the left of each privilege requested.
2. Sign form and submit **with the required documentation/case log/certificate(s). Experience can be from direct patient care, precepting, CCRMC simulation lab, or documented outside trainings.** Medical Staff Office can help you pull relevant reports from EPIC.

Education/Training	Successful completion of an Accredited Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA) and accredited residency in Preventive Medicine, Emergency Medicine, Obstetrics and Gynecology, Pediatrics, Internal Medicine, or Family Medicine.
Certification	Current certification or Board eligibility leading to certification in Preventive Medicine, Pediatrics, Internal Medicine, Emergency Medicine, Obstetrics and Gynecology, or Family Medicine by the appropriate Board. Board certification must be achieved within the Board eligibility timeframe following graduation from residency.
Continuing Education	As required by California license AND As required for special/non-core privileges as written below.

Community Health Core Privileges

For EACH core privilege requested you must demonstrate the following. If applying for two core privileges, you need to provide documentation of clinical experience in EACH.

Clinical Experience (Initial)	Documentation of required current experience: Prior experience as Health Officer or Deputy Health Officer with attestation of completion of consultation of 50 encounters in past 24 months with 25 in the last 12 months OR completion of 8U CME credits
Clinical Experience (Reappointment)	Active Certification in accordance with Medical Staff Bylaws AND Provision of care for at least 50 patient encounters in past 24 months with 25 in the last 12 months with completion of 8 CME credits or approved training for each privilege requested over past 24 months OR successful completion of accredited residency in past 24 months. AND 3. The Public Health Medical Director, Health Officer or the Public Health Director must certify the clinical need of the applicant. AND 10 Health Officer Call Days /AMION

Commented [HC1]: @Ori Tzviell I am trying to line up all low volume specialties to have consistent minimum requirements. Does this criteria sound achievable and reasonable to you. 50 consults per 24 months with 25 in the last 12 months. 8 CEU per 24 months.

You do not have to provide all of the care or the procedures listed, but given your training and expertise, you are allowed to do what is listed under each Core Privilege.

Request		**Chair Recommends**

☒	**Community Health Core Privileges**: Evaluate, diagnose, treat, and provide prevention methods and to all- [pediatric and adults] patients with tuberculosis, Latent TB, or exposures to TB. Evaluate, diagnose, treat, and provide consultation to all- [pediatric and adults] patients using medication assisted treatments for substance use disorders. Evaluate, diagnose, treat, and consultation to all- [pediatrics and adults] patients with sexually transmitted disease or exposure to a sexually transmitted disease, and provide prevention methods to those at risk for sexually transmitted disease or as primary prevention for any patient. Evaluate, diagnose, treat, and consultation to all- [pediatrics and adults] patients with communicable diseases or exposures to communicable diseases, and provide prevention methods to those at risk for communicable diseases or as primary prevention for any patient.	☐
____	**Tattoo Removal** **Criteria for Initial Request:** Completion of a hands on training in tattoo removal including minimum of 10 tattoo removal procedures (Documented Evidence of Training and clinical log required). **Criteria for Renewal of Privileges:** Demonstrated current competence and evidence of the performance of at least 5 tattoo removal procedures in the past 24 months (Clinical log required) OR Department approved in-service course in tattoo removal in the past 24 months	____

Focused Professional Practice Evaluation (FPPE) Requirements

1. Active Medical License and Meets Eligibility Requirements for Membership on Medical Staff
2. Attestation of participation in 25 Health Officer cases reviews.
3. 8 CEU in Community Health/Public Health approved by Department Chair, Health Officer or Designee.
4. Approval by Department Chair, Health Officer or Designee.
5. 10 HO call days scheduled on AMION
6. Letter to waive requirements must be included with application and signed by Health Officer if indicated.

Commented [HC2]: This will be part of Original application @Sefanit F. Mekuria @Ori Tzvieli All Deputy Health Officers should meet this criteria. It will be up to Ori to waive these requirements if CME's not required. Sofe', this is close enough though not exactly the same as what we reviewed. I am looking at all other packets and trying to align as much as is reasonable without adversely affecting any one department.

Commented [SM3R2]: Looks good to me Heather! Thanks for updating and working on this

ACKNOWLEDGMENT OF PRACTITIONER

I have requested only those privileges for which by education, training, current experience, and documented performance I am qualified to perform and for which I wish to exercise at Contra Costa Regional Medical Center, and I understand that:

a. In exercising any clinical privileges granted, I will adhere by hospital and medical staff policies and rules applicable generally and any applicable to the particular situation.
b. Any restriction on the clinical privileges granted to me is waived in an emergency situation, and in such situation my actions are governed by the applicable section of the medical staff bylaws or related documents.

Practitioner's Signature: _____ Date: _____

DEPARTMENT / DIVISION CHAIR'S RECOMMENDATION

I have reviewed the requested clinical privileges and supporting documentation for the above-named applicant and:

- ☐ **Recommend All Requested Privileges**
- ☐ **Recommend Privileges with the Following Conditions/Modifications:**
- ☐ **<u>Do Not</u> Recommend the Following Requested Privileges:**

Privilege	**Condition/Modification/Explanation**

Notes:
_____
_____
_____

Public Health Medical Director/Health Officer Name (Print): _____

Public Health Medical Director/Health Officer Signature: _____

Date: _____

Diagnostic Imaging
Privileges

Name: (Please Print)

Instructions to applicant

1. Initial to the left of each privilege requested.
2. Sign form and submit **with the required documentation/case log/certificate(s). Experience can be from direct patient care, precepting, CCRMC simulation lab, or documented outside trainings.** Medical Staff Office can help you pull relevant reports from EPIC.

Required Qualifications

Education/Training	Documentation of successful completion of an Accreditation Council for Graduate Medical Education (ACGME) – or American Osteopathic Association (AOA) – accredited residency in diagnostic radiology.
Certification	Current certification or Board eligibility (with achievement of certification within the required time frame set forth by the respective Boards) leading to certification in radiology by the American Board of Radiology or by the American Osteopathic Board of Radiology.
Continuing Education	Documentation of performance and interpretation of at least (100 radiological examinations, reflective of the scope of privileges requested, or successful completion of an ACGME– or AOA–accredited residency or clinical fellowship within the past 24 months. Please provide a clinical activity/procedure log.
Additional Certifications	Fluoroscopy

For EACH core privilege requested, you must demonstrate the following Clinical Experience:

Initial Applicants	Maintenance of Certification or Osteopathic Ongoing Certification is required.
Renewal	Current demonstrated competence and an adequate volume of experience (100 general radiological examinations) with acceptable results, reflective of the scope of privileges requested, within the past 24 months, based on results of ongoing professional practice evaluation and outcomes.

Diagnostic Imaging Core Privileges

Applicant: initial to request	**For Core Privileges:** you do not have to do all these procedures, but having the privilege allows you to.	Division/ Dept Chair: initial to recommend
(initials)	**Diagnostic Imaging and Tele-Imaging** Perform general diagnostic radiology (X-ray, ultrasound, and CT/MRI) to diagnose diseases of patients of all ages, including via a tele-radiographic link. Responsible for communicating critical values and critical findings to ordering providers. Procedures Include but are not limited to: CT of the head; neck; spine; body; chest (excluding cardiac); abdomen; pelvis; extremities and their associated vasculatures; MRI of the head; neck; spine; body; chest (excluding cardiac); abdomen; pelvis; extremities and their associated vasculatures; and muscular skeletal structures; etc.; routine imaging (e.g., interpretation of plain films). Imaging guided biopsies and fluid drainage.	(initials)

Vascular Interventional Diagnostic Imaging

To obtain these privileges, you must provide documentation of the minimum number of procedures required (provider, supervising attending, or during department in-service). Privileges will be considered based on applicability, scope of practice, and documentation of experience.

Applicant: initial to request	To be eligible to apply for privileges in vascular and interventional radiology, the initial applicant must meet the following criteria.	Division/ Dept Chair: initial to recommend
(initials)	*Initial Request:* Successful completion of an ACGME– or AOA–accredited residency in diagnostic radiology, followed by completion of a one-year accredited fellowship in vascular and interventional radiology. **AND** Documentation of current subspecialty certification or board eligibility (with achievement of certification within the required time frame set forth by the respective Boards) leading to subspecialty certification in vascular and interventional radiology by the American Board of Radiology or completion of a certificate of added qualifications in vascular and interventional radiology by the American Osteopathic Board of Radiology **AND** Documentation of at least 200 vascular or interventional radiology procedures, reflective of the scope of privileges requested, in the past 24 months, or successful completion of an ACGME– or AOA–accredited residency or clinical fellowship within the past 24 months. *Renewal/Reappointment:* Maintenance of Certification or Osteopathic Ongoing Certification is required. Current documented competence and at least 200 vascular and interventional procedures with acceptable results, reflective of the scope of privileges requested, for the past 24 months based on results of ongoing professional practice evaluation and outcomes. Continuing medical education related to vascular and interventional radiology is required.	(initials)
(initials)	Admit, evaluate, diagnose, and treat patients (> 14 years old) by various radiologic imaging modalities (fluoroscopy, digital radiography, CT, sonography, carotid doppler and MRI). May provide care to patients in the intensive care setting. Assess, stabilize, and determine the disposition of patients with emergent conditions regarding emergency and	(initials)

	consultative call services.	

Vascular Interventional Radiology Core Privileges

This is not intended to be an all-encompassing list. It defines the types of activities/procedures/privileges that most practitioners in this specialty perform at this organization and inherent activities/procedures/privileges requiring similar skill sets and techniques as determined by the department chair.

Applicant: initial to request		Division/ Dept Chair: initial to recommend
(initials)	Cardiovascular procedures including but not limited to insertion and management of central venous and dialysis access line, Angiography/arteriography, Angioplasty, Coil occlusions of aneurysms. Nonvascular interventional procedure, including soft-tissue biopsy, abscess and fluid drainage, gastrostomy, nephrostomy, biliary procedures, and ureteral stents, myelography and cisternography. , Nonvascular interventional procedure, including soft-tissue biopsy, abscess and fluid drainage, gastrostomy, nephrostomy, biliary procedures, and ureteral stents. Noninvasive diagnostic vascular radiology, including ultrasonography, pulse volume recordings, CT, and MRI. **Administration of Sedation and Analgesia** **Conscious Sedation** (e.g. versed, morphine, fentanyl) – DOES NOT INCLUDE USE OF KETAMINE OR PROPOFOL	(initials)

Vascular Interventional Radiology Non-Core Privileges

Non-core privileges are requested individually in addition to requesting the core. Everyone requesting non-core privileges must meet the specific threshold criteria as applicable to the applicant.

Applicant: initial to request	Non-core privileges are requested individually, in addition to requesting core privileges.	Division/ Dept Chair: initial to recommend
(initials)	**Mammography** Must have MQSA required qualifications [i.e. 960 exams in the last 2 years, 60 hours documented Category I CME in mammography (40 hours if initially qualified before April 28, 1999), at least 15 of which must have been acquired in the three years immediately prior to the physician meeting his/her initial requirements.	(initials)
(initials)	**Administration of Sedation and Analgesia**	(initials)

	Conscious Sedation (e.g. versed, morphine, fentanyl is part of core privilege) –Please request if meets requirements for Conscious sedation with Ketamine or Propofol. **Ketamine** (test required every 2 years) **Propofol** (test required every 2 years) *Initial Request:* Successful completion of an ACGME– or AOA–accredited post graduate training program which included training in administration of sedation and analgesia, including the necessary airway management skills, or department approved extra training and experience. **AND** Documented current competence and evidence of the performance of at least 5 cases (can be any combination) within the past 24 months, or completion of training within the past 24 months. Please provide clinical activity/procedure log. *Renewal/Reappointment:* Documented current competence and evidence of the performance of at least 5 cases (can be any combination) within the past 24 months.	

Other Privileges

If you wish to obtain any privilege not listed above, please list it here and the Credentials Committee will review.

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Initial Focused Professional Practice Evaluation (IFPPE) Requirements

For initial requests, providers must complete ALL IFPPE forms through Medical Staff Office (MSO) and return to MSO.

ACKNOWLEDGMENT OF PROVIDER

I have requested only those privileges for which by education, training, current experience, and documented performance I am qualified to perform and for which I wish to exercise at Contra Costa Regional Medical Center, and I understand that:

a. In exercising any clinical privileges granted, I will adhere by hospital and medical staff policies and rules applicable generally and any applicable to the particular situation.
b. Any restriction on the clinical privileges granted to me is waived in an emergency situation, and in such situation my actions are governed by the applicable section of the medical staff bylaws or related documents.

Provider's Signature: _____ Date: _____

DEPARTMENT CHAIR'S RECOMMENDATION

I have reviewed the requested clinical privileges and supporting documentation for the above-named applicant

and:

- ☐ **Recommend All Requested Privileges**
- ☐ **Recommend Privileges with the Following Conditions/Modifications:**
- ☐ **<u>Do Not</u> Recommend the Following Requested Privileges:**

Privilege	**Condition/Modification/Explanation**

Notes:

_____

_____

_____

Department Chair Name (Print): _____

Department Chair Signature: _____

Date: _____

Status **Pending** PolicyStat ID **19471812**

Origination	05/1997	Owner	Ashley Porteous (Ballard): Hospitalist Exempt
Last Approved	N/A	Area	Hospital & Health Centers
Effective	Upon Approval		
Last Revised	12/2025		
Next Review	3 years after approval		

Ethics Committee Policy

POLICY STATEMENT:

The Ethics Committee provides a multi-disciplinary forum to:

1. Develop and support bioethics education efforts for the benefit of Ethics Committee members, health care professionals within the Hospital and Health Centers, and the community at large.
2. Develop, review, and/or recommend institutional policies and procedures having ethical implications.
3. Provide clinical case consultation to elucidate ethically appropriate options for care and to facilitate communication between concerned parties regarding treatment decisions.

The Committee serves in a strictly advisory capacity to facilitate and support, but never supplant, the shared decision-making authority of the patient and physician in the clinical setting or of the Medical Staff and Administration in institutional matters.

The Ethics Committee serves under and reports to the Medical Staff President and the Medical Executive Committee as authorized by the Medical Staff Bylaws, Rules and Regulations.

GUIDELINES:

MEMBERSHIP and MEETINGS

A. A Chairperson is appointed by the Medical Staff President, subject to Medical Executive Committee approval. The Chairperson is responsible for the administrative functions of the Committee, presides over Committee meetings, and represents the Committee in its relations within and outside the organization. This person should be someone in good standing with

knowledge in both clinical medicine and bioethics.

B. ~~The~~While not mandatory, it is recommended that the Chairperson should have or be working towards a Healthcare Ethics Consultant Certificate (HEC-C) through the American Society for Bioethics and Humanities (ASBH)~~, or is dedicated to working towards this certification as Chairperson~~.

C. Members of the Committee are recommended by the Chairperson for approval by the Medical Staff President. At least one third of the Committee membership must be providers. There should be multi-disciplinary representation, including various clinical services of the medical and nursing staffs and ancillary support services (such as social workers, chaplains, etc.). In addition, the Committee should include at least one member representing hospital administration and must include at least one ~~member representing hospital administration and at least one~~ lay member.

D. Members of the Committee are expected to participate in education and training activities to prepare them for the work of the Committee.

E. Members of the Committee must attend a minimum of 80% of the meetings per annum in order to maintain membership in good standing.

F. With the approval of the Chairperson, guests (primary parties, consultants, community representatives, students, etc.) may be invited to attend Committee functions provided they understand and agree to respect standards of confidentiality. Guests may be required to sign a confidentiality agreement as a pre-requisite of attending Committee meetings.

G. The Committee will meet regularly – at least eight times yearly – and will also provide a mechanism for other meetings as necessary to fulfill its responsibilities.

CONFIDENTIALITY

Respect for confidentiality is expected of all parties participating in Committee functions. Case consultations are considered subcommittee meetings of the Bioethics Committee and as such will be non-discoverable under the usual hospital medical staff committee protection of the California Business and Professions Code.

QUALITY ASSURANCE

Ethics Committee activities occur under the oversight of the Medical Staff President and the Medical Executive Committee. The Chairperson of the Ethics Committee reports to the Medical Executive Committee annually.

RELATED LINKS:

Ethics Committee Procedure

REFERENCES

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) –Comprehensive Accreditation Manual for Hospitals – “Ethics, Rights, and Responsibilities” (RI-1-6).
Executive Committee Minutes of 9/21/92.

Contra Costa Regional Medical Center Medical Staff Bylaws and Rules and Regulations.

APPROVALS:

Medical Staff President

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
	Ashley Porteous (Ballard): Hospitalist Exempt	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **18355766**

Origination	N/A
Last Approved	N/A
Effective	Upon Approval
Last Revised	N/A
Next Review	3 years after approval

Owner	Sihina Tatum: Dir Of Hlth Info/Risk Mng
Area	Hospital & Health Centers

MyChart Account Governance Policy

POLICY STATEMENT:

In order to engage and involve patients in their care, the use of current technology in messaging and uploading images to their health care provider while at the same time ensuring the integrity of the tethered health record as a source of truth for legal, medical and operational purposes.

testing

GUIDELINES:

A. Inappropriate Message Content Defined
    1. Inappropriate or abusive language
        a. Words deemed by a responsible person to be obscene or hateful
        b. Derogatory statements and/or language that is abusive or defamatory
        c. Messaging that is unrelated to health care
        d. Language that is threatening, harassing or slanderous

B. Inappropriate Use of Features
    1. Reserving appointment times that are deemed excessive by the provider or health home team
    2. Frequent cancelling or not showing for scheduled appointments
    3. Multiple requests for refills without waiting three (3) working days for a response
    4. Not respecting the three (3) working daytime frame for responses

C. Inappropriate Image Upload Defined (may include but not limited to examples below)
    1. Any picture or image unrelated to health care
        a. Images of inanimate and/or household objects
        b. Images related to personal, non-medical use (i.e. receipts, personal mail, tax documents, court correspondence not related to competency or medical care.
        c. Any documentation including After Visit Summary (AVS) that is printed from and available in the ccLink electronic medical record.
        d. Social non-health care related imaging.
    2. Any image that depicts a copyrighted logo, branding or packaging for non-health related purposes.

D. Removal of Images or Pictures
    1. Any uploaded images or pictures defined above and/or determined by the patient's provider, and/or the Director of Health Information Management (HIM) and/or County Legal Counsel/Patient Safety to be inconsistent with the purposes of the health record will be removed without notification.

E. Investigating Suspected or Actual Misuse
    1. Any member of the patient's care team or authorized ccLink user may report a violation of any item listed in section A. through C. above

F. CCHS will provide education instead of warning of termination in some cases of misuse. For example, if a patient may not be aware that any response may take up to three (3) business days.

G. Warning of Termination of Access
    1. Initial Conversation and Awareness
        a. The patient will be messaged by their Clinical Services Manager or Program Manager regarding the inappropriate use.
        b. The message should be sent via the patient's MyChart account so there is documentation in the record that a warning/notice has been done ~~(Attachment #1)~~.
        c. The Director of HIM should be copied on that first warning message so the account can be tracked for improvement.
        d. The Director will create a MyChart Terms and Condition Violation Record ~~(Attachment #3)~~ which will be used for logging the violation(s) and tracking improvement.
    2. Once the warning of inappropriate use is sent, the Director of HIM will monitor the account for the continuation of the misuse for a period of three (3) months.
        a. If there is improvement, the Director of HIM will message theprovider to verify that they are satisfied the behavior has resolved and no further action will be taken.

b. If there is no improvement in the behavior, the Director of HIM will send a final message to the patient via MyChart that the account is now View Only and messaging and appointments will not be available.

3. Only one (1) warning per patient/user is issued. Any repeat misuse or violations will result in the immediate conversion of the MyChart Account to View Only.

H. Instant Termination or Instant Conversion to Read Only

1. CCHS reserves the right in cases where the violation is severe enough to bypass the warning or education phase and instantly terminate the MyChart account or instantly convert the MyChart access to view only.
2. These cases will be discussed with the Medical Director or Chief Medical Officer.
3. The Director of HIM will send the Message to View Only to the patient in a MyChart message, and via certified letter to patient.

REFERENCES:

CCHS My ccLink Terms and Conditions

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Ambulatory Policy Committee	Laura R. Colebourn [LC]	01/2026
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [SP]	10/2025
Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [TT]	09/2025
Ambulatory Clinical Practice Committee	Helena Martey: Chief Nursing Officer-Exempt	08/2025
	Sihina Tatum: Dir Of Hlth Info/ Risk Mng [TT]	07/2025

Standards

No standards are associated with this document

CONTRA COSTA HEALTH

ORAL AND MAXILLOFACIAL SURGERY

Privileges

Name: (Please Print)

Instructions to applicant

1. Initial to the left of each privilege requested.
2. Sign form and submit **with the required documentation/case log/certificate(s). Experience can be from direct patient care, precepting, CCRMC simulation lab, or documented outside trainings.** Medical Staff Office can help you pull relevant reports from EPIC.

Required Qualifications

Education/Training	Documentation of successful completion of a Commission on Dental Accreditation–accredited residency in oral and maxillofacial surgery that included training for procedures of the soft and hard tissues as well as history and physicals.
Certification	Documentation of current certification or Board eligibility (with achievement of certification within the required time frame set forth by the respective Boards) leading to certification in oral and maxillofacial surgery by the American Board of Oral and Maxillofacial Surgery.
Continuing Education	Documented current experience of at least six (6) cases within the past 24 months in each of the major surgery categories (dento-alveolar surgery, "pathology," reconstructive/cosmetic surgery, and trauma – see procedure/treatment list) for which privileges are requested; ***or*** successful completion of a Commission on Dental Accreditation –accredited residency within the past 24 months. Please provide clinical activity/procedure log.

For EACH core privilege requested, you must demonstrate the following Clinical Experience:

Initial Applicants	Maintenance of Certification by the American Board of Oral and Maxillofacial Surgery is required.
Renewal	Current documented competence and an adequate volume of experience (six (6) cases in each of the major surgery categories: (dento-alveolar surgery, "pathology," reconstructive/cosmetic surgery, and trauma – see procedure/treatment list) with acceptable results, reflective of the scope of privileges requested, within the past 24 months, based on results of ongoing professional practice evaluation and outcomes.

Oral and Maxillofacial Surgery Core Privileges

Applicant: initial to request	**For Core Privileges:** you do not have to do all these procedures, but having the privilege allows you to.	Division/ Dept Chair: initial to recommend
(initials)	**Initial request**: Admit, evaluate, diagnose, treat, and provide consultation to patients of all ages with pathology, injuries, and disorders of both the functional and aesthetic aspects of the hard and soft tissues of the head, mouth, teeth, gums, jaws, and neck, and perform surgical procedures and postoperative management. May provide care to patients in the intensive care setting. Assess, stabilize, and determine the disposition of patients with emergent conditions regarding emergency and consultative call services. **Dento-alveolar surgery**, including management of odontogenic infections, and erupted, unerupted, and impacted teeth, including third-molar extractions and defects. **Pathology**, including major maxillary sinus procedures, treatment of temporomandibular joint pathology, salivary gland/duct surgery, management of head and neck infection, including incision and drainage procedures, and surgical management of benign and malignant neoplasms and cysts. formities of the dento-alveolar complex. **Reconstructive surgery**, including bone grafting and soft tissue grafting procedures (distant bone graft sites may include but are not limited to the calvaria, rib, ilium, fibula, and tibia; distant soft tissue grafts include but are not limited to cartilage, skin, fat, nerve, and fascia); reconstructive surgery procedures include vestibuloplasties, augmentation procedures, temporomandibular joint reconstruction, management of continuity defects. **Maxillofacial Trauma,** including open and closed reductions of fractures of the mandible, maxilla, zygomatic-maxillary, nose, naso-frontal-orbital-ethmoidal and midface region, and repair of facial, oral, and soft-tissue injuries and injuries to specialized structures. This is a comprehensive but may not be all inclusive list of maxilofacial procedures. The expectation is that providers maintain and practice to community standard for this specialty.	(initials)

Oral and Maxillofacial Oncology Non-Core Privileges

Applicant: initial to request	Non-core privileges are requested individually, in addition to requesting core privileges.	Division/ Dept Chair: initial to recommend
(initials)	*Initial request:* Successful completion of a Commission on Dental Accreditation -accredited fellowship in oral and maxillofacial oncology or the equivalent in training and experience. **AND** Documented current competence and evidence of the performance of at least 10 oral and maxillofacial oncology procedures within the past 24 months, or completion of training within the past 24 months. *Renewal/Reappointment:* Documented current competence and evidence of 10 oral and maxillofacial oncology procedures within the past 24 months based on ongoing professional practice evaluation and outcomes.	(initials)

Administration of Sedation and Analgesia Non-Core Privileges

To obtain these privileges, you must provide documentation of the minimum number of procedures required (provider, supervising attending, or during department in-service). Privileges will be considered based on applicability, scope of practice, and documentation of experience.

Applicant: initial to	Non-core privileges are requested individually, in addition to requesting core privileges.	Division/ Dept Chair:

request		initial to recommend
(initials)	**Conscious Sedation** (e.g. versed, morphine, fentanyl) – DOES NOT INCLUDE USE OF KETAMINE OR PROPOFOL	(initials)
(initials)	**Ketamine** (test required every 2 years)	(initials)
(initials)	**Propofol** (test required every 2 years)	(initials)
(initials)	*Initial request:* successful completion of an appropriate post graduate training program which included training in administration of sedation and analgesia, including the necessary airway management skills, or department-approved extra training and experience. **AND** Documented current competence and evidence of the performance of at least 5 cases (can be any combination) within the past 24 months, or completion of training within the past 24 months. Please provide clinical activity/procedure log *Renewal/Reappointment:* Documented current competence and evidence of the performance of at least 5 cases (can be any combination) within the past 24 months.	(initials)

Other Privileges

If you wish to obtain any privilege not listed above, please list it here and the Credentials Committee will review.

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Initial Focused Professional Practice Evaluation (iFPPE) Requirements

For initial requests, providers must complete ALL iFPPE forms through Medical Staff Office (MSO) and return to MSO.

ACKNOWLEDGMENT OF PROVIDER

I have requested only those privileges for which by education, training, current experience, and documented performance I am qualified to perform and for which I wish to exercise at Contra Costa Regional Medical Center Hospital and Clinics, and I understand that:

a. In exercising any clinical privileges granted, I will adhere by hospital and medical staff policies and rules applicable generally and any applicable to the particular situation.
b. Any restriction on the clinical privileges granted to me is waived in an emergency situation, and in such situation my actions are governed by the applicable section of the medical staff bylaws or related documents.

Provider's Signature: _____ Date: _____

DEPARTMENT CHAIR'S RECOMMENDATION

I have reviewed the requested clinical privileges and supporting documentation for the above-named applicant and:

- ☐ **Recommend All Requested Privileges**
- ☐ **Recommend Privileges with the Following Conditions/Modifications:**
- ☐ **<u>Do Not</u> Recommend the Following Requested Privileges:**

Privilege	**Condition/Modification/Explanation**

Notes:
_____
_____
_____

Department Chair Name (Print): _____

Department Chair Signature: _____

Date: _____

Status **Pending** PolicyStat ID **19861554**

Origination	09/1997
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	3 years after approval

Owner	Cita Richeson: Nursing Program Manager
Area	Hospital & Health Centers

Policy for Adoption Services

POLICY STATEMENT:

Contra Costa Regional Medical Center and Health Centers ~~is~~are committed to providing patients with the best possible care while maintaining a positive, supportive work environment for all staff members and volunteers. Consistent with this goal, the organization supports the ability of staff members, volunteers, and patients to pursue adoptive services.

GUIDELINES:

A. To ensure that patients receive appropriate adoption services, Contra Costa Regional Medical Center and Health Centers staff and volunteers are prohibited from soliciting, brokering, coercing or initiating a patient's participation or the participation of a patient's family in the adoption process. This restriction is intended to include any adoption activity within the scope of a staff member or volunteer's official capacity as a County employee, which would tend to provide personal benefit such as, but not limited to: adopting a child; receiving monetary compensation for adoption broker services involving a patient or patient's family; or portraying oneself in the community as a provider of adoption services for Contra Costa Regional Medical Center and Health Centers patients.

B. Staff members and volunteers who receive inquiries from patients or their families regarding adoption placement services should immediately direct these inquiries to a Medical Social Worker.

C. Medical Social Services, Healthy Start Staff, or those receiving adoption inquiries, will provide information to patients and refer all serious adoption inquiries to the Contra Costa Children Services for further review.

REFERENCES:

The Joint Commission Standard 2024 RI.1, Ethics, Rights and Responsibilities

APPROVALS:

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
CCRMC Chiefs	David Culberson: CCRMC Chief Executive Officer	02/2026
	Cita Richeson: Nursing Program Manager	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19967423**

Origination	N/A	Owner	David Piccinati: Associate Medical Director
Last Approved	N/A	Area	Hospital & Health Centers
Effective	Upon Approval		
Last Revised	N/A		
Next Review	3 years after approval		

Policy for Anesthesia Assessments and Monitoring

POLICY STATEMENT:

Anesthesia care shall be provided in accordance with applicable regulatory and accreditation requirements. This policy DOES NOT apply to anesthesia procedures (i.e. epidural, spinal, block) performed in non-surgical areas in which anesthesia is the procedure.

POLICY:

A. **Administration of Anesthesia**

1. General anesthesia, regional anesthesia, and monitored anesthesia care shall be intentionally induced by a privileged physician.
2. Moderate sedation administered or supervised by non-anesthesia practitioners is governed by the Procedure For Moderate Sedation Administration By Non-Anesthesiologists
3. Anesthesia should only be administered in locations that are appropriately staffed and equipped with monitoring, resuscitation, and rescue equipment and personnel.

B. **Pre-Anesthesia Evaluation and plan:**

1. The pre-anesthesia evaluation must be completed and documented within forty-eight (48) hours immediately prior to any inpatient or outpatient surgery or procedure requiring general anesthesia, or moderate/deep sedation services. The delivery of the first dose of medication(s) for the purpose of inducing anesthesia, as defined above, marks the end of the forty-eight (48) hour time frame.
2. Elements of the pre-anesthesia evaluation should include:

a. A review of the patient's medical history, including anesthesia, drug, and allergy history; and

b. An interview, if possible, given the patient's condition, and an examination of the patient.

c. A notation of anesthesia risk using ASA classification of risk.

d. The identification of potential anesthesia problems, particularly those that may suggest potential complications or contraindications to the planned procedure (e.g., difficult airway, ongoing infection, limited intravascular access);

e. Additional pre-anesthesia data or information indicated by the judgment of the anesthesia practitioner or required elsewhere in hospital policy (e.g., standard laboratory testing);

f. A discussion with the patient (or patient's representative) of the anesthesia risks, benefits, and alternatives, in accordance with CCRMC's policy on Informed Consent.

C. **Intra-Procedural Assessments and Monitoring:**

1. In addition to taking part in the elements of the Universal Protocol, the anesthesia practitioner shall reassess the patient immediately prior to the induction of anesthesia. Documentation of vital signs at the time of the first dose of the anesthetic agent is sufficient to document this reassessment.

2. The anesthesia practitioner should maintain a record of intraoperative care that includes at least the following:

a. The name and hospital identification number of the patient;

b. The name(s) of the practitioner(s) who administered anesthesia, and if applicable, the name and profession of the supervising anesthesiologist or operating practitioner;

c. The name, dosage, route, and time of administration of drugs and anesthesia agents;

d. Technique(s) used and patient position(s), including the insertion/use of any intravascular or airway devices;

e. The name and amounts of IV fluids, including blood or blood products if applicable;

f. Time-based documentation of vital signs, as well as oxygenation and ventilation parameters; and

g. Any complications, adverse reactions, or problems occurring during anesthesia, including time and description of symptoms, vital signs, treatments rendered, and the patient's response to treatment.

D. **Post-Anesthesia Evaluation:**

1. Post-Anesthesia care may occur in various locations, depending on the nature of the procedure and the condition of the patient. Post-anesthesia care may occur in the

post-anesthesia care unit (PACU), on an inpatient unit, at the site and location of the procedure, or other appropriately staffed and equipped location.

2. At the conclusion of the procedure, the anesthesia practitioner shall document any intra-procedural events and transmit post-anesthesia treatment orders to nursing personnel.
3. An anesthesia practitioner shall conduct and document a post-anesthesia evaluation within 48 hours after the conclusion of anesthesia.
4. The evaluation should include the patient's participation to the extent allowed by the patient's condition. The medical record should indicate those instances where the patient is unable to participate.
5. The post-anesthesia evaluation should include:
    a. Respiratory function, including respiratory rate, airway patency, and oxygen saturation;
    b. Cardiovascular function, including pulse rate and blood pressure;
    c. Mental status;
    d. Temperature;
    e. Pain;
    f. Nausea and vomiting; and
    g. Post-operative hydration.
6. Although the anesthesia practitioner should address all of these elements, data for this assessment may be derived from assessments of other authorized personnel (e.g., post-anesthesia care nurses).

RELATED LINKS:

Procedure For Moderate Sedation Administration By Non-Anesthesiologists

REFERENCES:

"Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists," American Society of Anesthesiologists, Inc., Anesthesiology 4 2002, Vol. 96, p. 1004-1017.

Approval Signatures

Step Description	Approver	Date

Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [GS]	02/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [AL]	02/2026
Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [TT]	02/2026
	David Piccinati: Associate Medical Director [TT]	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **18941160**

Origination	03/2004	Owner	Geena Jester: Medical Director
Last Approved	N/A	Area	Hospital & Health Centers
Effective	Upon Approval		
Last Revised	03/2004		
Next Review	3 years after approval		

Policy for Emergency Airway Support by In-House Anesthesiology

POLICY STATEMENT:

In cases outside of the operating room where a patient is determined to have an airway emergency and the physician responsible has attempted intubation without success, the in-house OB Anesthesiologist will respond as contacted. An OB Anesthesiologist is available in house 24 hours a day. An airway emergency is defined as needing an airway within the next five minutes for preservation of life.

GUIDELINES:

A. See attached algorithm.

1. The OB Anesthesiologist is to be paged by staff, or paged by Operator both overhead and by beeper when requested.
2. The OB Anesthesiologist on-call is named on the staffing sheet each shift by staffing office personnel.

APPROVALS:

Attachments

Emergency Airway Algorithm Outside of OR

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	11/2025
	Geena Jester: Hospitalist Exempt	09/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19553075**

Origination	05/2007
Last Approved	N/A
Effective	Upon Approval
Last Revised	01/2026
Next Review	3 years after approval
Owner	Kathy Ferris: Infection Control Coord
Area	Infection Control

Policy for Management of Patient with Suspected or Confirmed Pulmonary Tuberculosis

POLICY STATEMENT:

To provide guidelines for all healthcare providers in screening, managing, and reporting a patient with suspected or confirmed Pulmonary Tuberculosis at CCRMC and Ambulatory Clinic. Under California law, Tuberculosis is a reportable disease. Patients who meet the criteria must be reported to Contra Costa Public Health Department. The Infection Prevention and Control Program Managers are available to assist with reporting. A manager can be reached at pager (925) 346-4122 or email at ICmanager@cchealth.org

Patients admitted to Contra Costa Regional Medical Center for suspected/confirmed active Tuberculosis infection will be housed in Negative pressure isolation room also called as Airborne Infection Isolation Room (AIIR) until infectivity is determined. If a negative pressure isolation room is unavailable in the hospital, the Infection Prevention and Control Program Manager or her designee must be contacted at pager 925-346-4122.

GUIDELINES:

Patient presenting with symptoms suggestive of active Pulmonary Tuberculosis will be ~~mask~~masked. ~~The~~If a negative pressure room is not available, the patient should be placed in an examination room with a door closed and with an HEPA filter ~~as soon as possible when a Negative pressure Isolation~~. Every effort should be madets to ensure that the patient is ~~not available. Efforts to ensure patient are~~ seen promptly and to minimize his/her waiting times in waiting room, exam/treatment room, triage area and other department such as diagnostic and laboratory department.

Regardless of clinical setting (e.g., inpatient, outpatient) persons with a positive AFB smear result and/or started on appropriate anti-tuberculosis medications will be reported to the Contra Costa County Public Health Department. Once reported the patient will be assigned to a Public Health RN case manager.
If the evaluating clinician feels that a patient is unable or unwilling to comply with an outpatient work-up, the patient should be admitted to Contra Costa Regional Medical Center for work-up and initiation of treatment. A patient may be considered a compliance risk in the following circumstances:

A. Current or history of non-compliance
B. Chemical Dependence
C. Homelessness
D. Psychiatric History
E. ~~Mental Retardation~~Intellectual Disability

The accepting physician must contact the Medical Center Supervisor (pager 925-346-4243) at Contra Costa Regional Medical Center to verify that a Negative Pressure Isolation Room is available prior to sending the patient for admission. Clinicians accepting a patient needing Airborne Isolation from another institution must verify with the Medical Center Supervisor that an isolation room is available.
If the patient refuses hospitalization, it is imperative that this patient be reported promptly to Contra Costa Public Health department. The Infection Prevention and Control Program Managers are available to assist with reporting. A manager can be reached at pager (925) 346-4122 or email at ICmanager@cchealth.org

Elective surgical or diagnostic procedures should be postponed until the diagnosis of Tuberculosis, or a determination of infectivity has been made. If this is not possible or if the procedure is emergent, the surgery department must be made aware of the tuberculosis diagnosis. Every effort must be made to schedule this procedure as the last case of the day in any room.

The Contra Costa Public Health Laboratory will call the Infection Prevention and Control Program with all positive AFB smear and culture reports that originate at Contra Costa Regional Medical Center and Contra Costa Health Centers.

The Infection Prevention and Control Program Manager will contact the patient's provider to verify that appropriate therapy has been instituted and that the patient has been reported to Public Health. The Infection Prevention and Control Program Manager will assist as needed.

A Patient on a Public Health and Safety Order is expected to comply as part of their order; failure to comply with hospital policy is to be reported to the Infection Prevention and Control Program. The Infection Prevention and Control Program Manager will notify Public Health and request an amendment to the order, or a visit to the patient by the Public Health Nurse Case Manager assigned to him/her.

If a patient is being housed at Contra Costa Regional Medical Center by a Health Safety Code Isolation Order (Public Health Hold), it must be remembered that physical restraint may not be used to keep the patient in the hospital against his/her will. If the patient leaves prior to the time specified on the Isolation Order the Public Health Division must be contacted immediately (Monday through Friday 8 am to 4:30 pm 925-313-6740, after hours weekends and holidays –Sheriff's Dispatch 925- 646-2441 ask for

"Communicable Disease Physician on Call" and they will determine what further action will be taken.

A written discharge plan needs to be faxed to Public Health before the patient may be discharged. Inpatients meeting reporting-criteria will not be discharged unless their discharge plan has been approved by the Contra Costa County Public Health Department

For the health and safety of others, patients in respiratory isolation for suspected or confirmed Tuberculosis will be expected to comply with housing guidelines, masks, and medication therapy. The Infection Prevention and Control Program personnel are available to speak with patients regarding Tuberculosis. Other available resources include the Public Health Department (925-313-6745 TB Section).

RELATED LINKS:

~~Procedure for Management of Patient with Suspected or Confirmed Tuberculosis in Ambulatory~~
~~Procedure for Management of Patient with Suspected or Confirmed Tuberculosis in Hospital~~
~~Procedure for Management of Employee Exposure to Tuberculosis~~
~~Procedure for Management of Employee with Suspected or Confirmed Tuberculosis~~Procedure for Management of Patient with Suspected or Confirmed Tuberculosis in Ambulatory Care
Procedure for Management of Patient with Suspected or Confirmed Tuberculosis in Hospital
Procedure for Management of Employee Exposure to Tuberculosis
Procedure for Management of Employee with Suspected or Confirmed Tuberculosis

REFERENCES:

A. Respirator Use in Health Care: Cal/OSHA ATD Standard Updated 3/24/2021
B. Tuberculosis (TB) | CDC
C. Health Care Settings | TB |CDC
D. Centers for Disease Control, "Guidelines for Using the QuantiFERON-TB Gold Test for Detecting Mycobacterium Tuberculosis Infection, United States", **MMWR**, December 16, 2005, Vol.54 No. RR-15

APPROVALS:

Infection Prevention & Control Committee: 8/22
Patient Care Policy & Evaluation Committee: 9/22
Medical Ethics Committee: 9/22

Approval Signatures

Step Description	Approver	Date

Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [GS]	02/2026
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [AL]	02/2026
Infection Prevention & Control Committee	Kathy Ferris: Infection Control Coord	01/2026
	Kathy Ferris: Infection Control Coord	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19303845**

Origination	12/2005	Owner	Kathy Ferris: Infection Control Coord
Last Approved	N/A	Area	Infection Control
Effective	Upon Approval		
Last Revised	01/2026		
Next Review	3 years after approval		

Policy for Pertussis Culture and PCR Specimen Collection

POLICY STATEMENT:

This policy outlines the guideline on specimen collection for Pertussis culture and PCR for healthcare provider at CCRMC and Ambulatory Clinics.

GUIDELINES:

Upon physician's order, a licensed health care personnel will obtain nasopharyngeal specimen from adult patient using the procedure as outlined in the policy.

Specimens for culture or PCR must be obtained from a nasal aspirate or nasopharyngeal swab. A nasal aspirate is the preferred specimen; however, a nasopharyngeal swab is acceptable. Collect a nasopharyngeal swab using the Copan **ElutionSwab** Transport System provided by the Contra Costa Public Health Lab.

Swab for PCR/Culture may be stored at room temperature or refrigerated (2-8°C). Transport swab to the Contra Costa Public Health Laboratory **as soon as possible**, or within 48 hours.

The turn around time is 24-48 hours for result. The Public Health Laboratory is open Monday -Friday from 8 a.m. to 5 p.m.

For any question call the Public Health Laboratory at 925-370-5775.

RELATED LINKS:

Bordetella Pertussis PCR/Culture

REFERENCES:

A. Specimen Collection and Diagnostic Testing | CDC

APPROVALS:

Infection Prevention & Control Committee: 3/21, 9/22
Patient Care Policy & Evaluation Committee: 10/22
Medical Executive Committee: 10/22

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
Infection Prevention & Control Committee	Kathy Ferris: Infection Control Coord	11/2025
	Kathy Ferris: Infection Control Coord	11/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19510370**

Origination	03/2011	Owner	Kathy Ferris: Infection Control Coord
Last Approved	N/A	Area	Infection Control
Effective	Upon Approval		
Last Revised	09/2022		
Next Review	3 years after approval		

Policy for Skin Cleansing with 2% Chlorhexidine Gluconate Impregnated Wipes

POLICY STATEMENT:

Cleansing of the skin with a 2% CHG impregnated wipe has been shown to be effective in reducing the presence of bacteria on the skin.

Chlorhexidine impregnated wipes will be used as outlined in this policy for patients undergoing surgery at CCRMC, central lines and as part of an MRSA decolonization protocol.

RELATED LINKS:

~~Procedure for Skin Cleansing with 2% Chlorhexidine Gluconate Impregnated Wipes~~Procedure for Skin Cleansing with 2% Chlorhexidine Gluconate Impregnated Wipes
CHG Instructions for Nurses

REFERENCES:

A. AORN, Standards and Recommended Practices, 2021
B. CDC Guidelines for the Prevention of Surgical Site Infections, 2017
C. CDC Guidelines for the Prevention of Intravascular Catheter Infections, 2011

APPROVALS:

Infection Prevention & Control Committee: 11/16, 4/19, 9/22
Patient Care Policy & Evaluation Committee: 4/19, 10/22

Medical Ethics Committee: 5/19, 10/22

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [SP]	01/2026
Infection Prevention & Control Committee	Kathy Ferris: Infection Control Coord	12/2025
	Kathy Ferris: Infection Control Coord	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19195537**

Origination	05/2017
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2024
Next Review	3 years after approval
Owner	Kathy Ferris: Infection Control Coord
Area	Infection Control

Policy for Transmission-Based Isolation Precautions

POLICY STATEMENT:

This document outlines the Transmission-Based Isolation Precautions that will be used to prevent the spread of communicable diseases in conjunction with Standard Precautions. Transmission-Based Precautions are meant to stop spread based upon recognized routes of transmission for communicable diseases and are applicable for all personnel and visitors. These interventions are specific to the types of disease intended and are not to be used unless applicable. Implementation of these interventions is the responsibility of all CCRMC and Health Center personnel.

GUIDELINES:

To increase effectiveness and awareness of isolation requirements, appropriate isolation signage will be placed on the door of a patient in isolation. This signage will include specific and appropriate requirements to be used by both staff and visitors.

In outbreak situations, or when novel, potentially virulent pathogens are suspected or identified (Ebola, MERS-CoV, SARS), isolation precautions should be enforced for all visitors. In addition, restricting visitors should be considered necessary.

During removal from a patient's body, bed or gurney, soiled linen is handled in a manner that prevents skin and mucous membrane contamination of clothing and transfer of microorganisms to other patients and to the environment.

Linen should not be shaken or manipulated in a way that might aerosolize lint.

A. Soiled linen will be place in covered hampers.

B. Environmental Services personnel will transport the linen hampers, remove the linen bags, and tie them. Bags are then placed into a laundry chute.

C. Doors to the laundry chutes will be kept locked. Keys will be kept by the Environmental Services workers.

D. Trash will be handled according to existing CCRMC policy.

The various types of Transmission-Based Isolation Precautions covered in this policy are as follows:

A. Contact Precautions, including Contact Plus Isolation Precautions

B. Droplet Isolation Precautions

C. Airborne Isolation Precautions, including Enhanced Airborne Isolation Precautions and Enhanced Airborne Special Precautions

D. Neutropenic (Protective Environment) Precautions

RELATED LINKS:

Type and Duration of Precautions Recommended for Selected Infections
Policy for Co-Horting Patients No Special Air Handling
Policy for Use of Droplet Isolation Precautions
Policy for Use of Neutropenic Isolation Precautions
Policy for the Use of Airborne Isolation Precautions
Policy for the Use of Contact and Contact Plus PrecautionsPolicy for Use of Droplet Isolation Precautions
Policy for Use of Neutropenic Isolation Precautions
Policy for the Use of Airborne Isolation Precautions
Policy for the Use of Contact and Contact Plus Precautions
Airborne Precautions Sign
Droplet Precautions Sign
Contact Precautions Sign
Contact Plus Precautions Sign
Neutropenic Precautions Sign
Enhanced Airborne Precautions Sign
Enhanced Airborne Special Precautions Sign

REFERENCES:

A. **Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings**. Appendix A – "Type and duration of Precautions Recommended for Selected Infections and Conditions." 2007.

B. "Hospital Visitors and Isolation Precautions: Clearing Up the Confusion." **Society for Healthcare Epidemiology of America (SHEA).** April 29, 2016.

C. Department of Health and Human Services, Centers for Disease Control and Prevention, "Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Settings", MMWR, December 30, 2005, Vol. 54 No. RR-17

D. Cal OSHA, Aerosol Transmissible Disease Standard, Title 8 Section 5199

E. Cal OSHA "COVID-19 Prevention" Title 8 Division 1 Chapter 4 Subchapter 7 Section 3205.

F. Association for Professionals in Infection Control and Epidemiology, **APIC Text of Infection Control and Epidemiology**, online version downloaded 4/18/2017

APPROVALS:

Infection Prevention & Control Committee: 3/22, 10/22
Patient Care Policy & Evaluation Committee: 4/22, 11/22
Medical Executive Committee: 5/22, 11/22
Joint Conference Committee: 5/22

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
Infection Prevention & Control Committee	Kathy Ferris: Infection Control Coord	11/2025
	Kathy Ferris: Infection Control Coord	10/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19377789**

Origination	01/2025
Last Approved	N/A
Effective	Upon Approval
Last Revised	01/2025
Next Review	3 years after approval

Owner	Kathy Ferris: Infection Control Coord
Area	Infection Control

Sudden Influx of Infectious Patient Surge Capacity Plan

Please see the attached file.

Attachments

Sudden Influx Infectious Patients Surge Capacity Plan

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
Infection Prevention & Control Committee	Kathy Ferris: Infection Control Coord	11/2025
	Kathy Ferris: Infection Control Coord	11/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **18995433**

Origination	08/2017
Last Approved	N/A
Effective	Upon Approval
Last Revised	01/2026
Next Review	3 years after approval

Owner	Grace Ma: Nursing Program Manager
Area	Nursing
References	TJC 2025

Policy for Blood and Blood Components, Transfusion

POLICY STATEMENT:

This policy provides CCRMC and Health Center healthcare personnel guidelines for the safe ~~administration~~transfusion of blood and ~~its~~blood components.

GUIDELINES:

A. ~~Administration and Handling~~

1. ~~A Registered Nurse or physician can administer blood and its components (Platelets, cryoprecipitate, fresh frozen plasma, Factor VIII, Albumin, and Immunoglobulin) as ordered by the physician using standard precautions.~~
2. ~~A Licensed Vocational Nurses (LVN) may pick up and verify blood/blood products. An LVN may administer RhoGAM® in accordance with the RhoGAM® policy.~~
3. ~~Blood/blood components will only be stored in Transfusion Service (Transfusion Service) refrigerator.~~
4. ~~Blood may not be returned to Transfusion Service after 30 minutes of being on the unit, or if the seal is broken.~~
5. ~~An infusion pump should be used for standard blood transfusions.~~
6. ~~All blood products will be administered using a (170 – 260) micron filter Y-site infusion blood set.~~
7. ~~Infusion blood set is discarded/changed after 4 units or after 4 hours of transfusing.~~
8. ~~Do not transfuse a unit of blood for more than 4 hours.~~
9. ~~Intravenous medications will not be administered into the same tubing line as the~~

~~blood/blood components.~~

B. A Registered Nurse (RN) or physician can administer blood and its components (Platelets, cryoprecipitate, fresh frozen plasma, Factor VIII, Albumin, and Immunoglobulin) as ordered by the physician using standard precautions.

C. A Licensed Vocational Nurses (LVN) may pick up and verify blood/blood products. An LVN may administer RhoGAM® in accordance with the RhoGAM® policy.

D. An infusion pump and Y-Type Blood set with (170-260 microns) filter should be used.

E. Do not transfuse a unit of blood for more than 4 hours.

F. Blood set is discarded/changed after 4 units or after 4 hours of transfusing.

G. Intravenous (IV) medications will not be administered into the same tubing line with blood/ blood components.

H. Blood/blood components will only be stored in Transfusion Service/ Blood Bank refrigerator.

I. Return sealed , unused units to Transfusion Service/ Blood Bank within 30 minutes from time of issue.

J. All platelet bag must be returned to Transfusion Service/ Blood Bank upon completion of transfusion.

K. Consent for transfusion ~~will~~should be ~~signed by~~documented in the patient~~/significant other~~'s electronic medical record (EMR) prior to transfusion except in a medical emergency, ~~except in a medical emergency~~excluding Albumin and Immunoglobulin which do not require a consent.

L. A brochure of " A Patient's Guide to Blood Transfusion " will be provided to patient and documented in patient's EMR.

M. Autologous blood (self-donated) ~~will~~should be labeled with patient's name, birth date, and date of procedure. ~~The autologous blood will be transfused following same guidelines as homologous blood transfusion.~~

N. In an emergency, ~~uncrossmatched~~uncross-matched or incompatible units of blood will be issued by Transfusion Service with a (MR117 Release for Uncrossmatched/Incompatible Units) form ~~to~~. It should be completed by the physician and returned to Transfusion Service/ Blood Bank.

O. In event of a Transfusion Reactions ~~= Notify~~, Transfusion Service / Blood Bank and physician should be notified immediately. ~~Print out and follow instructions from the Transfusion Reaction Evaluation form (see Attachment D).~~

RELATED LINKS:

~~712~~ Procedure for Blood and Blood Components, Transfusion
~~712A Attachment:~~MR68 Release for Uncrossmatched/Incompatible Units ~~(issued by Transfusion Services)~~
~~712B Attachment:~~
A Patient's Guide to Blood Transfusion - English
~~712C Attachment: A Patient's Guide to~~MR 68 Transfusion Reaction Evaluation
Policy for Administration of RhoGAM

Policy for Neonatal Blood Transfusion ~~– Spanish~~
~~712D Attachment:~~ ~~Consent for Blood or Blood Products Transfusion (MR39C)~~
~~MR 68 Transfusion Reaction Evaluation Form~~
~~2.82 Policy for Administration of RhoGAM~~
~~3.157 Policy for Neonatal Blood~~
Procedure for Massive Transfusion
~~528 Hospital Policy for Massive Transfusion~~ Protocol (MTP)

REFERENCES:

A. Smith, S., Duell, D., Martin, B., Gonzalez, L., & Aebersold, M. (2017). Blood transfusions. *In Clinical Nursing Skills: Basic to Advanced Skills* (9th ed., pp. 1097-1103). Pearson.

B. Perry, A., Potter, P., Ostendorf, W., & Laplante, N. (2022). Blood therapy. In *Clinical Nursing Skills & Techniques* (10th ed.,pp. 902 – 920). Elsevier.

C. Vossoughi, S., Paroder, M.. (2021), Administration of blood components. In Cohn, C.S., Delaney, M., Johnson, S.t., & Katz, L.M. (Eds.). *Technical Manual* (21st ed., pp.567 - 586). American Association of Blood Banks.

D. U. S. Food and Drug Administration/Center for Biologics Evaluation and Research. (2022, March). *An acceptable circular of information for the use of human blood and blood components: Guidance for Industry.* www.fda.gov. An Acceptable Circular of Information for the Use of Human Blood and Blood Components | FDAGorshi, L., Hadaway, L., Hagle, M., Broadhurst, D., Clare, S., & Kleidon, T.Alexander, M., (2021). Infusion therapy standards of practice, 8th edition. *Journal of Infusion Nursing,* 44(1S):S1-S224.

APPROVALS:

Infection Prevention & Control Committee: 3/21, 2/23
~~Patient Care Policy & Evaluation Committee: 9/17, 4/21, 3/23~~
~~Medical Executive Committee: 5/21, 3/23,10/24~~

Clinical Practice Committee: 10/25
Patient Care Policy & Evaluation Committee: 9/17, 4/21, 3/23
Medical Executive Committee: 5/21, 3/23,10/24

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [GS]	02/2026

Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [AL]	02/2026
Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	01/2026
	Grace Ma: Nursing Program Manager [TT]	01/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19937977**

Origination	01/2006	Owner	Ira-Beda Sabio: Director, Inpatient Nursing OP
Last Approved	N/A	Area	Nursing
Effective	Upon Approval		
Last Revised	02/2026		
Next Review	3 years after approval		

Policy for Medication Administration and Documentation

POLICY STATEMENT:

To provide guidelines for the administration and documentation of medications.

GUIDELINES:

~~A. Licensed nursing personnel will administer and document all medications as ordered by the practitioner, monitor medication effects, and report any side effects or untoward reactions to the practitioner as needed.~~

~~B. Call the practitioner for clarification of orders as needed.~~

~~C. Remove the medications from the Automatic Dispensing Machine (ADM) or from the patient drawer.~~

~~D. Verify that the medication has not expired, and that no contraindications exist for this patient to receive this medication. Visually inspect the medication for particulates, discoloration, or other loss of integrity prior to administration.~~

~~E. Observe all safety features for over-rides.~~

~~F. Prior to administering medication to the patient, follow the "Six Rights of Administering Medications: "**Right Patient, Right Medication, Right Dose, Right Time, Right Route, and Right Documentation."**~~

~~G. Keep medication labeled throughout the medication administration process.~~

~~H. A medication may be given within one hour of the prescribed time without being considered either an early or late administration error, except in certain specific situations such as, but are not limited to:~~

1. ~~For medication administrations surrounding dialysis, medications may be given within 30 minutes of the meal or appropriate dialysis schedule.~~

I. ~~Time- critical scheduled medications specific to each patient condition must be administered within 30 minutes before or after scheduled dosing time, for a total window of one hour.~~

J. ~~At the point of administration, the nurse must check two patient identifiers before administering any medication to the patient.~~

1. ~~Ask for the patient's name and date of birth.~~
2. ~~Compare the name on the Medication Administration Record (MAR) with the patient's wrist band prior to medication administration.~~
3. ~~Scan the medication and the patient's barcoded wristband.~~
4. ~~Inform the patient about the medication, the reason it is being given, and any side-effects from the medication.~~
5. ~~If the patient questions the medication, stop and re-check the order. Provide education as needed. Remain with the patient until oral medication is completely ingested.~~
6. ~~Verify correct Intravenous (IV) pump settings and IV access patency prior to IV administration.~~
7. ~~Document the medication administration on the electronic health record (EHR) while with the patient.~~

K. ~~If administering a medication for the first time, discuss the medication with the patient prior to administering.~~

1. ~~Check compatibility of medications patient is receiving and check to see if there are any food contraindications associated with this medication. Request a dietary consult as indicated.~~
2. ~~Check medication against patient's allergies.~~
3. ~~Check for other risk factors that may be contraindicated in administering the medication.~~
4. ~~Monitor the patient for any effects from the medication (including but not limited to vital signs, mental status, and pain).~~
5. ~~Document in the EHR any effects the medication has on the patient, especially when it is a first dose.~~

L. ~~See Unit-Specific Policy for Heparin, Insulin and Antineoplastic Drugs.~~

M. ~~Perform an independent double check prior to administering subcutaneous and intravenous push (IVP) Insulin and Heparin:~~

1. ~~Verify the correct drug and drawn dose with a 2nd licensed nurse.~~
2. ~~2nd licensed nurse will look up the order in the MAR and cross-reference with the vial and syringe on hand.~~
3. ~~Draw the medication and label the syringe prior to exiting the medication room.~~

a. ~~Insulin:~~

i. Verify the patient's blood glucose level with a 2nd licensed nurse prior to drawing insulin.

ii. Both licensed nurses sign in Omnicell.

b. Independent double check and dual sign off in the MAR is required for the following. infusions:

i. Insulin infusions

ii. PCA infusions

iii. Heparin infusions

N. Addressing unclear medication administration orders:

1. When the order contains more than one route the following is to be instituted:

a. PO, if taking and tolerating oral intake.

b. Intravenously (IV) or Intramuscular (IM) if unable to tolerate PO.

2. When the order contains Therapeutic duplication:

a. Check that medications with duplicate orders have priority, sequence, and/or patient conditions for use clearly outlined.

b. New orders for the same medication with the same indication will be processed as change orders, and will override the previous order, including dose, route, and frequency changes.

c. Contact the provider for clarification of duplicate orders.

3. Opioid Administration:

a. Monitor closely for respiratory depression: assess rate and depth of respirations, signs of circum-oral cyanosis, and monitor oxygen saturation rate with pulse oximetry or capnography as indicated by unit specific policies. Assess sedation level by using unit specific sedation scale.

b. **The waste or return of a controlled substance must be witnessed by a second licensed staff member. The waste and/or return must be recorded in Omnicell.**

c. Document in military time the dosage, route, and the site, if applicable, of each medication administered on the EHR.

d. Document the reason and outcome of any PRN medications given in the EHR.

e. Document the reason in the EHR for any medications not given or held per clinical parameters. Notify the practitioner and document that the provider has been notified and the time of notification.

f. Indicate on the MAR or Patient Care Flow Record "see PCA Flow Sheet" for medication received per the Patient Controlled Analgesia pump (Policy for Patient Controlled Analgesia).

g. Nursing staff monitors and reports medication effects on a daily basis. For

~~any adverse reactions, follow Policy for Adverse Drug Events: Reporting, Intervention & Analysis .~~

~~h. Medication containers are labeled whenever medications are prepared but not immediately administered to the patient. NOTE: An immediately administered medication is one that is prepared or obtained, taken directly to a patient, and administered to that patient by a licensed staff member, without any break in the process.~~

~~i. Medications will be stored and transported under secure conditions that limit access to authorized personnel only.~~

~~j. Nurses and physicians may carry saline flushes on their person throughout the day in order to have them readily available to provide necessary patient care.~~

~~k. The following applies to the infusion center ONLY: Nurses and physicians may carry heparin flushes on their person throughout the day in order to have them readily available to provide necessary patient care.~~
~~**Note: It is very important to minimize distractions and interruptions during the entire medication administration process.**~~

~~O. During ccLink "Downtime" document all of the above on the appropriate paper records. These will later be transcribed onto the EHR.~~

~~P. Documentation.~~

~~1. Document in EMAR in ccLink.~~

A. Licensed nursing personnel will administer and document all medications as ordered by the provider monitor medication effects, and report any side effects or untoward reactions to the provider as needed.

1. Call the provider for clarification of orders as needed.
2. Remove the medications from the Automatic Dispensing Machine (ADM) or from the patient drawer.
3. Verify that the medication has not expired, and that no contraindications exist for this patient to receive this medication. Visually inspect the medication for particulates, discoloration, or other loss of integrity prior to administration.
4. Observe all safety features for over-rides.
5. Prior to administering medication to the patient, follow the "Seven Rights of Administering Medications: "**Right Patient, Right Medication, Right Dose, Right Time, Right Route, Right Documentation and Right Indication."**
    a. Right Patient: Check two patient identifers (Section B)
    b. Right Medication: Confirm the medication matches the prescription, checking for look-alike, sound-alike medications.
    c. Right Dose: Ensure the prescribed dose is correct, considering patient-specific factors and high-alert medications.
    d. Right Time: Give medications at the prescribed time, accounting for

frequency, food interactions, and timing factors.

e. Right Route: Administer the medication via the prescribed and correct route (oral, IV, IM, subcutaneous) to ensure proper absorption and effect.

f. Right Documentation: Accurately document administration details in the eMAR.

g. Right Indication: Understand the medication's purpose, pharmacokinetics, and potential side effects to ensure safe administration and educate patients and/or family.

6. Keep medication labeled throughout the medication administration process.

7. A medication may be given within one hour of the prescribed time without being considered either an early or late administration error, except in certain specific situations such as, but are not limited to:

    a. For medication administrations surrounding dialysis, medications may be given within 30 minutes of the meal or appropriate dialysis schedule.

    b. Time- critical scheduled medications specific to each patient condition must be administered within 30 minutes before or after scheduled dosing time, for a total window of one hour.

8. Nursing staff monitors and reports medication effects as needed. For any adverse reactions, follow Policy for Adverse Drug Events: Reporting, Intervention & Analysis .

9. Medication containers are labeled whenever medications are prepared but not immediately administered to the patient. NOTE: An immediately administered medication is one that is prepared or obtained, taken directly to a patient, and administered to that patient by a licensed staff member, without any break in the process.

10. Medications will be stored and transported under secure conditions that limit access to authorized personnel only.

11. Nurses and physicians may carry saline flushes on their person throughout the day in order to have them readily available to provide necessary patient care.

12. The following applies to the infusion center ONLY: Nurses and physicians may carry heparin flushes on their person throughout the day in order to have them readily available to provide necessary patient care.
Note: It is very important to minimize distractions and interruptions during the entire medication administration process.

B. At the point of administration, the nurse must check two patient identifiers before administering any medication to the patient.

1. Ask for the patient's name and date of birth.

2. Compare the name on the Medication Administration Record (MAR) with the patient's wrist band prior to medication administration.

3. Scan the medication and the patient's barcoded wristband.

4. Inform the patient about the medication, the reason it is being given, and any side-

effects from the medication.

5. If the patient questions the medication, stop and re-check the order. Provide education as needed. Remain with the patient until oral medication is completely ingested.
6. Verify correct Intravenous (IV) pump settings and IV access patency prior to IV administration.
7. Document the medication administration on the electronic health record (EHR) while with the patient.

C. If administering a medication for the first time, discuss the medication with the patient prior to administering.
    1. Check compatibility of medications patient is receiving and check to see if there are any food contraindications associated with this medication. Request a dietary consult as indicated.
    2. Check medication against patient's allergies.
    3. Check for other risk factors that may be contraindicated in administering the medication.
    4. Monitor the patient for any effects from the medication (including but not limited to vital signs, mental status, and pain).
    5. Document in the EHR any effects the medication has on the patient, especially when it is a first dose.

D. See Unit-Specific Policy for Heparin, Insulin and Antineoplastic Drugs.

E. Perform an independent double check prior to administering subcutaneous and intravenous push (IVP) Insulin and Heparin:
    1. Verify the correct drug and drawn dose with a 2nd licensed nurse.
    2. 2nd licensed nurse will look up the order in the eMAR and cross-reference with the vial and syringe on hand.
    3. Draw the medication and label the syringe prior to exiting the medication room.
        a. Insulin:
            i. Verify the patient's blood glucose level with a 2nd licensed nurse prior to drawing insulin.
            ii. Both licensed nurses sign in Omnicell.
        b. Independent double check and dual sign off in the MAR is required for the following. infusions:
            i. Insulin infusions
            ii. PCA infusions
            iii. Heparin infusions

F. Addressing unclear medication administration orders:
    1. When the order contains more than one route the following is to be instituted:

a. PO, if taking and tolerating oral intake.

b. Intravenously (IV) or Intramuscular (IM) if unable to tolerate PO.

2. When the order contains Therapeutic duplication:

a. Check that medications with duplicate orders have priority, sequence, and/or patient conditions for use clearly outlined.

b. New orders for the same medication with the same indication will be processed as change orders, and will override the previous order, including dose, route, and frequency changes.

c. Contact the provider for clarification of duplicate orders.

G. Opioid Administration:

1. Monitor closely for respiratory depression: assess rate and depth of respirations, signs of circum-oral cyanosis, and monitor oxygen saturation rate with pulse oximetry or capnography as indicated by unit specific policies. Assess sedation level by using unit specific sedation scale.

2. **The waste or return of a controlled substance must be witnessed by a second licensed staff member. The waste and/or return must be recorded in Omnicell.**

H. PRNs and One-Time Administration:

1. Reassessment for prn and one-time orders will occur within 60 minutes of administration and be documented., excluding (IV) medications which require 30 minutes reassessment or as ordered by the provider.

I. Documentation:

1. Document in military time the dosage, route, and the site, if applicable, of each medication administered on the EHR.

a. Document the reason and outcome of any PRN medications given in the EHR.

b. Document the reason in the EHR for any medications not given or held per clinical parameters. Notify the practitioner and document that the provider has been notified and the time of notification.

c. Document on the eMAR or Patient Care Flow Record "see PCA Flow Sheet" for medication received per the Patient Controlled Analgesia pump (Policy for Patient Controlled Analgesia).

d. During ccLink "Downtime" document all of the above on the appropriate paper records. These will later be transcribed onto the EHR.

RELATED LINKS:

Policy for Patient Controlled Analgesia
Policy for Adverse Drug Events: Reporting, Intervention & Analysis

REFERENCES:

A. ~~TJC 2023 Medication Management~~TJC National Performance Goals
B. Title 22: Section 71233:2g.
C. ~~2023 TJC National Patient Safety Goal, #3, "Use medications safely."~~
D. ~~Smith~~Perry, ~~Duell~~Potter, Ostendorf & ~~Martin~~Laplante. **Clinical Nursing Skills & Techniques.** ~~9~~10th Edition, ~~2017~~2022.p. ~~568 - 630~~597.
E. Pharmacy Policy for Standard Administration Times for Medications

APPROVALS:

Pharmacy Department
Clinical Practice Committee: 6/2014, 09/2016; 10/2017, 9/2019, 1/2023
Patient Care Policy and Evaluation Committee: 7/2014, 10/2016; 10/2017, 10/2019, 1/2023
Medical Executive Committee: 11/2016, 11/2019, 8/2022, 1/2023
Joint Conference Committee: 9/2022, 3/2023

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [GS]	02/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [AL]	02/2026
Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	02/2026
	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19876751**

Origination	06/2006	Owner	Ira-Beda Sabio: Director, Inpatient Nursing OP
Last Approved	N/A	Area	Nursing
Effective	Upon Approval	References	TJC 2025
Last Revised	02/2026		
Next Review	3 years after approval		

Policy for Restraints And Seclusion

POLICY STATEMENT:

Patients shall be restrained and/or secluded only when clinically justified to prevent the patient from causing injury to self, other(s) or to enhance medical healing and in accordance with applicable state and federal statutes and regulations.

GUIDELINES:

A. **Definitions**

1. **Restraint** is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely. **Exemptions:** The following are **not** considered restraint under this policy (SEE RELATED LINKS):
    a. Standard practices that include limitation of mobility or temporary immobilization related to medical, dental, diagnostic, or surgical procedures and the related post-procedure care processes (for example, surgical positioning, intravenous arm boards, radiotherapy procedures, protection of surgical and treatment sites in pediatric patients).
    b. Adaptive support in response to assessed patient need (for example, postural support, orthopedic appliances, tabletop chairs).
    c. Measures taken to protect the patient from falling out of bed.
    d. Helmets.
    e. Forensic and correction restrictions in the direct custody of a law enforcement officer.

2. **Violent/Self-Destructive Restraint** is the restriction of patient movement for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, including physical holding of a patient.
3. **Seclusion** is the involuntary confinement of a person alone in a room or an area where the person is physically prevented from leaving. Seclusion does not include confinement on a locked unit or ward where the patient is with others. Seclusion may only be used for the management of violent or self-destructive behavior.
4. **"Attending Physician":** ~~The~~A physician responsible for the care and treatment of the patient or his or her physician-designee, including members of the house staff (e.g. residents) working under the supervision of the attending physician.
5. **Non-Violent/Non-self-destructive Restraint** is all restraint other than Violent/Self-Destructive Restraint in A.2 above.
6. **Chemical ~~restraint~~Restraint** – ~~**not used in this institution**. (Chemical restraints are medications given to restrict a~~A drug or medication when it is used as a restriction to manage the patient's ~~freedom of movement which are not a standard treatment for~~behavior or restrict the patient's ~~new or continuing medical or behavioral~~freedom of movement and is **not** a standard treatment or dosage for the patient's condition.~~)~~

B. **General Provisions**

1. **Orders/Initiation:** Each instance of restraint or seclusion shall be initiated:
    a. Upon the order of a physician member of the medical staff who is responsible for the patient, or
    b. By a trained Registered Nurse when he or she determines it is necessary to protect the patient. An order from a physician responsible for the patient will be obtained as soon as clinically reasonable and possible after such initiation.
    c. PRN restraint orders for restraint or seclusion shall not be accepted and the ordering practitioner shall be contacted to clarify or discontinue the order.
2. **Restraint Type**: The order shall specify the method of restraint and/or seclusion to be used.
3. **Notification of the "Attending" Physician:** If the restraint was not ordered by a physician with attending responsibility, an attending physician shall be notified that restraint was applied within 24 hours following initiation. Documentation anywhere within the medical record by an attending physician, whether or not it addresses restraint, is considered evidence that the physician was notified of the restraint instance. For the purposes of this policy, the "Attending" physician is the physician responsible for the care and treatment of the patient or his or her physician-designee, including members of the house staff (e.g. residents) working under the supervision of the attending physician.
4. **Indications:** Restraint and/or seclusion shall be used when less restrictive means are not sufficient to protect the physical safety of patients, staff members or others.

Seclusion may only be used for the management of Violent Behavior.

5. **Release:** Restraint/seclusion shall be discontinued when the behavior or condition which was the basis for the restraint/seclusion order is resolved, regardless of the duration of the enabling order.
6. **Patient and Family Involvement:** Efforts shall be made to discuss the issue of restraint/seclusion, when practical, with the patient and the family. Such efforts shall be documented.
7. **Care Plan:** The patient's written plan of care in the Electronic Health Record shall be modified to address restraint/seclusion interventions to assure patient safety.
8. **Reporting of Death:** Hospital personnel shall promptly contact the hospital Medical Center Supervisor/Administrative Officer of the Day whenever:
    a. a patient dies while restrained;
    b. a patient dies within 24 hours of the removal of restraint; or
    c. a patient dies as a result of a restraint-related condition within 7 days after removal of restraint.
    d. Designated hospital representatives shall notify the Centers for Medicare and Medicaid Services (CMS) Regional Office of such deaths within one business day of the discovery. Such notification shall be documented in the patient's medical record. EXCEPTION: Such deaths may be recorded in a log rather than reported to CMS if :
    e. the death was not a result of or related to the restraint, **and**
    f. only soft wrist ties were used to restrain the patient most proximate to death.
9. **Training and Qualifications:** Hospital and medical staff members receive the training as described in Attachment B.

C. **NON-Violent/Non-Self-destructive RESTRAINT:**

1. **Indications:** Examples of when restraint may be used in protecting the patient include:
    a. The patient is pulling at tubes, lines, or dressings.
    b. The confused patient is interfering with the provision of care.
    c. The patient's actions are endangering themselves; for example, if the patient is thrashing around in bed or attempting to get out of bed in a way or under conditions where it might cause harm (including when such behavior is related to acute withdrawal syndrome).
    d. The patient's diagnosis or condition is such that they may unpredictably and suddenly awaken and harm themselves; for example, 1) when an intubated patient is being weaned from Propofol or, 2) when an intubated patient has a neurological condition that may cause them to unpredictably and suddenly awaken with a significant risk of self-extubation before staff have an opportunity to intervene.

2. **Initial Physician Assessment:** The physician shall perform a face-to-face assessment of the patient within 24 hours of the initiation of the restraint.
3. **Duration of the Order**: **An order for Non-Violent restraint** shall remain in effect until the patient's behavior or situation no longer requires restraint. The order for restraint expires at the end of the calendar day following a previous (initial or renewal) order, unless otherwise specified (Example: order for restraint written at 9:00 a.m. on Wednesday will expire after 11:59 p.m. on Thursday.)
4. **Discontinuation:** Restraints shall be discontinued when the indications no longer exist. A new restraint order is necessary in the Electronic Health Record if these indications re-emerge.
    a. If a patient was recently released from restraint and exhibits behavior that can only be handled through the reapplication of restraint, a new order is required. **Staff cannot discontinue a restraint intervention, and then re-start it under the same order**. This would constitute a PRN order. A "trial release" constitutes a PRN use of restraint, and, therefore, is not permitted. A temporary, directly-supervised release, however, that occurs for the purpose of caring for a patient's needs (e.g., toileting, feeding, or range of motion exercises) is not considered a discontinuation of the restraint. As long as the patient remains under direct staff supervision, the restraint is not considered to be discontinued because the staff member is present and is serving the same purpose as the restraint.
5. **Patient Assessment, Monitoring, and Documentation:**
    a. **Ongoing monitoring and assessment shall occur at least every 2 hours**.
    b. Monitoring includes assessment of distress/mental status, circulation and skin integrity of the restraint site. Nutritional, elimination, and hydration needs are assessed throughout each shift.
    c. Instances of restraint may be documented on assessment and monitoring forms or fields. Concurrent documentation of monitoring for patients restrained for the management of non-violent behaviors is not required and may be documented in summary and/or end of shift note(s).

D. **Violent/Self-Destructive RESTRAINT AND/OR SECLUSION, including physical hold:** Requirements for All Settings
1. **Duration of Restraint/Seclusion Order:** Orders for restraint or seclusion applied to manage Violent / self-destructive behavior shall remain in effect until the patient's behavior or situation no longer requires restraint or seclusion, but no longer than:
    a. 1 hour for patients 8 years of age or younger,
    b. 2 hours for patients from 9 to 17 years, and
    c. 4 hours for patients 18 years of age and older.
    d. If, at the end of the Physician ordered period of restraint or seclusion, the nurse assesses that the patient's behavior is such that restraint/seclusion is still necessary, **the nurse is to call for another MD order.**
    e. Continuation / renewal of restraint or seclusion for the management of

Violent Behavior for longer than 24 hours shall be based on an in person evaluation by a responsible licensed independent practitioner.

2. **Initial Physician Assessment:** The physician shall perform a **face-to-face** assessment of the patient's physical and psychological status **within one hour** of the initiation of the restraint and/or seclusion and document this assessment in the Electronic Health Record. The entry of a face to face note may occur at a later time than the actual assessment. If the patient is released prior, a face-to-face assessment is still performed. The assessment note includes the patient's current medical and behavioral status, the patient's response to the intervention, and plan for continuing or discontinuing restraints or seclusion.
3. **Monitoring, Care, and Assessment:** Patients in restraints or seclusion are monitored by individuals trained to do so.
    a. Simultaneously restrained and secluded patients shall be continuously monitored through
        i. Face to face observation by staff, or
        ii. Remote observation by staff members located near the patient who are viewing a simultaneous video image and audio signal of the patient.
    b. Monitoring, appropriate to the type of restraint and/or seclusion may include mental status, level of distress and/or agitation, skin integrity and circulation. Nutritional, elimination, and hydration needs are assessed during the restraint and/or seclusion instance.
    c. Assessments by a Registered Nurse or competent healthcare professional, or evaluations completed by a responsible physician, shall occur as often as indicated by the patient's condition, behavior, medication administered, and environmental considerations and **at least once every 15 minutes** for the duration of the restraint or seclusion.
    d. At least two staff members will be immediately available at all times when providing care to a secluded patient. At least two staff members will also be present when releasing a patient from seclusion.
    e. Patients placed in violent restraints and/or seclusion will be thoroughly searched. Potentially dangerous items and contraband will be removed. Two staff members will be present during any search of a patient.
    f. **Documentation:** Documentation is required at least every fifteen minutes.
    g. **Debriefing:** As soon as possible, preferably within 24 hours after the conclusion of each restraint or seclusion instance for Violent and/or Self Destructive behavior, the patient and, if appropriate, the patient's family, may be invited to participate with staff members who were involved in the incident in a debriefing. (There is an approved debriefing form(s) for documentation in the Electronic Health Record, which shall guide the content of that debriefing.)

E. **Guidelines for Chemical Restraint**

NOT a Chemical Restraint	Chemical Restraint
Intent	
The intent of the medication and dose is the treatment of the patient's symptoms (e.g.agitation, confusion) or behavior (e.g., aggression, combativeness) in order to help them better and more safely interact with their environment.	The intent of the medication is to restrict the patient's behavior through sedation.
Requirements	
Can be PRN	Can NOT be PRN
Nursing follows the hospital's: **Policy for Medication Administration and Documentation**	Nursing follows the hospital's: Policy for Medication Administration and Documentation
Clinical documentation to reflect the patient's situation and symptoms.	There must be a note reflecting a face-to-face evaluation as described in section D.2 of this document.
The medication may be repeated or continued as indicated by the patient's condition and situation.	The medication must be discontinued and, if indicated, re-ordered within the time frames specified in section D.1 of this document.

RELATED LINKS:

~~Examples of Restraint and Seclusion~~

Restraint and Seclusion Training Plan

REFERENCES:

1. ~~Smith~~Perry, ~~Duell~~Potter, ~~Martin~~Ostendorf et al. Clinical Nursing Skills & Techniques, ~~9~~10th ed. ~~2017~~2022. P. ~~153~~391 -~~154~~402.
2. The Joint Commission (TJC) ~~2023~~2026 Standards: PC 03.05.01, PC 03.05.03, PC 03.05.05, PC 03.05.07, PC 03.05.09, PC 03.05.11, PC 03.05.13, PC 03.05.15, PC 03.05.17, PC 03.05.19.

Approval Signatures

Step Description	Approver	Date

Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [GS]	02/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [AL]	02/2026
Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	02/2026
	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19025344**

Origination	01/1998
Last Approved	N/A
Effective	10/2025
Last Revised	10/2025
Next Review	3 years after approval
Owner	Stephanie Dockham: Dietitian
Area	Nutrition

Patient Menu Policy

POLICY STATEMENT:

Contra Costa Regional Medical Center's (CCRMC) patient menu is developed and approved by ~~a Registered Dietitian~~the Assistant Director of Food and Nutrition Services to promote currently recognized nutritional guidelines and to standardize nutritional care. Food Preferences, including but not limited to cultural, religious, and ethnic food practices are obtained by Food and Nutrition Services personnel via the patient visitation process and/or communication to Food and Nutrition Services by a member of the multidisciplinary team.

GUIDELINES:

A. The Assistant Director of Food and Nutrition Services is responsible for approval of patient menus for use at ~~Contra Costa Regional Medical Center~~CCRMC.

B. The house (non-select) patient menu is a seven-day cycle menu with three meals served per day. The patient menu diet spreads offered at Contra Costa Regional Medical Center include:

~~1. Regular~~

~~2. Consistent Carbohydrate~~

~~3. Consistent Carbohydrate - Gestational~~

~~4. Cardiac~~

~~5. Low Sodium~~

~~6. Renal~~

~~7. Easy to Chew~~

~~8. Soft and Bite-Sized~~

9. ~~Mechanically Altered/Minced and Moist~~
10. ~~Pureed~~
11. ~~Full Liquid~~
12. ~~Clear Liquid~~
13. ~~Vegan~~
14. ~~Gluten Free~~

1. Regular (House)
2. Full Liquid
3. Clear Liquid
4. Sodium Restricted
5. Heart Healthy (Cardiac)
6. Carbohydrate Consistent 75g (Cardiac Friendly)
7. Carbohydrate Consistent Gestational
8. Chronic Kidney Disease (Renal)
9. Fiber Restricted
10. Gluten Free
11. Easy to Chew
12. Soft Bite Sized
13. Minced & Moist
14. Pureed

C. Patient food allergies, intolerances, and preferences (including, but ~~are~~ not limited to ethnic, cultural, and religious considerations) are included in the 24-hour nursing admission assessment and relayed to Food and Nutrition Services via the Electronic Medical Record and/or phone communication.

D. Additional patient visitations to clarify or update preferences/allergies may be done by Food and Nutrition Services personnel by day 3 of patient admission and/or upon request by a multidisciplinary team member if appropriate.

E. Alternative menu items and food products may be provided to patients when requested by a member of the multidisciplinary team or patient. Items will be deemed appropriate based on the ~~Physician~~provider's current diet order by a Registered Dietitian and/or Nutrition Assistant.

~~RELATED LINKS:~~

~~Attachment A: Approval of Patient Menu by Qualified Dietitian~~

REFERENCES:

~~A. The Joint Commission Standard PC.02.01.03 EP 1, 7 & 20, Pc.02.02.03 EP 7 & 9~~

B. ~~Center for Medicare and Medicaid Services § 482.28, § 482.28 (b)(1), § 482.28 (b)(3)~~

C. ~~22 California Code of Regulations § 70273~~

~~APPROVALS:~~

~~Clinical Practice Committee:~~
~~Patient Care Policy and Evaluation Committee: 9/2023~~
~~Medical Executive Committee: 1/1998, 6/2018, 9/2023~~
~~Joint Conference Committee:~~

A. Centers for Medicare & Medicaid Services: State Operations Manual for Hospitals (2018)

B. The Joint Commission: Comprehensive Accreditation Manual for Hospitals (2019)

C. US Food & Drug Administration: Food Code (2022)

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	11/2025
	Stephanie Dockham: Dietitian	10/2025

Standards

No standards are associated with this document

MEDICATION ERROR REDUCTION PLAN-ANNUAL MERP REVIEW

CONTRA COSTA REGIONAL MEDICAL CENTER (3/2024-3/2027 cycle)

Approval	Signatures	Date
Chief Executive Officer		**3/2026**
Chief Medical Officer		**3/2026**
Chief Nursing Officer		**3/2026**
Director of Safety and Performance Improvement		**3/2026**
Medical Executive Committee		**3/2026**
Patient Safety and Performance Improvement Committee		**3/2026**
Patient Care Policy and Evaluation		**3/2026**
Governing Body		**3/2026**
Director of Pharmacy Services, Medication Safety Committee		**3/2026**

The Medication Error Reduction Plan submitted to CDPH in 2001 as a facility plan to eliminate or substantially reduce medication-related errors (by authority of SB1875/801) and Health & Safety code 1339) has been incorporated in this policy.

Annual review of the effectiveness of the plan will be performed. If the plan is not effective in reducing medication errors, MERP will be revised to redesign actions and achieve goals.

Background

CDPH shall monitor the implementation of the plan upon licensure visit every three years.

CCRMC cycles per CDPH audits: started in 2009 and repeats every three years.

MEDICATION ERROR REDUCTION PLAN-ANNUAL MERP REVIEW

CONTRA COSTA REGIONAL MEDICAL CENTER (3/2024-3/2027 cycle)

Table of content

MEDICATION ERROR REDUCTION PLAN-ANNUAL MERP REVIEW
CONTRA COSTA REGIONAL MEDICAL CENTER (3/2024-3/2027 cycle)

I. INTRODUCTION

The following is Contra Costa Regional Medical Center (CCRMC) and Healthcenters' plan (HC) to eliminate or substantially reduce medication-related errors as part of Senate Bill 1875/ 801 and Health & Safety Code 1339 (MERP).

A. CONTRA COSTA REGIONAL MEDICAL CENTER AND HEALTHCENTERS MERP

Contra Costa Regional Medical Center is a 167 bed county hospital located in Martinez California. We are directed and guided by established policies and procedures, protocols and guidelines to minimize medication errors and adverse drug events. Events are reported through an electronic event reporting system (SERS), a voluntary, non-punitive reporting system for all problems/risks identified. Preventive action plans are designed for implementation to reduce errors or potential risks. Medication safety initiatives were developed in 2001. Over the years we have incorporated into our medication safety and quality system risk reduction requirements from Federal and State Laws, including but not limited to CMS, CDPH, FDA, other governmental agencies, TJC standards; National Patient Safety Goals & applicable clinical practice guidelines and recommendations from nationally recognized organizations (e.g., ISMP, The Medical Letter, IDSA, SIDP etc…), professional societies and associations (e.g., ASHP, CSHP, APhA, ADA, etc…) as well as shared learnings from any external resources with successful medication practices demonstrated in reducing medication errors and adverse drug events.

B. VISION

To be the health care system of choice in Contra Costa County where partnerships with patients and employees exist to promote individuals and community wellness.

C. MISSION

The mission of Contra Costa Health Services is to care for and improve the health of all people in Contra Costa County with special attention to those who are most vulnerable to health problems.

- We provide high quality services with respect and responsiveness to all.
- We are an integrated system of health care services, community health improvement and environmental protection.
- We anticipate community health needs and change to meet those needs.
- We work in partnership with our patients, cities and diverse communities, as well as other health, education and human service agents.
- We encourage creative, ethical and tenacious leadership to implement effective health policies and programs.
- We have a department-wide goal to reduce health care disparities and health disparities by addressing issues of diversity and linguistic and cultural competence

D. VALUES

Respect, Safety, Learning, Honesty, Excellence, Functional, Communication, Stewardship, Creativity, and Compassion.

E. STRATEGIC DIRECTIVES

CCRMC and Clinics use a system-wide approach to identify high risk and problem prone patient care processes, redesign unsafe care processes, implement best practices, and adopt successful practices from other organizations that will improve and ensure patient safety. Our goal is to increase the safety of patients receiving medications at CCRMC and Clinics.

II. OVERVIEW OF CCRMC's MERP

A. SCOPE OF THE MEDICATION ERROR REDUCTION PLAN

1. Ensuring provision of pharmaceutical services meet the patient's therapeutic goal by improving safe medication use processes that optimize therapeutic outcomes
2. Ensuring the safe administration of medications according to physician's orders
3. Ensuring compliance with regulatory requirements related to medication safety and security throughout the hospital

4. Reviewing, analyzing, and trending medication errors and adverse drug events (i.e., Adverse Drug Reactions as well as medication errors), and identifying processes and practices which require improvement
5. Implementing evidence-based practices in medication administration, medication safety and security, and improved technologies and pharmaceuticals

B. GOAL AND OBJECTIVE

Our objective is to increase effectiveness in the implementation of evidence-based medication practices shown to reduce preventable adverse medication events. Medication safety will be improved through compliance with medication error reduction standards and safety practice implementation required by CMS, CDPH, FDA, Board of Pharmacy, TJC and its National Patient Safety Goals.

- Development and revision of policies and procedures and protocols to minimize Adverse Drug Events (ADE) will be based on review of facility reported adverse drug events, medication use evaluation, chart reviews, observed medication passes, accepted professional principles, incorporation of Federal & State laws and regulations, TJC medication management standards and National Patient Safety Goals, as well as its Sentinel Event Reports, other external alerts and/or recommendations from national associations including but not limited to the Institute For Safe Medication Practices (ISMP), National Coordination Council for Medication Error Reporting and Prevention (NCCMERP), Institute of Healthcare Improvement (IHI), other governmental agencies such as FDA Medwatch program, as well as clinical practice guidelines and standards of practice from nationally recognized professional organizations (e.g., American Pharmaceutical Association (APhA), American Society of Healthcare Systems Pharmacists (ASHP), California Society of Healthcare Pharmacists (CSHP), etc.

Our processes include but are not limited to the following:

1. Identify the causes of preventable Adverse Drug Events (ADE)
2. Identify the causes of preventable Rescue medications
3. Implement selected short-term changes, as well as
4. Identify, evaluate and implement long-term strategies that require operational and capital expenditures that will ensure safe medication processes and systems with or without technology.

C. ACTION PLANS AND INITIATIVES

See Medication Safety documents for updated medication safety QA/PI projects, demonstrating numerous medication safety goals, initiatives, and medication related best practices. Our priority is to achieve continual implementation of safe medication practices to substantially reduce medication errors and/or proactively prevent adverse events by addressing issues, actual or potential risk points or deficiencies associated with CDPH MERP elements.

III. ORGANIZATIONAL RESPONSIBILITY AND ACCOUNTABILITIES

(DHS-CDPH guiding principle #1-Establish an organized quality system that addresses the issue of a facility wide reduction of medication errors)

1. CCRMC has an ongoing approved and leadership-supported Medication Error Reporting Program with policies and procedures which clearly establish organizational structure in providing the leadership and quality system in advancing patient safety, risk management, and error reduction. Approved policies and procedures establishing our medication management and quality system are continually addressing issues in improving and refining processes, based on what went wrong, to design corrective actions for implementation and prevent re-occurrence.
2. Under the oversight of the PCP&E, a multidisciplinary Medication Safety Committee was formed in 2001. The Medication Safety Committee (MSC), run by the Department of Pharmacy (SEE

Addendum I), has oversight on all medication management processes, system wide. MSC is a subcommittee of the Patient Care Policy and Evaluation Committee (PCP&E) and reports to several medical staff committees i.e., PCP&E (i.e, P&T), PS&PIC, and MEC on a monthly basis. MSC oversees/addresses ALL medication errors and meets on a multidisciplinary note, every month, to discuss in detail all medication errors that occurred during that month. Medication errors are trended using NCCMERP ratings and through ongoing data aggregation analysis and preventative action design. In addition, at CCRMC, Pharmacy Dept trends near misses as well as harm index (see SBARs in MERP binder or electronic MERP document).

3. The MERP plan for the upcoming year is drafted annually submitted to executive members of this organization as well as medical staff committees (PCP&E, PS&PIC, and MEC) once MSC endorses it.
4. This committee is Chaired by the Director of Pharmacy Dept. The quality of different services in ensuring compliance with all MERP elements and established hospital policies is assessed and monitored via data collection. (See Annual Medication Error Reports in the MERP binder).
5. MSC has oversight on all medication related processes and generates many reports, including but not limited to Medication Errors, Rescue Meds, CSPs (Compounding Sterile Products), Clinical Monitors, Overrides, ADRs, ISMP reports, etc.
6. Medication error reports and adverse drug reaction reports with executive summary and pertinent data feedback relative to the user/user department are sent/referred to relevant medical staff, nursing unit/departments. Action response is requested from unit management/department head before SERS is closed.
7. Feedbacks on medication safety initiatives are reported to the Medical staff as well as Nursing staff through leadership of these departments.

8. A summary of all MSC agenda items are reported to PCP&E, PS&PIC as well as MEC. The Director of Pharmacy Department is a member of all these committees and presents the report on all pertinent information on a monthly basis to the aforementioned committees.
9. Implementation of our MERP is integrated into the facility-wide quality assurance/performance program.
10. Ongoing educational efforts are in place to heighten the awareness of medication safety to our patients.

IV. REPORTING SYSTEMS AND MONITORING

(DHS-CDPH guiding principles #2-Develop effective reporting mechanisms to ensure medication related errors are reviewed)

Reduction of medication errors and adverse reactions can be achieved by effective reporting systems that proactively identify causative factors and are used to implement corrective actions to reduce or prevent reoccurrences. To facilitate reporting, CCRMC adopted a medication error definition that is broad enough in scope to capture actual, potential, or "near miss" events and an adverse drug reaction (ADR) definition to capture suspected as well as actual ADRs.

CCRMC conducts proactive identification of adverse drug events or unsafe care processes including concurrent and retrospective review of patient's clinical records, monitoring of targeted high-risk drugs with pertinent lab results, observing medication passes, conducting drug use evaluation and drug regimen review for high-risk patients for drug and or dosage adjustment to prevent potential adverse drug events, as well as performing other QA/PI initiatives.

At CCRMC the Pharmacy Department believes in transparency and uses our event reporting system (SERS) to place in all near misses as well as discrepancies. Pharmacy Department

believes that SERS is a means of trending and alerting healthcare members of the ongoing challenges in the system. In addition, Pharmacy Department uses analyzed data as a means of identifying QA and PI projects. See Medication Safety documents for examples of system enhancement projects using this methodology by the Pharmacy Department.

Pharmacy Department is the biggest contributor to SERS entry in the organization. All relevant data from our monitors and reports are entered into this system on a concurrent and retrospective basis. Through subsequent follow up with Nursing, Medical Staff, and Quality departments, we have been able to overcome many medication safety challenges in the past few years.

A. CCRMC has a voluntary, non-punitive reporting system to monitor and report Adverse Drug Events (ADE) via a long-standing effective medication error reporting as well as an Adverse Drug Reaction program (ADR) with data collection, aggregation, analysis, and special emphasis on designing and implementation of preventative actions on an ongoing basis.

B. Medication events, actual, potential, or near misses are reviewed and trended to evaluate changes in our systems that could improve patient safety. Evaluation and implementation of medication safety initiatives follow our continuous quality improvement process using the PDSA (Plan-Do-Study-Act) model, the Rapid Cycle Improvement techniques, the Failure Mode and Effect Analysis (FMEA), and the Root Cause Analysis (RCA) model for sentinel event or “near misses” in conjunction with our Quality department / Risk management & Patient Safety Officer.

V. PROCESS-MERP IMPLEMENTATION ASSESSMENT

A. ASSESSMENT

(DHS-CDPH guiding principle #3- Establish a baseline assessment and then, at a minimum annually review the effectiveness of the plan to reduce medication-related errors)

Baseline assessment of medication related problems and annual review of the effectiveness of the plan are performed using an objective based critical review. If the plan is not effective in reducing medication errors, MERP will be revised to redesign actions to achieve goals.

B. CDPH REQUIREMENT IN ASSESSING EFFECTIVENESS OF MERP IMPLEMENTATION:

Evaluate, assess, and include a method to address each of the procedures and systems listed under 1339, H&S, subdivision (d) to identify weaknesses or deficiencies that could contribute to errors in the administration of medications. CDPH categorized and focused on evaluating twelve elements on MERP implementation for ongoing improvement.

At CCRMC we use our medication error reports to trend challenging elements. Medication errors are reviewed periodically (i.e., monthly and annually).

The following year's plan is drafted after meticulous review of all Medication Errors, analyzing the cumulative data using monthly, quarterly, and annual Med Error patterns. Subsequently thereafter, plans are implemented to reduce the likelihood of the errors in those certain areas.

Pharmacy Dept uses the Run Chart methodology to graph each MERP element to assess the effectiveness of the instituted plans and whether those plans were adequate in reducing medication errors over time.

Run Charts are cumulative; using Median Line, we can detect any trends, shifts, or astronomical data points. We also insert annotations on the aforementioned run charts to be able to describe the cause and effects concerning any peaks or trough vs any observed isolated incidents.

Pharmacy Dept works very well with ALL departments (Nursing, medical staff, or ancillary departments) in conjunction with Quality Managers and the Professional Development Department (PDD) to apply corrective actions. Success is measured by following SERS in the affected areas to see if the action plan was proven effective or not and reflected on the run charts as cited above.

Education and Information dissemination

1. CCRMC disseminates information to hospital leadership, physicians, nurses, pharmacists, and quality managers. The following activities are currently underway to increase awareness of patient safety:
   a. Data feedback to physicians by Pharmacy Department's leadership on medication errors, adverse drug reaction reporting and medication use quality assurance and use audits.
   b. Data feedback to nursing by Pharmacy Department's leadership on medication errors, rescue meds, adverse reactions, and quality audits.

   At CCRMC we have actively received and used new information and notices related to:

   - Medication errors
   - Processes for avoiding errors
   - Recalls
   - Problem prone medications and
   - Resources related to adverse events associated to medications.

A monthly memo is generated by the Pharmacy Department with all the PCP&E updates. In addition, a memo is generated and sent to the Medical Staff president regarding "Preventable ADRs as well as Preventable Rescue Meds as a learning and educational opportunity.

Technology Strategies

(DHS-CDPH guiding principle #4-Technology implementation shall be part of the plan)

Technology will be used whenever possible to improve effectiveness and efficiency in the medication use processes to make errors difficult to commit and to promote a culture of safety and quality in the workplace. Listed below are technological applications completed at CCRMC.

Technology action plan:

1. Automated Dispensing Cabinets (i.e, Omnicell)
    - Continue using the alerts, reports, and paging system available by the Omnicell software
2. Provide ongoing support to maintain quick access and availability to medical information or current IV administration guidelines, online:
    - Micromedex-available to all staff
    - Lexicomp- available to all staff
3. Expanding reporting capabilities of EPIC (our EHR) to generate more and more meaningful reports in form of system lists, workbench reports, or crystal reports.
4. Usage EHR, i.e, ordersets, Best Practice Alerts (BPA's), First Data Bank (FDB) warnings (i.e., concerning allergy, Drug-Drug Interaction, high dose, etc…) enables us to ensure safe medication practices at CCRMC.
5. Utilizing different software and technologies to extract data and trend values

6. VigiLanz (A data mining system)
    - VigiLanz is programmed to include many monitors. It filters the data and reports all monitors that need to be addressed by the pharmacists on a daily basis
    - Bayesian software for vancomycin dosing
7. SERS (Safety Event Reporting System)
    - Electronic event reporting system with the built in reporting mechanism
8. Smart pumps
    - Smart pumps have been programmed to match our EHR rates of administration for all formulary drugs. The use of basic infusion is monitored and use of guardrail is encouraged. Data is trended using its report functionality. Rounds are made by Pharmacy and Nursing to assure compliance with set safety parameters.
9. Kitcheck®
    - Kit check® uses the RFID technology. Pharmacy Dept uses this technology to improve the efficiency of monitoring the expired medications in variety of kits and carts.
    - Kit Check® technology was instituted in Anesthesia Workstations to better manage the inventory of the trays.
10. EHR (ccLink)
    - Barcoding technology
        - Introduced globally as BCMA
        - Introduced departmentally in most areas of the Pharmacy dept

- Antimicrobial Stewardship (ASP) module

11. Central Temperature monitoring software
12. Controlled substance surveillance system

C. Literature review for ongoing review of the plan

(DHS-CDPH guiding principle #5- Review pertinent literature related to the reduction of medication related errors in the development and ongoing review of the plan.)

Pertinent literature related to the reduction of adverse drug events has been and will continue to be reviewed in the development and review of the plan. The ultimate goal is to deliver safe medication practices at CCRMC and Clinics.

Literature for ongoing learning and sharing are readily obtained from any of our resources at CCRMC. We have a very generous library of resources made available to staff, electronically. A few examples would be Micromedex, Up-To-Date, and many journals through our library. In addition to that, we benefit from nationally recognized entities and their publications such as ASHP, FDA Medwatch alerts, etc… (SEE Goal and Objective section above)

D. CCRMC participates in the following medication safety collaborative for learning from errors and sharing of best practices:

- East Bay Society of CSHP (California Society of Healthcare Pharmacists): Collaboration of all East Bay Pharmacy Leadership
- South Bay Society of CSHP (California society of Healthcare Pharmacists): Collaboration of all South Bay Pharmacy Leadership
- ARC-Gordon and Betty Moore foundation: Avoid Readmission Coalition. Pharmacy Director has done a number of presentations for this organization and currently is the expert speaker/presenter for Avoid Readmission Campaign in the East Bay

- ISMP Canada: Pharmacy Director has been invited to ISMP in Canada to share the Medication Reconciliation Process at CCRMC as IHI model hospital

VI. MERP ELEMENTS OF THE PLAN TO MONITOR AND EVALUATE SAFE MEDICATION PRACTICES IN ERROR REDUCTION:

The main section of this report will be categorized by the twelve elements of medication practices: Prescribing, Dispensing, Distribution, Administration, Competency related to medication use, Product-labeling, Packaging and Nomenclature, Compounding, Prescription Order Communication, Monitoring, Use, and Transition of Care.

The annual MERP program assessment review and effectiveness evaluation in support of identifying plan weaknesses and deficiencies for change implementation and MERP program modification are highlighted in our Medication Safety documents.

Processes to Reduce Medication Errors:

Methodologies to reduce medication errors include on-going proactive surveillance and retrospective tools to identify the root causes of variation or deviation in medication management process and system performance. Examples of on-going proactive surveillance tools include the use of trigger tool to identify areas for improvement in clinical care and patient safety, the reviews of medication usage evaluations, and daily monitoring of Automated Dispensing Cabinets medication overrides.

Data from comprehensive review of reported medication events and on-going proactive and retrospective reviews of system performance will be utilized to determine and evaluate medication safety systems related to, but not limited to: prescribing, prescription order

communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, medication use and storage of medications.

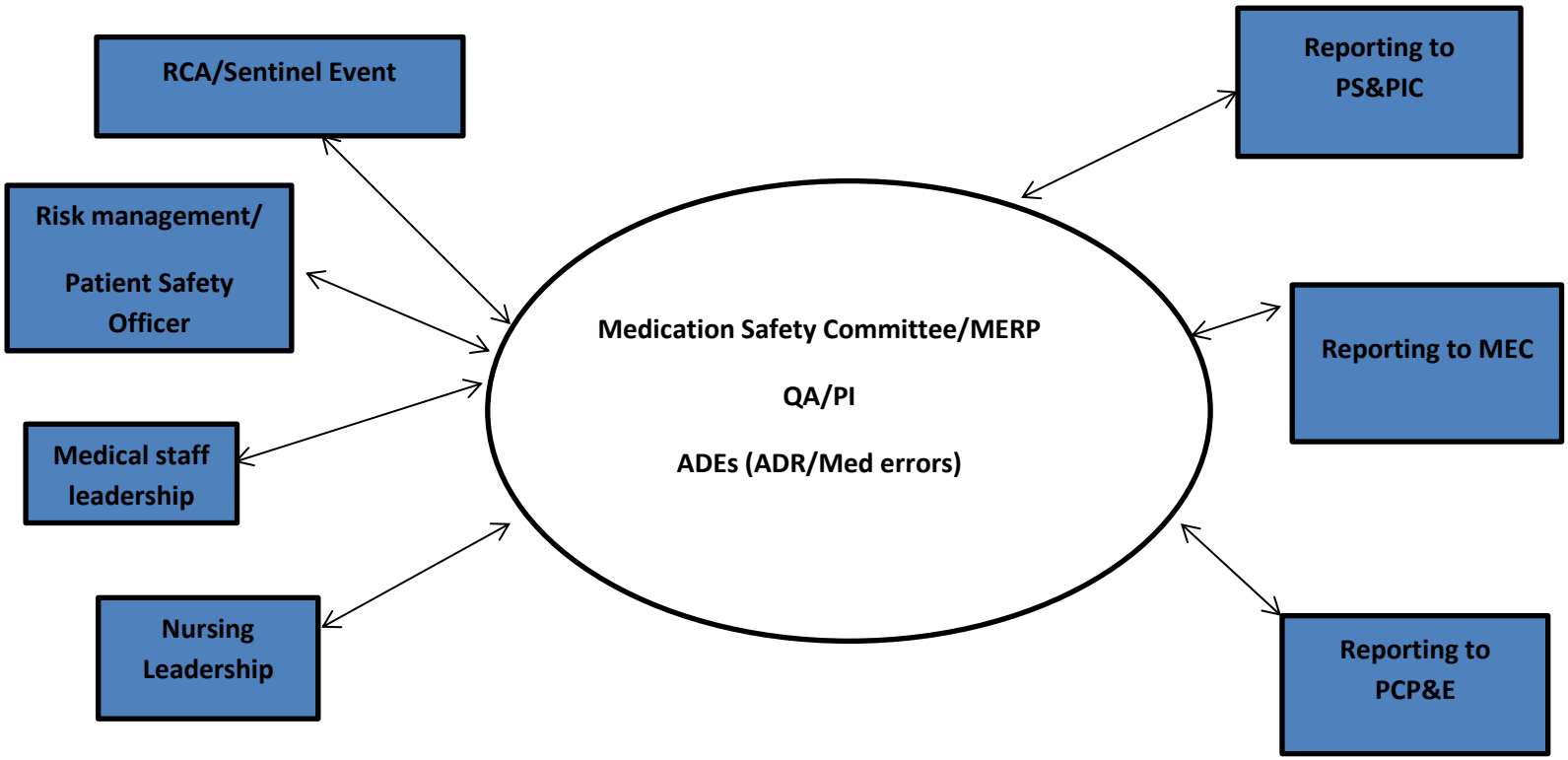
Corrective actions are promptly initiated to address each of the eleven processes and systems once a significant trend or pattern has been identified through the on-going monitoring methodologies as described above. Corrective actions may include changes in systems, procedures, staff and management in-services, and revision in policies and procedures. Should the corrective actions as implemented prove to demonstrate a decrease or reduction in medication errors overtime, then the specific hospital policy and corresponding procedures will be revised and forwarded to the Medication Safety Committee (MSC) as well as the oversight committees (i.e, PCP&E, etc…) for review and approval.

Annually, all the revised and changed procedures and systems will be reviewed and evaluated by the MSC as well as PCP&E to determine if the changes undertaken have been effective, or not; and whether the ongoing indicator should continue to be monitored for the forthcoming year. Frequency of monitoring for the specific indicator that has demonstrated a reduction in medication errors will also be revisited and determined by the Medication Safety Committee and approved by the PCP&E Committee.

VII. Effectiveness of the Plan:

The program has been effective in detecting medication errors and in developing corrective actions for the past year (see Medication Safety documents).

Addendum I- Pharmacy Department's QA/PI collaborative structure



Status **Pending** PolicyStat ID **19194068**

Origination	02/2014
Last Approved	N/A
Effective	Upon Approval
Last Revised	10/2025
Next Review	1 year after approval

Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for 340B Drug Discount Program

POLICY STATEMENT:

This policy provides the background, definitions, and general compliance obligations relating to the 340B drug discount program. The policy helps govern decisions regarding all 340B transactions and to ensure they are highly auditable. It is the intent of the 340B Program to permit covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." 340B is part of an overall comprehensive pharmacy services strategy to: Provide patients affordable access to medications, strategically manage financial aspects of pharmacy services, and ultimately, improve patient health.

GUIDELINES:

The 340B Program is a federal drug discount program authorized under section 340B of the Public Health Service Act and established by Congress under the Veterans Health Care Act of 1992 as part of Public Law 102-585. Section 340B requires drug manufacturers to enter into pharmaceutical pricing agreements (PPAs) with the Secretary of Health and Human Services (HHS) as a condition of Medicaid and/or the Medicare Part B program covering and paying for the manufacturer's covered outpatient drugs. The PPAs specify, among other things, that manufacturers may not sell covered outpatient drugs above 340B ceiling prices to covered entities. The program is administered by the Office of Pharmacy Affairs (OPA), a part of the federal Health Resources and Services Administration (HRSA)/Department of Health and Human Services (DHHS).

The covered entity must register with the Office of Pharmacy Affairs (OPA) in order to participate in the program. Upon registration on the OPA Information System (OPAIS) database as a participant in the 340B program, covered entities agree to abide by specific statutory requirement and prohibitions. A Covered Entity (CE) is the statutory name for a facility or program eligible to purchase discounted drugs through the 340B program. Covered entities include 6 categories of hospitals and 13 categories of non-hospitals. See Glossary of Terms for definitions and acronyms of different qualifying covered entities.

Contra Costa Regional Medical Center and Health Centers is registered in OPAIS as a Disproportionate Share

Hospital (DSH). This category of hospitals is defined under the Social Security Act (42 CFR § 412.106) and eligible to participate in the 340B drug discount program if they meet certain 340B eligibility criteria. A DSH hospital serves a disproportionately large share of low-income patients. The Medicare and Medicaid programs provide additional payments to DSH hospitals to compensate them for the higher costs attributable to treating low-income patients. The Medicare DSH adjustment is a percentage add-on to a hospital's prospective payment and is based on the share of Medicaid patients and supplemental security income (SSI) recipients that the hospital serves on an inpatient basis. For a DSH hospital to qualify for the 340B program, it must have a Medicare DSH adjustment percentage of greater than 11.75%.

Other pertinent definitions in this policy are below:

A. **Parent Site:** The main facility of the covered entity that becomes eligible to use 340B drugs by virtue of the entity's enrollment in the 340B program.

B. **Child Site:** Outpatient clinic that has a different street address than the entity's main facility. It must have a separate OPA registration and on a reimbursable line of the Medicare Cost Report with allocated revenues and expenditures.

C. **Eligible Patient:** To be eligible to receive 340B-purchased drugs, patients must receive health care services (more than just drugs) from the 340B covered entity such that:

    1. the covered entity has established a relationship with the patient and maintains records of the patient's health care: **and**
    2. the patient receives health care services from a provider who is either employed by the covered entity or provides services under a contractual or other arrangement (e.g. referral for consultation) such that the responsibility for the care remains with the covered entity: **and**
    3. the patient is an outpatient **and**
    4. the prescription is written or administration originated from an eligible 340b location

D. **Mixed-Use Setting:** A location that serves both inpatients and outpatients (e.g., radiology, recovery room, endoscopy, etc.). Provided the location and patient qualify for 340B, the outpatient medications would be purchased at 340B pricing. The medications used on inpatients would not qualify.

E. **Covered outpatient drug**: Defined in Section 1927(k) of the Social Security Act (https://www.ssa.gov/OP_Home/ssact/title19/1927.htm), and summarized as:

    1. An FDA approved prescription drug, an over-the-counter (OTC) drug that is written on a prescription, a biological product that can be dispensed only by a prescription (other than a vaccine), or FDA-approved insulin
    2. See Attachment A for exclusions and not-covered outpatient drugs (NCODs) from this definition

I. *GENERAL RESPONSIBILITIES*

A. As a participant in the 340B Program, Contra Costa Regional Medical Center and Health Centers:

    A. Meets all 340B Program eligibility requirements.

    B. Maintains electronic records via Third Party Administrator (~~i.e., through SunRx®~~ TPA), that are available to demonstrate compliance.

C. Has systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements.

D. Elects to receive information about the 340B Program from trusted sources, including, but not limited to:

1. The Office of Pharmacy Affairs
2. The 340B Prime Vendor Program, managed by Apexus
3. 340B Health

B. Covered entities are prohibited from selling, giving, or otherwise transferring covered outpatient drugs purchased under the program to anyone other than a "patient" of the covered entity as defined under HRSA guidance.

C. Covered entities are prohibited from requesting payment under Medicaid for a covered outpatient drug purchased under the 340B program if the state claims a Medicaid rebate for the same covered outpatient drug from the manufacturer. If the covered entity plans to bill Medicaid for such drugs, then the entity must provide OPA with a relevant Medicaid billing number(s) and/or National Provider Identifier(s) (NPI).

D. Covered Entities must monitor their continuing eligibility to participate in the 340B program, must inform HRSA if it is determined that the hospital or any of its child sites are no longer eligible (e.g., hospital was sold, services were discontinued), and must cease purchasing 340B drugs for the hospital or its registered outpatient sites once the hospital has concluded such locations are no longer eligible.

E. The main hospital, all off-site hospital outpatient locations that dispense or otherwise use 340B drugs, ~~and all contract pharmacies~~ must be registered with OPA.

F. The 340B information on the ~~OPA website~~OPAIS database (https://340bopais.hrsa.gov/home) is reviewed and updated as needed, but no less frequently than annually. CCRMC completes this annual review at the time of the annual recertification ~~and notifies OPA of any changes~~.

1. Upon filling of a new Medicare Cost Report or amendment, OPAIS and qualification tab is updated.

G. DSH hospital enrolled in the 340B program are not allowed to purchase covered outpatient drugs through a GPO or other group purchasing arrangement.

1. Maintains a non-GPO/wholesaler acquisition cost (WAC) account(s).
2. Has tracking systems and safeguards in place (via split-billing software) to prevent GPO violations

H. ~~340B covered entities that use one or more contract pharmacies must comply with HRSA's contract pharmacy guidelines. Refer to Contra Costa Health Plan Policies on Contract Pharmacies.~~

I. 340B covered entities must maintain auditable records that demonstrate compliance with 340B program requirements and are accessible to government auditors, manufacturers or any other party authorized to audit the 340B program.

J. The covered entity must retain ownership of the 340B drugs purchased through the approved wholesaler. Although the 340B inventory is property of the covered entity, it must be kept separate from drugs purchased for inpatient use. Virtual separation of 340B drugs requires tracking and replenishment at the NDC 11-digit level. CCRMC is to maintain separate virtual inventory through a split billing software.

1. In exceptional circumstances when an 11-digit NDC replenishment is not possible (e.g., NDC availability, inner vs. outer NDC packaging), 9-digit NDC level replenishment may be used.

II. *ROLES AND RESPONSIBILITIES*

The following individuals have specific obligations to the 340B program:

A. **Chief Financial Officer:** Responsible as the Authorizing Official and principal officer in charge for the compliance and administration of the program

B. **Fiscal Manager/Director of Compliance**: Responsible as the Primary Contact and for communicating any changes in site eligibility information/status immediately to the Director of Compliance and to the Director of Pharmacy Services

   a. Site registration and accuracy and completeness of information provided to the OPA

   b. Annual site recertification with OPA for all CCRMC 340B-enrolled locations

   c. Submitting change request to the OPA in the event any site registration data is incorrect or if any changes occur

C. **Director of Pharmacy Services**: Accountable agent for 340B compliance at CCRMC and Health Centers

D. ~~**Contra Costa Health Plan Pharmacy Manager**: Accountable agent for 340B compliance at Contract Pharmacies~~

E. **340B Committee**: CCRMC has established a 340B Committee that is responsible for oversight of the 340B program that meets on a regular basis

III. *ENROLLMENT RECERTIFICATION AND CHANGE REQUESTS*

A. Enrollment

1. Authorizing Official or Primary Contact identifies upcoming registration dates and deadlines.
2. Authorizing Official or Primary Contact has available the required documents:
   a. Medicare Cost Report:
      1. Worksheet S, S-2, S-3
      2. Worksheet E, part A
      3. For outpatient facilities:
         a. Worksheet C
         b. Worksheet A
         c. Working trial balance
   b. Certification of ownership status
3. Authorizing Official or Primary Contact completes registration on 340B OPAIS (https://340bopais.hrsa.gov/).

B. Recertification procedure

1. Authorizing Official or Primary Contact annually recertifies information on 340B OPAIS.
2. Authorizing Official or Primary Contact completes the annual recertification by following the directions in the recertification email sent from HRSA prior to the stated deadline.
3. Authorizing Official or Primary Contact submits specific recertification questions to 340b.recertification@hrsa.gov.

C. Enrollment procedure: New Outpatient Facilities

1. Authorizing Official or Primary Contact determines that a new outpatient service or facility is eligible to participate in the 340B Program.
    a. The criteria used include that the outpatient service is fully integrated into the hospital, appears as a reimbursable service or clinic on the most recently filed Cost Report, has outpatient drug charges and has patients who meet the 340B patient definition.
2. Authorizing Official or Primary Contact completes the online registration process during the registration window.
3. Authorizing Official or Primary Contact will submit any updated Medicare Cost Report information, as required by HRSA.

D. Procedure for Changes to Information in 340B OPAIS

1. Authorizing Official or Primary Contact notifies HRSA immediately of any changes to the Medicare disproportionate share adjustment percentage resulting in a disproportionate share percentage ≤ 11.75%.
    a. Covered Entity will stop the purchase of 340B drugs as soon as it files its cost report with a disproportionate share percentage ≤ 11.75%.
    b. Authorizing Official or Primary Contact will complete the online change request as soon as a change in eligibility is identified.
2. Authorizing Official or Primary Contact will notify HRSA immediately of any changes to Covered Entity information on 340B OPAIS.
3. Authorizing official will complete the online change request as soon as a change in eligibility is identified.

IV. *PATIENT ELIGIBILITY/DEFINITION*

CCRMC ensures that 340B drugs are dispensed/administered/prescribed only to eligible patients by:

A. Validating site eligibility:

1. The hospital and clinic sites listed on the Medicare Cost Report and registered on the OPAIS database are eligible to receive 340B drugs

B. Determining patient status (outpatient vs. inpatient)

1. Only patients with an outpatient status at the time of medication charge (on administration or dispensation) is eligible to receive 340B drugs
2. Retrospective changes in patient status are not taken into consideration in either direction (e.g. status changing from inpatient to outpatient or outpatient to inpatient).

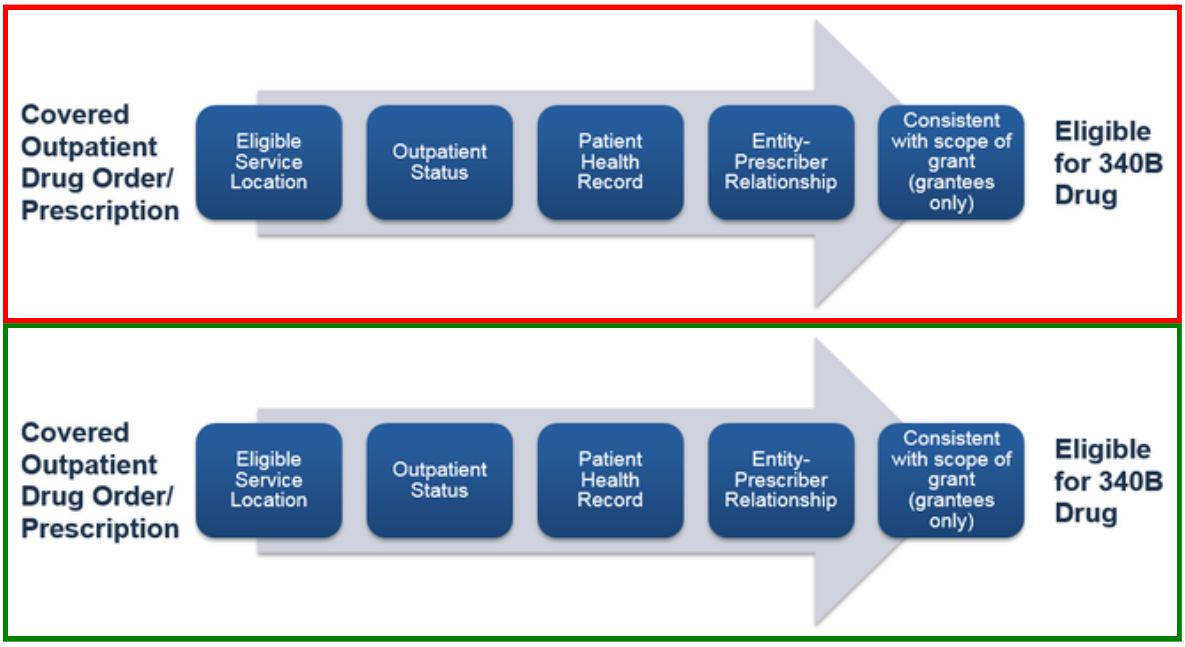
C. Maintaining records of individual's health care

D. Determining provider's eligibility

1. Prescriber is on the hospital's eligible prescriber list as employed by the entity, or under contractual or other arrangements with the entity, and the individual receives a health care service from a health care professional such that the responsibility for care remains with the entity

E. Determining patient's Medicaid status

1. Medicaid claims are flagged with appropriate modifiers to prevent duplicate discounts



V. *PREVENTION OF DUPLICATE DISCOUNTS*

CCRMC Hospital and Health Centers is registered with OPA as a **"carved-in"** entity, meaning our entity bills Medicaid for drugs purchased at 340B prices that may be subject to a payment of a Medicaid rebate to the state. Our entity is listed on the Medicaid Exclusion File so that Medicaid knows not to request reimbursement from drug manufacturers for 340B drugs, thus preventing duplicate discounts.

A. To meet the Federal requirements, Medicaid Provider Numbers and/or NPIs are listed on the OPAIS for the parent and each registered child site location.

1. In addition, out of state Medicaid Programs will not be billed.

B. To meet the State requirements,

1. the required claim identifier ("UD modifier") is used on claims to indicate 340B drugs were administered to Medicaid beneficiaries.
2. drug cost submission on the claim reflects the 340B AAC (Welf. & Inst. Code § 14105.46(d)).
3. ~~Fee-for-Service and Managed Care Medicaid are carved-out for contract pharmacy claims.~~

C. The Health Centers do not use Medicaid Fee-for-Service billing.

1. If patient seen by a licensed practitioner, the billing claim form will list medication claims with applicable state requirements (as above) as 'information only.' The information only line does NOT have units/quantity or a dollar amount.
2. If patient not seen by a licensed practitioner, the billing claim form will list medication claims with applicable state requirements (as above), a unit/quantity, and a dollar amount. However, the third-party claims scrubber will not send the bill to Medicaid and the medication charges are written off.
3. There are some program-specific exceptions (e.g. Family Pact) that are billed based on the California Medicaid requirements. Charges that do not meet the program-specific requirements may appear on the claim form as required, but are not billed, not sent to the payor, and written off.

VI. *PROCUREMENT, INVENTORY MANAGEMENT, AND DISPENSING PROCESS*

A. 340B inventory is procured and managed in the following settings:

1. Hospital pharmacy servicing mixed-use areas of the hospital and providing discharge medications to certain patient populations (at no charge/not billed)
2. Outpatient pharmacy servicing health center child sites
3. ~~Contract Pharmacy~~

B. CCRMC Hospital and Health Centers uses a hybrid (physical and virtual) approach to inventory management.

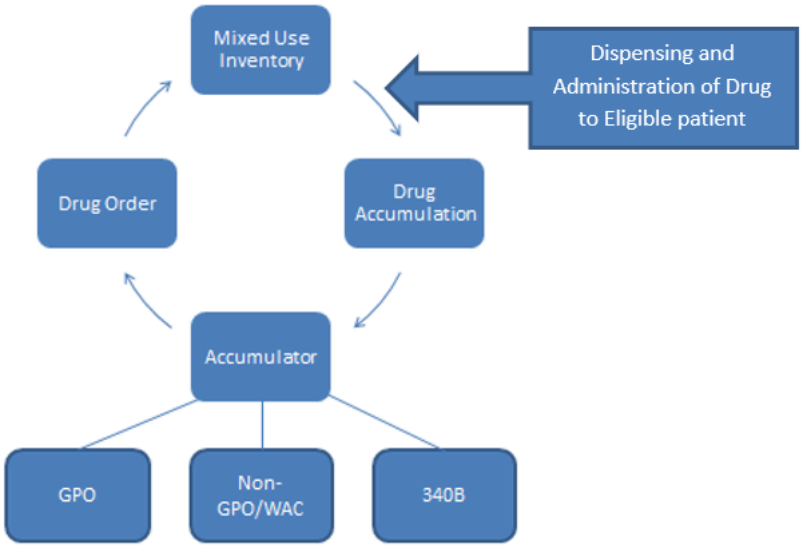
1. The parent entity (hospital pharmacy and mixed-use areas of the hospital): uses a ***virtual mixed-used replenishment inventory*** (i.e., neutral) using a split billing software
2. The parent entity also dispenses discharge medications to patients that are not billed to payers or charged to the patient and therefore are not included on a billing claim form; however, are a part of the virtual inventory.
3. The outpatient pharmacy and health center child sites use ***physically separated 340B and non-340B inventory.***

C. ***Virtual Mixed-use Inventory Replenishment System*** is maintained at the PARENT ENTITY (hospital pharmacy and mixed-use areas of the hospital)

1. Split-billing software is used to perform split-billing on medication procurement orders.
2. Medications administered to specific patient(s) within the hospital are tracked by 11-digit NDC. This information is transmitted to split-billing software with coding indicating patient eligibility for 340B medications.
3. Medications are charge on administration in the hospital setting~~, with some exceptions for bulk dispense medications (i.e. topicals, inhalers, etc.) which~~ Only medication charges are ~~charge on dispense. Only medication charges are~~ sent to the split-billing software for accumulation.
4. Split-billing software accumulates eligible and non-eligible medication administrations and allows for appropriate replenishment. Accumulation occurs at the 11-digit NDC level, and a full package size must be accumulated before replenishment.

a. In exceptional circumstances when an 11-digit NDC replenishment is not possible (e.g., NDC availability, inner vs. outer NDC packaging), 9-digit NDC level replenishment may be used.

5. Purchasing agent exports daily orders from wholesaler ordering system to split-billing software, which then splits the order based on accumulations of 11-digit NDC into corresponding purchasing accounts (i.e., 340B, GPO, or WAC).
6. Procurement order is then placed with wholesaler and accumulations are automatically reduced accordingly from split-billing software.
7. Upon receipt of the drug shipment, pharmacy personnel verify quantity received with the quantity ordered and identifies/resolves inaccuracies in split-billing software.
8. If/when consignment inventory is acquired, and dispensed to a 340B eligible patient, it will be replenished like all other inventory based on accumulations.
9. If medications are unable to be acquired from usual wholesaler channels, medications may be purchased outside of the accumulation process and obtained directly from secondary or tertiary resources on non-340B/non-GPO accounts when needed to fulfill patient medication orders. If 340B or WAC accounts are unavailable direct from the manufacturer, communication will be retained.



D. ***Physical Inventory*** is maintained at the OUTPATIENT PHARMACY and HEALTH CENTER CHILD SITES

1. Medication procurement is performed through wholesaler on the **340B account** for facility-administered medication requests from child site locations registered on OPAIS as 340B eligible.
2. Medication procurement is performed through wholesaler on the **GPO account,** which is separate from the Parent hospital/mixed-use account, for medication requests from off-site non-340B eligible locations.
3. Drugs procured for off-site non-340B eligible locations are stored in the central Outpatient Pharmacy in a physically separate location from drugs procured for 340B eligible locations.
4. Medications are charge on administration in the child sites.

E. Inventory of 340B medications wasted do not go back into the accumulator.

F. Patient-specific waste is defined as waste associated with the unused portion of a dosage form of a drug provided (e.g., dispensed, administered) to a patient. The patient-specific waste may be documented and allocated for accumulation and/or purchased based on the patient's eligibility status.

G. In a state of emergency CCRMC will continue to ensure it has policies and procedures in place to address the purchasing and dispensing of 340B drugs, and it will continue to keep auditable records.

H. As a hospital subject to the GPO prohibition, if unable to purchase a covered outpatient drug at the 340B price, CCRMC will first try and obtain the drug at WAC. If it is unable to purchase the product at WAC due to shortages, the hospital may use a GPO or GPO private label product (e.g. Novaplus) according to the following circumstances described below.

    1. A suitable alternative is not available for purchase.
    2. The drug is required for a medically necessary treatment.
    3. The manufacturer will not or cannot supply the equivalent drug at 340B or WAC pricing, after hospital has attempted to work with the manufacturer to do so. OPA also should be notified.

I. Documentation maintained includes, but is not limited to, screenshots of the WAC, GPO, and 340B accounts for the product being purchased, showing that no stock is available from CCRMC's Primary Drug Wholesaler, and documentation of communications with manufacturer and/or wholesaler regarding non-availability.

VII. *340B COMPLIANCE MONITORING/REPORTING*

A. Routine and/or random self-audit monitoring will be done by the pharmacy department to assure continued compliance with 340B requirements.

B. CCRMC develops an annual internal audit plan approved by the 340B Oversight Committee.

C. ~~CCRMC has established processes in place to ensure 340B Program compliance and oversight at the contract pharmacy location(s).~~

D. CCRMC reviews 340B policies and procedures annually.

E. CCRMC reviews the HRSA 340B OPAIS to ensure the accuracy of the information for the parent site, off-site locations, ~~and contract pharmacies~~ annually and as needed.

F. CCRMC reviews the Medicaid Exclusion File (MEF) to ensure the accuracy of the information for the parent site, off-site locations, ~~and contract pharmacies~~ annually and as needed.

G. CCRMC updates the prescriber eligibility files regularly.

H. CCRMC reconciles purchasing records and dispensing records to ensure that covered outpatient drugs purchased through the 340B Program are dispensed or administered only to patients eligible to receive 340B drugs and that any variances are not the result of diversion quarterly.

I. CCRMC reconciles dispensing records and Medicaid billing practices to demonstrate that CCRMC practice is following the Medicaid billing question on the HRSA 340B Database.

J. CCRMC 340B Oversight Committee reviews the internal audit results:

    1. Assess if audit results are indicative of a material breach.

2. CCRMC maintains records of 340B-related transactions for a period of 3 years in a readily retrievable and auditable format.

VIII. *REPORTING 340B NON-COMPLIANCE/ MATERIAL BREACH*

A. A material breach is defined as a discrepancy that results in a negative impact of more than 10% of total 340B purchases in a fiscal year and does not self-correct within six (6) months.

B. The Self-Disclosure for Material Breach will be used to take proper action.

RELATED LINKS:

Non Covered 340B Outpatient Drugs (NCODs) (i.e. exclusions)

Self-Disclosure for Material Breach

REFERENCES:

A. HRSA (Health Resources and Services Administration) Health Resources and Services Administration | HRSA

B. OPA (Office of Pharmacy Affairs) 340B Drug Pricing Program | HRSA

C. 340B Health https://www.340bhealth.org/

D. 340B Prime Vendor Program Managed by Apexus 340B Tools (340bpvp.com)

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 8/2024~~
~~Medical Executive Committee: 8/2024~~
~~Joint Conference Committee: 11/2024~~

Attachments

C. Glossary of Terms

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026

Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
	Shideh Ataii: Director Of Pharmacy Svcs	11/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19940579**

Origination	04/2001
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Access to Automated Drug Delivery Systems (ADDS)

POLICY STATEMENT:

This policy establishes access privileges for CCRMC's Automated Drug Delivery System (ADDS's). All departments with access will follow the policies and procedures for the automated drug delivery system (ADDS's) to ensure the safe and accurate dispensing of medications, accountability of controlled substances and other medications, patient confidentiality, medication security and to ensure compliance with state and federal rules and regulations.

Nurses, respiratory therapists, pharmacists, pharmacy technicians & anesthesiologists shall have access to designated automated drug delivery system. The above personnel shall be assigned a permanent identification code and temporary password to access the automated drug delivery system.

Access to medications stocked in the ADDS is limited to medication orders that have been reviewed by a pharmacist, except for emergency situations, as defined in the ADDS override policy.

GUIDELINES:

~~Automated Drug Delivery System (ADDS~~**Automated Drug Delivery System (ADDS**): means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

~~Automated Unit Dose System (AUDS~~**Automated Unit Dose System (AUDS**): an ADDS for storage and

retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

~~Automated Patient Dispensing System (APDS)~~**Automated Patient Dispensing System (APDS)**: an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

The patient care nurse program managers/department managers will request an identification code and temporary password for designated personnel using the online User Access Form (UAF). Personnel must have an ID for the hospital's computer system before the assignment of ID code to the ADDS system.

The Pharmacy Department will create access for the user, using the same ID created for the hospital system, by the next business day. Completion of this process is electronically documented on the UAF.

Level of access is determined by the position held by the user.

A. Staff Nurses' access will include:
    1. Login and witness
    2. Report access
    3. Return medications to the ADDS
    4. Remove all medications
    5. Inventory all controlled medications. (Controlled substances require a witness)
    6. Override meds, based on override status of particular medication.

B. Medical Center Supervisors, Charge Nurses and Nurse Program Managers' access will include:
    1. All the above
    2. Inventory all medications.
    3. Create temporary users.
    4. Register fingerprints.

C. Nursing Instructors will have:
    1. Permanent access with staff nurse access

D. Nursing students will have:
    1. Access only through their instructor

E. Respiratory Therapists' access will include:
    1. Login and witness
    2. Report access
    3. Return medications removed.
    4. Remove medications categorized as respiratory drugs.
    5. Override respiratory drugs, based on override status of particular medication.

F. Anesthesiologists' access will include:

1. Login and witness
2. Remove medications from ADDSs that are in the operating rooms.
3. Return medications removed.
4. Override medications based on override status of medications.

G. Pharmacy technicians' access will include:
    1. Login and witness
    2. Report access
    3. Inventory all medications. (Controlled substances require a witness)
    4. Load new medications
    5. Unload medications
    6. Refill medications

H. Staff pharmacists' access will include:
    1. All the access of the pharmacy technician
    2. Create temporary users.
    3. Return medications.
    4. Admit, edit, discharge patients.
    5. Remove all medications.
    6. Inventory all medications (Controlled substances requires a witness)
    7. Override meds

I. Pharmacy ADDS Administrators' access will include**:**
    1. All the above access
    2. Register fingerprints.

The Pharmacy Department will be notified of any staff changes, within 24 hours, by the nurse manager/ department manager. This includes terminations, promotions, or a permanent assignment to another unit.

If a staff member suspects someone is using their password, they must immediately notify the pharmacy department to change their password in the system and notify their nurse manager/ department manager.

If a staff member forgets his/her password, the Pharmacy Department must be notified. A new temporary password will be issued and then entered into the computer system. As above, the staff member must then sign on to the automated drug delivery system and enter a new secret password.

REFERENCES:

A. TJC Standard MM.03.01.01
B. CMS CoP § 482.23(c), 482.25(a)(b)

C. CCRMC Nursing Policy #701

D. California Pharmacy Law

E. Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 § 4119.11, Article 24 § 4427

~~**APPROVALS:**~~

~~Patient Care Policy and Evaluation Committee:1/2023, 7/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **20001040**

Origination	05/2001
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval

Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Antineoplastic and Hazardous Drug Handling

POLICY STATEMENT:

All health care personnel who handle Hazardous Drug (HD) preparations and entities that store, prepare, transport, or administer hazardous drugs must comply with the standards described in USP <800> to promote patient safety, worker safety, and environmental protection. Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, transport, administration, and disposal of sterile and non-sterile products and preparations.

The Designated Person (DP), Pharmacist II, is responsible for developing and implementing appropriate procedures and overseeing compliance of USP <800>.

GUIDELINES:

A. List of Hazardous Drugs (see Attachment A)

1. All containment requirements of USP <800> must be followed for drugs on NIOSH list if they are APIs or **antineoplastic** HDs requiring manipulation
    a. Antineoplastic HDs are defined as those with AHFS classification of 10:00 antineoplastic agents on Table 1 of the most current NIOSH list
2. An Assessment of Risk (AoR) may be performed and implemented for:
    a. Final dosage forms of compounded HD preparations
    b. Conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging
    c. Non-antineoplastic drugs on Table 1 of the most current NIOSH list

d. All drugs listed in Table 2

3. CCRMC maintains a list of HDs that includes all items on the current NIOSH list, and is reviewed at least every 12 months
4. Assessment of Risk considers type of HD (e.g., antineoplastic, non-antineoplastic), dosage form, risk of exposure, packaging, and manipulation to determine alternative containment strategies and/or work practices to minimize occupational exposure.
    a. AoR is reviewed and documented every 12 months.
5. CCRMC's AoR developed 2 Categories of HD handling:
    a. **Category C:**
        i. NIOSH Table 1 injectable **antineoplastic** drugs that require compounding/ manipulation
        ii. NIOSH Table 2 injectable **antineoplastic** drugs that require compounding/ manipulation
    b. **Category H:**
        i. NIOSH Table 1 non-antineoplastic drugs – all dosage forms
        ii. NIOSH Table 2 non-antineoplastic HDs – all dosage forms
        iii. NIOSH Table 2 **antineoplastic** HDs – oral and topical dosage forms

B. Responsibilities of Personnel Handling HDs

1. All personnel who handle HDs are responsible for practices and precautions to prevent patient harm, minimize worker exposure, and minimize environmental contamination.
2. Only Pharmacy Department personnel specially trained and competent in chemotherapy handling will prepare or handle these drugs outside of the manufacturer's packaging.

C. Facilities and Engineering Controls

1. HD Receiving area(s):
    i. Signs designating the hazard are displayed at entrance
    ii. Neutral or negative pressure relative to surrounding areas
2. HD Storage area(s):
    i. Signs designating the hazard are displayed at entrance
    ii. HD drugs are not stored on the floor and in a manner that prevents spills and breakage
    iii. **Antineoplastic** HDs requiring manipulation (other than counting or repackaging of final dosage forms) are stored separately from non-HDs
    iv. Refrigerated **Antineoplastic** HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH
    v. **Antineoplastic** HDs are stored in externally vented, negative pressure room with at

least 12 ACPH

vi. NIOSH Table 1 and NIOSH Table 2 **antineoplastic** and non-antineoplastic HDs in final dosage forms may be stored with other inventory

D. Personal Protective Equipment

1. **Chemotherapy glove characteristics:**
    a. Gloves are powder-free and meet ASTM standard D6978
    b. Gloves are sterile for sterile compounding
    c. Gloves are changed when torn, punctured, or contaminated
    d. Glove manufacturer documented breakthrough time determines the frequency of glove change. If unknown, change gloves every 30 minutes. Gloves may be changed sooner than recommended time frame at the discretion of the department.
2. **Chemotherapy gown characteristics:**
    1. Gowns are shown to be resistant to HD permeation
    2. Gowns are disposable and:
        a. Are made of polyethylene-coated polypropylene or other laminate materials
        b. Close in back, are long-sleeved and have closed cuffs that are elastic or knit
        c. Does not have seams
    3. Gowns must be changed immediately after a spill or splash
    4. Gown manufacturer's documented breakthrough time determines the frequency of gown change. If unknown, change gowns every 2-3 hours.
3. Second pair of **shoe covers** are to be donned in upon entering the containment secondary engineering control for sterile compounding of antineoplastic hazardous drugs
4. **Eye and face protection**: must be worn when risk for spills or splashes (e.g. working at or above eye level, cleaning a spill, etc.)
5. **Respiratory protection**
    a. Powered air-purifying respirator (PAPR) should be worn when unpacking HDs not contained in plastic until packaging integrity can be ensured that no breakage or spillage occurred during transport.
    b. Surgical N95 respirator provides adequate respiratory protection and provides barrier to splashes, droplets, and sprays around nose and mouth.
    c. It is recommended that a full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR) should be worn when there is a risk of respiratory exposure to HDs, including when:
        i. Attending to HD spills larger than what can be contained with a spill kit
        ii. Deactivating, decontaminating, and cleaning underneath the work surface

of a C-PEC

iii. There is known or suspected airborne exposure to powders or vapors.

6. Used disposable PPE is not reused and discarded according to local, state, and federal regulations

E. Personnel Training

1. Initial training for HD handling is provided and documented (see Policy for Compounding Competency Assessment, Attachment D. Cytotoxic Drug Handling Informed Consent)
2. Initial HD handling competency is evaluated and re-validated at least every 12 months
3. Training is provided prior to introduction of new HD, new equipment, or new/significant change in process or SOP.

F. Environmental Quality and Control

1. Environmental wipe sampling for HD residue may be performed at baseline and every 6 months at the discretion of the department
2. The department takes action to identify, document and contain the cause when measurable contamination is found
3. Facility & personnel compliance with USP <797> (sterile compounding) with regards to nonviable and viable air sampling, surface sampling, and employee competency gloved fingertip sampling are assessed and documented (See Policy for Maintenance of Sterile Compounding Facilities and Equipments, Policy for Compounding Competency Assessment).

G. Hazard Communication Program

1. Workers who handle HDs are informed of the risks and methods of reducing exposure.
2. Written hazard communication program in place (see Policy for Pharmacy Hazard Communication Program and Policy for HSD Hazard Communication Program)
3. All HD containers are labeled with a hazard warning
4. SDS are available for each hazardous chemical and accessible to personnel in all locations and at all times (http:hq.msdsonline.com/contracostareghealthsl)
5. Personnel of reproductive capability confirm understanding of risks in writing (see Attachment D. Cytotoxic Drug Handling Informed Consent)

H. Medical Surveillance

1. The Personnel Department in conjunction with affected Departments, has process to identify workers who are potentially exposed to HDs and offers periodic medical surveillance

RELATED LINKS:

CCRMC Assessment of Risk for Hazardous Drugs

Policy for Pharmacy Hazard Communication Program

Policy for HSD Hazard Communication Program

Policy for Maintenance of Sterile Compounding Facilities and Equipments

Policy for Compounding Competency Assessment

Procedure for Chemotherapy and Hazardous Drugs – Administration, Disposal, Exposure and Spills, Extravasation

REFERENCES:

A. TJC Standard MM.01.01.03, MM 05.01.07, IC.02.02.01, E.02.04.03

B. CMS CoP § 482.11(a), 482.23(c), 482.25(a)(b), 482.41(a)(b)(c), 482.42(a)

C. NIOSH [2023]. Managing hazardous drug exposures: information for healthcare settings. By Hodson L, Ovesen J, Couch J, Hirst D, Lawson C, Lentz TJ, MacKenzie B, Mead K. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2023-130, https://doi.org/10.26616/NIOSHPUB2023130

D. NIOSH "List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings," December 2024

E. OSHA Standards: Hazard Communication Standard (29 CFR 1910.1200) Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450)

F. OSHA Technical Manual Guidelines "Controlling Occupational Exposure to Hazardous Drugs"

G. USP General Chapter <797>. Pharmaceutical Compounding – Sterile Preparations

H. USP General Chapter <800>. Hazardous Drugs – Handling in Healthcare Settings

I. Title 16 California Code of Regulations Articles 4.5~~, 7 and 7.5~~ § 1735, ~~1751~~1736, 1737

Attachments

- A: Hazardous Drugs List
- B: <USP 800> Assessment of Risk Template
- D: Cytotoxic Drug Handling Informed Consent
- E: Chemo/HD Spill Cleanup Procedure
- F. Equashield® Procedure Manual for Using Equashield Closed System Drug Transfer Device

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	03/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19939413**

Origination	04/2001
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval

Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Automated Drug Delivery System – Closure of a Patient Care Unit

POLICY STATEMENT:

This policy establishes the process for handling of the automated drug delivery system (ADDS) in the event of a patient care unit closure.

GUIDELINES:

The patient care unit Nurse Program Manager will notify the Pharmacy Department of the closing of a patient care unit. ~~Pharmacy is responsible for taking the ADDS off-line.~~

~~If this is a temporary closure, of less than two (2) weeks duration, the automated dispensing machine may be left in the secured med room.~~

~~If the closure is 2 weeks or longer, the ADDS will be brought down to Pharmacy.~~

Pharmacy is responsible for taking the ADDS off-line, if necessary.

When the patient care unit reopens, the Pharmacy Department will coordinate the reactivation of the ~~automated dispensing machine~~ADDS, if necessary.

REFERENCES:

A. TJC Standard MM.03.01.01
B. CMS CoP § 482.23(c), 482.25(a)(b)
C. Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 §

4119.11, Article 24 § 4427

D. Health and Safety Code § 1261.6

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 7/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19940339**

Origination	10/2003	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	02/2026		
Next Review	1 year after approval		

Policy for Automated Drug Delivery System – Removing Medications

POLICY STATEMENT:

To provide guidelines for the removal of medications from automated drug delivery systems (ADDS's) and the documentation of administration.

The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

Licensed nursing personnel will remove medications for patients from the ~~ADDSs~~ADDS's only after a licensed provider has ordered the medication and Pharmacy has reviewed and verified the order. An exception is made for the pharmacist review requirement in emergency situations as outlined in Policy for Automated Drug Delivery Systems - Override and Emergency/STAT Medication Orders.

DEFINITIONS:

Automated Drug Delivery System (ADDS): means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability

Automated Unit Dose System (AUDS): an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

Automated Patient Dispensing System (APDS): an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

GUIDELINES:

The nurse will review the patient's MAR prior to accessing the automated drug delivery system to identify medications needed.

The MAR is the official record of active medications, not the patient profile on the automated drug delivery system. The accuracy of the MAR is to be checked against the provider's orders. Any discrepancies are researched and corrected.

When accessing the automated drug delivery system, the nurse may be prompted to inventory the medication prior to removal. If the count is incorrect, it should be corrected. If the medication is a controlled substance, a discrepancy will be created. The Charge Nurse must be notified immediately.

The ADDS will then require the nurse to enter the quantity/dose removed. More than one medication for the same patient can be removed in one transaction. The automated drug delivery system will prompt the nurse to remove the medication(s) for the patient from the designated drawer(s). This process documents the removal in the ADDS.

Check the expiration date of all medications removed from the automated drug delivery system and always follow the six (6) rights of medication administration:

- Right patient
- Right medication
- Right dose
- Right time
- Right route
- Right documentation

If no medications are found in the compartment, verify the correctness of the pocket. If no medications are present, cancel the transaction and immediately notify the Pharmacy Department.

When using multi-dose vials, follow the Policy for Multidose Vials. Draw up the dose prescribed in a syringe and place the vial back in the pocket before closing the drawer. The syringe must be labeled with the drug and concentration/dose.

Any medication removed from the automated drug delivery system that is not administered and still in its original, unopened packaging must be returned to the automated drug delivery system. Use the return option and place the medication in the applicable drawer. Non-controlled medications may be returned to the pocket from which they came. Controlled substances are returned to the external return bin.

Partial doses or unused doses where the packaging has been opened must be wasted. Wastage is documented in the ADDS. Wasting controlled substances requires a witness.

For removal of controlled substances see Automated Drug Delivery Systems - Policy for Controlled Substances, Removal and Wasting: Automated Drug Delivery Systems

Patient-Specific Medications:

- ~~Patient~~Multi-use patient-specific medications such as inhalers, ointments, eye drops, ear drops, and non-formulary medications are not ~~stocked~~stored in the automated dispensing machine. ~~The Pharmacy Department will dispense these items, labeled with the patient's information, to the patient care unit. These items are then stored in the patient's drawer in the medication cabinet in the med room. In areas without a secured med room, these medications are stored in the ADDS by room and bed location.~~
    - Multi-use medications may be dispensed from the ADDS for a specific patient's use, but not returned to the ADDS for storage. The patient's information is adhered to the multi-use medication package and then stored in the patient's drawer in the medication cabinet in the medication room.
    - If not available from the ADDS, the Pharmacy Department will dispense these items, labeled with the patient's information, to the patient care unit.
- When transferring a patient to another unit, send all medications in the patient's ~~bin~~drawer along with any refrigerated medications to the new patient care unit.
- Upon discharge, return all of the above medications to the Pharmacy Department for appropriate credit/disposal.

Discharge Prescriptions:

- DO NOT remove medications from the automated drug delivery systems on inpatient care units to dispense to inpatients as discharge medications.
- No drugs supplied by the hospital shall be taken from the hospital unless a prescription or medical record order has been written for the medication. The medication must be properly labeled and prepared in accordance with state and federal laws for use outside of the hospital.
- Discharge prescriptions are to be sent electronically to the pharmacy of their choice to be filled. See Policy for Patient Discharge Medications

Prior to installation, and annually thereafter, the pharmacy holding the ADDS license shall provide training on the operation and use of the ADDS to personnel using the ADDS.

RELATED LINKS:

Policy for Automated Drug Delivery Systems - Override and Emergency/STAT Medication Orders

Policy for Multidose Vials

Policy for Controlled Substances, Removal and Wasting: Automated Drug Delivery Systems

Policy for Patient Discharge Medications

REFERENCES:

~~TJC Standard MM.05.01.01, MM.05.01.07, MM.06.01.01, EC.02.04.03~~
~~CMS CoP § 482.13(c), 482.23(c), 482.25(a)(b), 482.41(a)(c)~~
~~Title 22, Section 71233:2g~~
~~Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 § 4119.11, Article 24 § 4427~~

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2022~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

A. TJC Standard MM.05.01.01, MM.05.01.07, MM.06.01.01, EC.02.04.03
B. CMS CoP § 482.13(c), 482.23(c), 482.25(a)(b), 482.41(a)(c)
C. Title 22, Section 71233
D. Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 § 4119.11, Article 24 § 4427
E. Health and Safety Code § 1261.6

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19940349**

Origination	04/2001	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	02/2026		
Next Review	1 year after approval		

Policy for Automated Drug Delivery System (ADDS) – Stocking Medications

POLICY STATEMENT:

To provide an accurate and efficient means of distributing medications to the patient care areas.

DEFINITIONS:

Automated Drug Delivery System (ADDS): means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability

Automated Unit Dose System (AUDS): an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

Automated Patient Dispensing System (APDS): an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

GUIDELINES:

Pharmacy and Nursing will utilize automated drug delivery system (ADDS's) as an inventory, dispensing, and recording system for the following types of medications:

- Controlled substances
- First doses

- STAT doses
- Stock medications
- Emergency medications
- Service-specific medications

The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

The standard medication inventory for each ADDS will be determined by the Patient Care Unit Nurse Manager and the Pharmacy Department.

The Pharmacy Department is responsible for stocking and unloading of all medications in the ADDS. Inventory refill reports are generated at least once per day and all medications below PAR are refilled. Medications at critical low are to be refilled right away. Critical low reports are run at least once per day. A Pharmacist or a Pharmacy Technician under the supervision of a Pharmacist shall stock the automated dispensing machines.

All medications stocked in the ADDS will be documented and signed by the Pharmacist and Pharmacy Technician. These records are maintained by the Pharmacy Department for a period of three (3) years.

All medications stocked in the ADDS shall be packaged and labeled in accordance with federal and state regulations.

The Pharmacy Department is responsible for tracking medication expiration dates and removing those medications from the machines upon expiration. The report is run at least twice weekly. Expirations are also checked monthly by a pharmacist and a pharmacy technician. See details in Policy for Automated Drug Delivery Systems – Inspection and Inventory and Policy for Automated Drug Delivery Systems - Maintenance & Monitoring

If a medication is found to be low after the Pharmacy Department personnel stock the automated dispensing machine, the Pharmacy Department will be notified.

On a routine basis, pharmacy will evaluate and change, as indicated, PAR levels and medications stocked in each ADDS. No medication will be added or removed without the supervising pharmacist's approval.

Nursing staff will inventory all controlled substances at the beginning and end of each shift. Noncompliance will be reported to the appropriate Nurse Program Manager (NPM) and Chief Nursing Officer.

Pharmacy staff will empty the return bin and save the transaction slip whenever medications are returned to the ADDS.

Prior to installation, and annually thereafter, the pharmacy holding the ADDS license shall provide training on the operation and use of the ADDS to pharmacy personnel.

RELATED LINKS:

Policy for Automated Drug Delivery Systems – Inspection and Inventory

Policy for Automated Drug Delivery Systems - Maintenance & Monitoring

REFERENCES:

~~TJC Standard MM.03.01.01~~
~~CMS CoP § 482.23(c), 482.25(a)(b)~~
~~Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 § 4119.11, Article 24 § 4427~~

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 7/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

A. TJC Standard MM.03.01.01
B. CMS CoP § 482.23(c), 482.25(a)(b)
C. Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 § 4119.11, Article 24 § 4427
D. Health and Safety Code § 1261.6

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19948516**

Origination	09/2003
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Automated Drug Delivery Systems – Inspection and Inventory

POLICY STATEMENT:

Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy.

~~To assure~~The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drug inventory in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, checking expiration dates and ensuring that ~~all medications kept in automated drug delivery systems (ADDSs) are stored under proper conditions and sanitation and are in date, the automated drug delivery systems on each patient care unit will be inspected every 28 days by the Pharmacy Department. This includes verifying the inventory of stocked medications, checking expiration dates and ensuring that~~ "look-alike sound-alike" medications are not stored in adjacent pockets. The inspection will be documented.

~~The hospital implements the policy and procedures approved by the Pharmaceutical & Therapeutics Committee (i.e, called Patient Care Policy and Evaluation-PCP&E at CCRMC) to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quantity, potency and purity of stored drugs.The policies and procedures define access to the ADDS and limits access to equipment and drugs.~~

~~Inventory levels for each unit are determined by usage. Periodic Automatic Replenishment (PAR) levels are established so as to provide sufficient stock but minimize the potential for diversion.~~

GUIDELINES:

A. Inventory Count/Expiration Dates:

1. Inventory levels for each unit are determined by usage. Periodic Automatic Replenishment (PAR) levels are established so as to provide sufficient stock but minimize the potential for diversion and wastage due to underutilization.
2. The expiration date of all medications will be checked. Unless the medication has a short expiration date due to stability or supply issues, all medications with an expiration date within three (3) months of the current date will be removed from the automatic drug delivery system and the stock level will be adjusted. The earliest expiration date of the remaining items is entered into the automatic drug delivery system. Short-dated medications are to be removed before the expiration date is reached.
3. A physical count of all medications in the automatic drug delivery system will be done. If the physical count does not match the ADDS's record, enter the correct count.

B. Look-a-Like, Sound-a-Like Medications:

1. The Pharmacy Department personnel will ensure that look-a-like medications are not stored in adjacent pockets in the automatic drug delivery system. Look-a-like variables include: same packaging, same color label, same color top, same drug in a different dose, etc. Policy for Look-Alike, Sound-Alike Medication Management
2. Look-a-like, sound-alike medications on CCRMC's LASA list will be stored with a secondary caution label, alerting staff for the necessity of taking additional dispensing precautions.

C. Refrigerated Medications:

1. The procedure for checking the inventory and expiration dates of refrigerated medications is the same as above.
2. If the refrigerator has a thermometer in place, check that it is functioning correctly. The temperature range should be 36 – 46 degrees F.

D. Multi-dose Vials:
All opened multidose vials are to be removed from the ~~ADDSs~~ADDS's every 28 days. They are to be considered and processed as expired medications. Policy for Multidose Vials

E. Documentation:
The inspection is documented on the appropriate audit forms and signed by Pharmacy staff. These forms are maintained in the Pharmacy Department.

RELATED LINKS:

Policy for Look-Alike, Sound-Alike Medication Management

Policy for Multidose Vials

REFERENCES:

A. TJC Standard MM.03.01.01
B. CMS CoP § 482.23(c), 482.25(a)(b)
C. California Pharmacy Law 4105.5, 4106.5, 4426.6, 4426.
D. Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 § 4119.11, Article 24 § 4427
E. Health and Safety Code § 1261.6

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 7/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Attachments

A: Location of ADCs at CCRMC

B: Location of ADCs in Ambulatory Care Clinics

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19948381**

Origination	04/2001
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Automated Drug Delivery Systems - Maintenance & Monitoring

POLICY STATEMENT:

The Pharmacy Department, Biomedical Engineering Department, and the automated drug delivery system vendor will all contribute to preventive maintenance of the automated dispensing machines, in order to keep the automated drug delivery systems (~~ADDSs~~ADDS's) in clean and in proper working order.

The Pharmacy Department reviews all transaction records in order to verify the security and accountability of the ADDS.

Automated Drug Delivery System (ADDS): means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability

Automated Unit Dose System (AUDS): an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

Automated Patient Dispensing System (APDS): an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

GUIDELINES:

A. The following records will be maintained on the ~~ADDSs~~ADDS's:

1. Manufacturer's name and model types/numbers and customer service number

2. Serial numbers on all machines
3. CCRMC's customer identification number
4. Location of all machines

B. ~~Each automated drug delivery system will have reference materials attached regarding daily maintenance and cleaning, operations chart and troubleshooting information.~~

C. If an ADDS should fail

1. During regular business hours, Nursing unit may contact the Pharmacy Department. BioMed may also be contacted for assistance. If unable to fix the machine, the service center will be contacted
2. After Pharmacy hours, Nursing should contact the service center. The phone number is posted on all the ~~ADDSs~~ADDS's.
3. If necessary, the vendor will send a service technician to perform repairs. This service is available 24 hrs/day. If the technician does not arrive in 8 hours or less, Pharmacy Administration must be notified.

D. New medications are added to the ADDS drug database as necessary to match the pharmacy computer system drug dictionary. The mnemonics must match.

E. The ADDS database is monitored daily for orders that were not accepted and are in the suspense file. The reason for these orders not crossing over must be researched and corrected.

F. In addition, the users and patients' databases are routinely monitored to watch for the creation of multiple access codes for the same user (i.e a registry nurse who works regularly) and patients with multiple accounts due to addition of the patient at the station rather than through the computer interface.

Pharmacy shall maintain comprehensive oversight of the Automated Drug Dispensing System (ADDS) to safeguard medication security and accountability through the following measures:

A. **Profiled System and Real-Time Verification**

- The ADDS operates in profiled mode, requiring all medication removals to be linked to an active patient profile.
- Pharmacists perform real-time verification of medication orders prior to dispensing, ensuring accuracy and appropriateness at the point of removal.

B. **Override Controls and Review**

- Overrides are permitted only under emergent circumstances as defined in Policy for Automated Drug Delivery Systems - Override and Emergency/STAT Medication Orders
- Each override transaction is subject to immediate pharmacist review at the time of occurrence and a secondary retrospective review within 48 hours by a different pharmacist to confirm clinical appropriateness and compliance.

C. **Transaction Monitoring and Reporting**

- Pharmacy utilizes automated reporting tools to monitor override activity, temporary patient and user accounts, controlled substance vault withdrawals, and cabinet restocking.
- Reports are reviewed routinely to identify irregularities, reconcile discrepancies, and prevent diversion.

D. **Controlled Substance Diversion Prevention**

- A dedicated diversion monitoring system continuously compares medication orders against ADDS transactions.
- Any variance or anomaly is promptly investigated and documented in the Safety Event Reporting System (SERS) in accordance with internal and external regulatory reporting requirements as detailed in the following policies:
    - Policy for Controlled Substance Diversion Prevention
    - Policy for Reporting Diversion of Controlled Substances
    - Policy for Licensed Employee – Theft or Impairment

E. **Audit and Record Retention**

- Audits are conducted to evaluate override trends, account reconciliation, and inventory accuracy.
- All transaction records, verification logs, and audit findings are retained for the period required by applicable state and federal regulations and are available for inspection by regulatory authorities.

RELATED LINKS:

Policy for Automated Drug Delivery Systems - Override and Emergency/STAT Medication Orders

Policy for Controlled Substance Diversion Prevention

Policy for Reporting Diversion of Controlled Substances

Policy for Licensed Employee – Theft or Impairment

REFERENCES:

A. TJC Standard EC.02.04.01, EC.02.04.03
B. CMS CoP § 482.13(c), 482.23(c), 482.25(a)(b), 482.41(a)(c), 482.42(a)
C. Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 § 4119.11, Article 24 § 4427
D. Health and Safety Code § 1261.6

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2022~~

~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19946098**

Origination	04/2001
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval

Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Automated Drug Delivery Systems – Malfunction & Failure

POLICY STATEMENT:

The Pharmacy Department will initiate steps to return the automated drug delivery system to service and/or provide another means of service when a malfunction occurs, and to ensure there are processes in place in case any/all of the automated drug delivery systems should fail, for whatever reason.

Automated Drug Delivery System (ADDS): means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability

Automated Unit Dose System (AUDS): an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

Automated Patient Dispensing System (APDS): an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

GUIDELINES:

A. Malfunctions/Power Failures:

1. Malfunctions and downtimes must be reported to the Pharmacy Department by Nursing.
2. If an ADDS should fail
    a. During regular business hours, Nursing may contact the Pharmacy Department. If

unable to fix the machine, the service center will be contacted

b. After Pharmacy hours, Nursing should contact the service center. The phone number is posted on all the ADDSs.

c. If necessary, the vendor will send a service technician to perform repairs. This service is available 24 hrs/day. If the technician does not arrive in 8 hours or less, Pharmacy Administration must be notified.

3. In the event of a power failure, the ADDSs will continue to function as long as they are plugged into the emergency (red) power outlets.
4. If the emergency circuit should fail or the Omnicell is completely down/off:
    a. **During Pharmacy operational hours**: The floor nurse can obtain medications from other Omnicells and/or Pharmacy will dispense medications per order. If necessary and in certain situations, the Pharmacy Department will unlock the automated drug delivery system(s) to provide access to medications. A pharmacist will be present at the Omnicell to facilitate medication removal and assure the security of medications during Pharmacy operational hours.
    b. **During Pharmacy non-operational hours**: The unit Charge Nurse must notify Medical Center Supervisor who can facilitate the retrieval of medications from Night locker or from other Omnicells in the hospital. Medications removed from the automated drug delivery system will be documented on the Downtime Log.
    c. Refer to Policy for Pharmacy ccLink Downtime Plan and Procedure for Turning off Medication Verification in Omnicell if ccLink or Omnicell interface is down.
5. If the system loses connectivity, Pharmacy Administration will determine if the medication order profile function will be disabled. (See Policy for Pharmacy Department Disaster Plan)

B. Drawer Failure:

1. Nursing will notify the Pharmacy Department of a drawer failure. The Pharmacy Department will attempt to walk the nurse through steps to correct the failure. If this does not correct the problem, a Pharmacy staff member will be sent to the patient care unit to correct the problem.
2. If Pharmacy cannot resolve the problem, the ADDS service center will be contacted. It is expected that they will send a repair technician within 8 hours of making the call. If they do not meet this expectation, Pharmacy Administration is to be notified.
3. If a drawer failure occurs in one that contains a controlled substance, two (2) nurses will inventory the drawer once the failure is corrected.
4. If the failure cannot be resolved in a timely, the nurses should use the automated dispensing machine at the closest patient care unit whenever possible.

RELATED LINKS:

~~Pharmacy~~Policy for Pharmacy Department Disaster Plan
~~Pharmacy~~ ~~Policy for Pharmacy ccLink Downtime Plan~~
~~ADDS Downtime Log~~

Policy for Pharmacy ccLink Downtime Plan

Procedure for Turning off Medication Verification in Omnicell

REFERENCES:

A. TJC Standard EC.02.04.01, EC.02.04.03
B. CMS CoP § 482.12(f), 482.13(c), 482.23(c), 482.25(a)(b), 482.41(a)(c), 482.55
C. Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 § 4119.11, Article 24 § 4427
D. Health and Safety Code 1261.6

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2022~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Attachments

Automated Drug Delivery System Downtime Log for Medication Removal

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19940509**

Origination	04/2004	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	02/2026		
Next Review	1 year after approval		

Policy for Automated Drug Delivery Systems - Override and Emergency/STAT Medication Orders

POLICY STATEMENT:

To establish guidelines for when medications may be removed from the automatic drug delivery system (~~ADDM~~ADDS) to assure timely access to and administration of medications to patients in urgent situations prior to a pharmacist's review of the order ~~and the pharmacist's responsibility to review the order and the override ASAP~~.

All medication orders will be reviewed by a pharmacist prior to administration, unless waiting for pharmacist review would result in harm to the patient or in a licensed independent practitioner (LIP) controlled environment. Exceptions are made for urgent situations when the resulting delay would harm the patient, including situations in which the patient experiences a sudden change in clinical status or sudden onset of symptoms (e.g. nausea, pain, cardiac events, sepsis, fever); if waiting for a pharmacist to review the order would result in clinical harm to the patient. If an override of a medication from the ADDS is necessary, it is the pharmacist's responsibility to review the order and the override within 48 hours.

I. ~~**DEFINITIONS:**~~

~~**Automated Drug Delivery System (ADDS):** means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability~~

~~**Automated Unit Dose System (AUDS):** an ADDS for storage and retrieval of unit doses of~~

~~drugs for administration to patients by persons authorized to perform these functions.~~

~~**Automated Patient Dispensing System (APDS):** an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.~~

DEFINITIONS:

Automated Drug Delivery System (ADDS): means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability

Automated Unit Dose System (AUDS): an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

Automated Patient Dispensing System (APDS): an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

GUIDELINES:

All medication orders must be reviewed by a pharmacist prior to administration to the patient, with the following exceptions:

- In an environment where a licensed practitioner with appropriate clinical privileges controls prescribing, preparation, and administration. LIP controlled environments include, but is not limited to:
    - Emergency Department
    - Pre- and Post-Operative Care
    - Surgery Department
    - Interventional radiology
    - General radiology
    - Labor & Delivery
    - GI lab
    - Anesthesiology
- STAT orders, or one-time orders in urgent situations where the resulting delay would harm the patient, including (but not limited to) situations in which the patient experiences a sudden change in clinical status or sudden onset of symptoms (e.g., nausea, pain, cardiac events, etc.). the automatic drug delivery system may be accessed for this dose.
- If waiting for a pharmacist to review the order would result in clinical harm to the patient.

Drug classes available for the above scenarios include:

- Short-acting, injectable pain medications
- Antipyretic medications

- ~~Injectable cardiac~~Cardiac medications (e.g., antithrombolytics, antiarrhythmics, anticoagulants, antihypertensives, etc.)
- Antiemetics
- Code ~~and~~ , antidotes, and reversal/rescue medications (e.g. D50, naloxone, flumazenil, vitamin K, protamine, glucagon, lipids, calcium chloride, calcium gluconate, sugammadex, etc.)
- Antibiotics (~~i.~~e.g., for sepsis, febrile neutropenia, etc.) and other anti-infectives
- Injectable anti-epileptics (e.g., for acute management and/or prevention of seizures)
- Injectable corticosteroids and breathing treatments (e.g., for acute asthma exacerbation)
- Injectable antipsychotics and benzodiazepines (e.g., for management of acute agitation)
- Insulin regular
- Tocolytics

Any medications falling outside any of the above categories are considered non-overridable.

When it becomes necessary for a nurse to remove an unfamiliar medication on override, he/she will review the order for:

- Appropriateness of drug, dose, route, and frequency.
- Real or potential allergies or sensitivities.
- Real or potential interactions between this medication and other medications the patient is taking, food, and clinical lab values.
- Therapeutic duplication.

Medications removed from the automated drug delivery system prior to pharmacist review of the order require the Nurse to enter a reason for the removal. The nurse will select one of the following override reasons from the ~~ADDM~~ADDS pop-up screen:

- Physician present.
- STAT or one-time order. Delay in therapy would harm patient.
- Waiting for RPh to review order will result in clinical harm.
- Different strength required.
- Newborn not in system.
- Order on Omnicell profile; med not available.

It is the pharmacist's responsibility to review the order and the override medication removal ASAP within 48 hours.

Override pulling errors will be reported as medication errors, following established policies and procedures.

Pharmacy Department will monitor compliance with override criteria and will report to the appropriate committees on a regular basis.
Medication errors related to the ~~ADMs~~ADDS will be reported via the SERS reporting system.

REFERENCES:

~~TJC Standard MM.03.01.01, MM.05.01.01, MM.05.01.11, MM.06.01.01 (2022)~~
~~CMS CoP § 482.12(f), 482.13(c), 482.23(c), 482.25(a)(b), 482.55~~
~~Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 § 4119.11, Article 24 § 4427~~

~~APPROVALS:~~

~~Clinical Practice Committee: 6/2022~~
~~Patient Care Policy and Evaluation Committee: 3/2022~~
~~Medical Executive Committee: 4/2022~~
~~Joint Conference Committee:~~

A. TJC Standard MM.03.01.01, MM.05.01.01, MM.05.01.11, MM.06.01.01 (2022)
B. CMS CoP § 482.12(f), 482.13(c), 482.23(c), 482.25(a)(b), 482.55
C. Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 § 4119.11, Article 24 § 4427.3, 4427.65
D. Health and Safety Code 1261.6

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19940551**

Origination	03/2004	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	02/2026		
Next Review	1 year after approval		

Policy for Automated Drug Delivery Systems – Pharmacist Order Verification

POLICY STATEMENT:

To ensure safe ordering and dispensing of medications from automated drug delivery systems.

A pharmacist will review all prescriptions or orders for medication. Exceptions are made for a licensed independent practitioner (LIP) controlled environment when the LIP controls the ordering, preparation, and administration of the drug. Such environments include, but not limited to:

A. Emergency Department
B. Pre- and Post-Operative Care
C. Surgery Department
D. Interventional radiology
E. General radiology
F. Labor & Delivery
G. GI lab
H. Anesthesiology

Other exceptions include urgent situations when the resulting delay would harm the patient, including situations in which the patient experiences a sudden change in clinical status or sudden onset of symptoms (e.g., nausea, pain, cardiac events, sepsis, fever); if waiting for a pharmacist to review the order would result in clinical harm to the patient. If an override of a medication from the ADDS is necessary, it is the pharmacist's responsibility to review the order and the override within 48 hours.

Drug classes that are available for the above scenarios include:

~~A. Pain and antipyretic medications~~

~~B. Cardiac medications (e.g., antithrombolytics, antiarrhythmics, anticoagulants, antihypertensives, etc)~~

~~C. Antiemetics~~

~~D. Code medications~~

~~E. Antibiotics & other anti-infectives~~

~~F. Any other medication required urgently for various clinical conditions~~

A. Short-acting, injectable pain medications

B. Antipyretic medications

C. Cardiac medications (e.g., antithrombolytics, antiarrhythmics, anticoagulants, antihypertensives, etc.)

D. Antiemetics

E. Code, antidotes, and reversal/rescue medications (e.g. D50, naloxone, flumazenil, vitamin K, protamine, glucagon, lipids, calcium chloride, calcium gluconate, sugammadex, etc.)

F. Antibiotics (i.e. for sepsis, febrile neutropenia, etc.) and other anti-infectives

G. Injectable anti-epileptics for acute management and/or prevention of seizures

H. Injectable corticosteroids and breathing treatments for acute asthma exacerbation

I. Injectable antipsychotics and benzodiazepines for management of acute agitation

J. Insulin regular

K. Tocolytics

DEFINITIONS:

Automated Drug Delivery System (ADDS): means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability

Automated Unit Dose System (AUDS): an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

Automated Patient Dispensing System (APDS): an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

GUIDELINES:

Pharmacy shall review and verify the original physician's order in ccLink.

A pharmacist will review all orders, checking for:

A. Completeness of the order
B. Correctness of the drug ordered
C. Allergies (including drug, food, latex)
D. Drug incompatibilities
E. Therapeutic duplications
F. Interactions with food or other drugs
G. Appropriateness of dosage, route, frequency, and indications
H. Pertinent lab values
I. Contraindications
J. Variations from CCRMC's criteria for use
K. Applicable black box warning

A Pharmacist will verify the physician's order in the computer. Order verification by the pharmacist will result in the order appearing on the patient's profile on the automated drug delivery system. This will make the medication available to Nursing, notwithstanding the emergent situations that would permit the Nurse to remove the medication prior to pharmacist review.

Any questions or clarification of the order shall be directed to the provider by the pharmacist. The pharmacist will page the provider, attending physician, or house officer. In the event all of these avenues fail, the pharmacist will attach a note to the patient's electronic medical record.

Verbal clarification from the provider shall be entered into ccLink, read back to the provider, and electronically sent to the provider for a co-signature.

The following are the expected turn-around times for orders, once they are received in pharmacy. This includes entry into the computer and delivery to the floor:

A. 'STAT' orders: immediately. They are to receive the highest priority.
B. CAP and sepsis antibiotic orders: immediately
C. 'Urgent' orders: within 1 hour
D. 'Routine" orders: within 1.5 hours.
E. 'Non-urgent' orders: within 2 hours

REFERENCES:

A. TJC Standard MM.05.01.01, MM.05.01.07, MM.06.01.01, PC.02.01.03
B. CMS CoP § 482.11(a), 482.23(c), 482.24(c), 482.25(a)(b), 482.28(b)
C. Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 § 4119.11, Article 24 § 4427
D. Health and Safety Code 1261.6

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/22~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19946559**

Origination	10/2007
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Automated Drug Delivery Systems – Policies and Procedures

POLICY STATEMENT:

Policies and Procedures are approved by the Pharmaceutical & Therapeutics Committee (i.e, called Patient Care Policy and Evaluation-PCP&E at CCRMC) to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quantity, potency and purity of stored drugs stored in the Automated Drug Delivery System (ADDS).

All Pharmacy Department and Nursing Services policies and procedures covering the prescribing or ordering, preparation, distribution and administration of controlled and non-controlled substances apply to ~~the automatic drug delivery system~~drugs removed from the Automated Drug Delivery System (ADDS) used at CCRMC.

~~To assure that the automated drug delivery systems are used appropriately and safely.~~

DEFINITIONS:

Automated Drug Delivery System (ADDS): means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability

Automated Unit Dose System (AUDS): an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

Automated Patient Dispensing System (APDS): an ADDS for storage and dispensing of prescribed drugs

directly to patients pursuant to prior authorization by a pharmacist.

GUIDELINES:

All polices applicable to the ordering, preparation, distribution and administration of medications shall be followed when using the automated drug delivery systems.

Policies and Procedures are reviewed annually.

Policies and Procedures ensure safety, accuracy, accountability, security, patient confidentiality, maintenance of the quality, potency, and purity of stored drugs. See Policy for Quality Assurance in Pharmacy

Policies and Procedures define access to the ADDS and limits access to equipment and drugs. See Policy for Access to Automated Drug Delivery Systems (ADDS)

Policies and Procedures are available for viewing at the pharmacy location operating the ADDS and at the location where the ADDS is being used.

RELATED LINKS:

Policy for Access to Automated Drug Delivery Systems (ADDS)

Policy for Automated Drug Delivery System (ADDS) – Stock Medications

Policy for Automated Drug Delivery System – Removing Medications

Policy for Controlled Substances, Removal and Wasting: Automated Drug Delivery Systems

Policy for Automated Drug Delivery Systems - Override and Emergency/STAT Medication Orders

Policy for Automated Drug Delivery Systems – Pharmacist Order Verification

Policy for Automated Drug Delivery Systems – Inspection and Inventory

Policy for Automated Drug Delivery Systems - Maintenance & Monitoring

Policy for Automated Drug Delivery System – Closure of a Patient Care Unit

Policy for Automated Drug Delivery Systems – Malfunction & Failure

Procedure for Turning off Medication Verification in Omnicell

Policy for Quality Assurance in Pharmacy

REFERENCES:

A. TJC Standards MM.03.01.01, MM.05.01.11, MM.06.01.01
B. CMS CoP § 482.23(c), 482.25(a)(b)
C. Nursing Policy for Medication Administration and Documentation
D. Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 §

4119.11, Article 24 § 4427

E. Health and Safety Code 1261.6

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 7/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19217253**

Origination	05/2005	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	10/2025		
Next Review	3 years after approval		

Policy for CCRMC Drug Formulary

POLICY STATEMENT:

The Patient Care Policy & Evaluation Committee (PCP&E) will develop a system whereby medications are evaluated, appraised and selected to all those drugs considered most useful for patient care to be stocked within in the hospital. When feasible, Pharmacy will attempt to purchase medications consistently from the same manufacturer. When possible, Pharmacy will limit the availability of drugs in different strengths/concentrations in designated areas for medication safety purposes. Selected drugs will be listed on the hospital formulary and can be classified as formulary, restricted formulary, or investigational. Drugs not selected for inclusion are considered non-formulary. The formulary is reviewed annually.

GUIDELINES:

The formulary shall be broadly constructed and maintained in such a way that the need for use of "non-formulary drugs" is minimized. It is recognized that on occasion the use of a "non-formulary" drug may be indicated for a particular patient. The PCP&E will develop guidelines for the provision of "non-formulary" drugs and review the use of non-formulary drugs.

The drug formulary undergoes continual updating and revision, which reflects the current clinical judgment of the medical and pharmacy departments, with the advice and consent of other professional disciplines.

Definitions:

A. **Formulary Drug**: A drug approved by the committee for inclusion on the hospital formulary. Formulary drugs are generally available for routine use.

B. **Restricted Drug**: A drug approved by the committee for inclusion on the hospital formulary, however, prescribing of this drug will be limited in scope (i.e., to a particular physician or medical service).

C. **Investigational Drug**: A drug undergoing investigation as a part of a research protocol approved by the committee. Such investigational drugs are stocked by the Pharmacy Department and are available for use only by the authorized investigator in the manner designated in the study protocol.

D. **Non-formulary Drug**: Any drug which has not been reviewed by the committee or has been reviewed and denied inclusion on the formulary. Non-formulary drugs are not stocked by the Pharmacy Department and are not available for routine use. However, non-formulary drugs may be ordered for individual patients when sound pharmacologic and/or therapeutic considerations so dictate.

RELATED LINKS:

Procedure for CCRMC Drug Formulary

CCRMC Formulary with Indications

REFERENCES:

A. TJC Standard MM.02.01.01

B. CMS CoP § 482.12(a)(c), 482.23(c), 482.25(a)(b)

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 1/2023~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
	Shideh Ataii: Director Of Pharmacy Svcs	11/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19978843**

Origination	04/2004
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Compounding Competency Assessment

POLICY STATEMENT:

The Designated Person (DP), Pharmacist II, is responsible for creating and implementing a training program for personnel. The DP ensures that compounders, personnel who have direct oversight of compounders, and personnel who perform cleaning and disinfection duties (i.e. Environmental Services (EVS)) are initially trained and qualified by the DP, demonstrating knowledge and competency in maintaining the quality of the sterile compounding environment before being allowed to perform their job functions independently. The DP may separately train designee(s) to be an assigned trainer. The competency assessment program is continuous and ongoing.

GUIDELINES:

DP assigns **trainers** didactic and practical education every 12 months. While trainers ~~didactic and practical education every 12 months. While trainers~~ are in-date with their competency, they can observe each other, DP, and other personnel as necessary and validate their "practical" competency. DP will continue to have oversight on all compounding competencies.

~~All Pharmacy staff who prepare, or who might prepare, **sterile** parenteral products will receive a competency assessment of his/her aseptic technique no less frequently than once every 6 months. Staff who only have direct oversight of sterile compounding activities will receive a competency assessment of his/her aseptic technique no less frequently than once every 12 months. In addition to having a working knowledge of containment isolators, aseptic technique, and the dangers and precautions in dealing with chemotherapeutics, the staff member must successfully pass a knowledge-base assessment test, gloved fingertip test, a media-fill test, and a chemo aseptic technique test. Failure of any of the tests will result in immediate removal from all IV compounding duties, re-education, and~~

~~retesting. Repeated failure may result in disciplinary action, as appropriate. New hires must perform a media-fill challenge (with no turbidity growth in the media fill) and 3 glove fingertip samples (all fingers of both hands with zero colony forming units for both hands), and take the knowledge-base assessment test, before being allowed to compound sterile products. Employees who will be compounding chemotherapeutics must also successfully pass a ChemoTest and skills assessment.~~

All Pharmacy staff who ~~prepare~~**compound,** or who may compound, ~~or might prepare, or have direct oversight of compounding of~~ ***non-sterile*** ~~compounded products must be initially trained and qualified by demonstrating knowledge and~~***sterile parenteral products*** will receive a competency ~~and~~assessment of his/her aseptic technique no less frequently than once every ~~12 months.~~6 months.

~~GUIDELINES:~~

~~A. All pharmacy staff members who prepare sterile parenteral products as part of their job description must successfully pass all phases of the "Sterile Compounding Competency."~~

~~B. The individual must have a good working knowledge of:~~

~~1. Hand hygiene~~

~~2. Garbing attire in the compounding rooms~~

~~3. Traffic flow in the compounding rooms~~

~~4. Cleaning and disinfection of the compounding room and compounding aseptic isolators~~

~~5. Working in the required conditions for aseptic processing~~

~~6. Aseptic manipulations of sterile products~~

~~7. Compounded Sterile Products (CSP's):~~

~~a. Identification~~

~~b. Accurate measuring, weighing, dilution and mixing of ingredients~~

~~c. Purification, sterilization, if applicable~~

~~d. Packaging~~

~~e. Labeling~~

~~f. Storage~~

~~g. Dispensing~~

~~h. Transport~~

~~8. Quality assurance~~

~~C. Proper use and maintenance of all equipment and supplies~~

~~D. The media-fill test duplicates the complexity and potential of contamination when compounding a Category 1 or 2 CSP.~~

~~1. New employees must complete a media-fill test successfully in each type of primary engineering control (PEC) in all sterile compounding locations.~~

2. ~~Testing is performed once initially, then at least once every 6 months.~~

E. ~~Gloved fingertip test is performed in two situations:~~

1. ~~After hand hygiene and garbing and donning the sterile gloves over the PEC (Restricted-access Barrier System [RABS] i.e., CAI or CACI) gauntlet gloves to assess the ability of the compounding staff to maintain sterility while donning the sterile gloves~~
2. ~~After the media-fill test to assess the ability of the compounding staff to maintain the sterility of gloves while compounding a Category 1 or 2 CSP~~
3. ~~Gloved fingertip test is performed in each type of primary engineering control (PEC) in all sterile compounding locations. See Procedure A for Gloved Fingertip Test.~~
4. ~~Testing is performed initially three times after separate and complete hand hygiene and garbing procedures and once after media fill test.~~
5. ~~Thereafter, at least once every 6 months, it is performed once after hand hygiene and garbing procedures and once after media fill test.~~

F. ~~A surface sample of the direct compounding area is also taken after the media-fill test. Testing is performed once initially, then at least once every 6 months.~~

G. ~~Media Fill Test(s), Gloved Fingertip Tests, and Surface Samples are sent out to an external laboratory for incubation, enumeration, and microbial identification, if indicated.~~

1. ~~Media Fill Test(s) are incubated at 20-25°C for 7 days, followed by 30-35°C for 7 days, for a total of 14 days.~~
2. ~~Gloved Fingertip Tests and Surface Samples are incubated at 30-35°C for least 48 hours, followed by 20-25°C for at least 5 additional days.~~

H. ~~Action level for Media Fill Test(s) is any turbidity.~~

1. ~~Action level for gloved fingertip tests after garbing is >0 CFU total from both hands. Action level for gloved fingertip tests after media-fill testing is >3 CFUs total from both hands.~~
2. ~~Action level for Surface Samples is >3 CFUs.~~
3. ~~Results of any of the tests (gloved fingertip test, media test, or surface sample) above the action levels will undergo microbial identification at least to the genus level, be reported to the Designated Person(s), and addressed as per detailed procedure outlined in Procedure for Handling of Positive Cultures from Pharmacy Monitoring.~~
4. ~~Intervention may be necessary if the microbials identified are highly pathogenic.~~
5. ~~The Designated Person(s) may consult with external laboratory microbiologist, Infection Control, or the Director of Laboratory to determine a plan of action/ correction for each positive result as deemed appropriate.~~

I. ~~The plan may include some/all of the following:~~

1. ~~Re-education by a qualified individual~~
2. ~~Conducting a retest of the entire competency assessment~~

3. ~~Direct observation of aseptic technique~~
4. ~~Sampling of the compounding area(s) for potential contamination~~
5. ~~Evaluation of cleaning procedures, for Pharmacy and Environmental Services~~
6. ~~Evaluation of primary and secondary engineering controls~~

J. ~~Corrective action(s) taken will be documented.~~

K. ~~Failure of any component(s) of the aseptic technique competency assessment by an employee will result in immediate removal from all sterile compounding duties. Pharmacy Administration will determine the appropriate plan of action. Only after successfully passing the entire competency assessment will the staff member be allowed to return to his/her normal duties.~~

L. ~~Repeated failure may result in disciplinary action.~~

M. ~~The Sterile Compounding Competency Assessment (Attachment A. Sterile Compounding Competency Assessment) will be kept in the employee's departmental personnel file for 3 years.~~

N. ~~The Non-Sterile Compounding Competency Assessment (Attachment B. Non-Sterile Compounding Competency Assessment) will be kept in the employee's departmental personnel file for 3 years.~~

O. ~~The competency assessment program is continuous and ongoing.~~

Pharmacy Staff who only have **direct oversight** of ***sterile compounding*** activities will receive a competency assessment of his/her aseptic technique no less frequently than once every 12 months.

All Pharmacy staff who **compound**, or may compound, or have **direct oversight** or verify ***non-sterile compounded products*** will be initially trained and qualified by DP or assigned trainer, and receive a competency assessment no less frequently than once every 12 months.

Sterile Compounding Competency Training Program

A. The “Sterile Compounding Competency” training program (Sterile Compounding Competency Assessment) includes:
    1. Didactic learning
        a. Aseptic technique, principles of high-efficiency particulate air (HEPA) unidirectional airflow within the PECs (ISO Class 5 area), proper handling and movement of materials into and within the compounding area, and safe proper handling of hazardous drugs (i.e. antineoplastic, chemotherapy)
        b. Proper use, cleaning, and disinfection of Primary Engineering Controls (PECs) and Secondary Engineering Controls (SECs)
        c. Container closure, component and equipment selection and use/handling, including supplemental engineering controls (i.e. closed system transfer devices [CSTDS])
        d. Calculations, measuring, and mixing

e. Documentation of compounding process (e.g. compounding records)

f. Quality assurance and quality control procedures

2. ***Garbing and Hand Hygiene Competency Assessment with Gloved Fingertip Test*** (see Procedure for Garbing and Hand Hygiene Competency Assessment (Gloved Fingertip Test))

3. ***Aseptic Manipulation Competency Assessment with Media-Fill Test*** (see Procedure for Aseptic Manipulation Competency Assessment (Media Fill Test))

    a. If assigned to hazardous drug handling, the aseptic technique with media-fill test is performed using CSTDs

4. Knowledge-based assessment test

B. Competencies from one premise may be used for another premise if all the following conditions are met:

1. The Standard Operating Procedures (SOPs) related to compounding are identical

2. Secondary Engineering Control (SEC) facility designs are sufficiently similar to accommodate the use of the same SOPs

3. The Primary Engineering Controls (PECs) are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning

4. CCRMC has two (2) sterile compounding pharmacies on campus, hospital inpatient pharmacy and outpatient infusion pharmacy, which operate utilizing the same compounding staff, standard operating procedures, sufficiently similar SECs, and sufficiently similar type of PECs. Therefore, competencies performed in the hospital inpatient pharmacy may reciprocate to the outpatient infusion pharmacy, and vice versa.

C. **INITIAL Training of NEW EMPLOYEES**

1. ***"Part 1:" Garbing and Hand Hygiene Competency Assessment with Gloved Fingertip Test***

    a. Successfully complete an initial competency evaluation no fewer than **three (3) separate times** in succession

    b. **Three (3) separate and complete** hand hygiene and full garbing procedures must be visually audited and documented and followed by a gloved fingertip and thumb sampling after garbing

2. ***"Part 2:"Aseptic Manipulation Competency Assessment with Media-Fill Test***

    a. Successfully complete an initial visual observation, media fill test, followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area to assess aseptic technique and related practices

    b. The media-fill test duplicates the complexity and potential of contamination when compounding a Category 1 or 2 Compounded Sterile Preparation (CSP)

D. **ONGOING Training of EXISTING EMPLOYEES (every 6 months or every 12 months)**

1. ***"Part 1:" Garbing and Hand Hygiene Competency Assessment with Gloved Fingertip Test***

    a. Successfully complete competency evaluation at least **one (1) time** at one of the following frequencies:

        i. Every 6 months for personnel compounding Category 1 or Category 2 CSPs

        ii. Every 12 months for personnel with direct oversight of compounding personnel

2. ***"Part 2:" Aseptic Manipulation Competency Assessment with Media-Fill Test***

    a. Successfully complete competency evaluation at least **one (1) time** at one of the following frequencies:

        i. Every 6 months for personnel compounding Category 1 or Category 2 CSPs

        ii. Every 12 months for personnel with direct oversight of compounding personnel

E. **Successful Completion** for both initial training of new employees and ongoing training of existing employees is defined as below:

1. ***Garbing and Hand Hygiene Competency Assessment with Gloved Fingertip Test***

    a. Acceptable visual observation of hand hygiene and garbing procedures and gloved fingertip and thumb sampling results that are less than or equal to **0 CFU total** from both hands.

2. ***Aseptic Manipulation Competency Assessment with Media-Fill Test*** (all three components)

    a. The media-fill test: **no turbidity or other visual manifestations of growth in the media**

    b. The gloved fingertip and thumb sampling: less than or equal to **3 CFU total** from both hands

    c. The surface sampling: less than or equal to **3 CFU total** from both hands

F. **Failure** for both initial training of new employees and ongoing training of existing employees of ***"Part 1:" Garbing and Hand Hygiene Competency Assessment with Gloved Fingertip Test*** and ***"Part 2:" Aseptic Manipulation Competency Assessment*** **(**media-fill test, gloved fingertip and thumb sampling, surface sampling) triggers personnel re-evaluation and corrective action(s).

1. Corrective action(s) will include the following:

    a. Re-education by the Designated Person (DP) ONLY

    b. Re-testing by the Designated Person (DP) of failed relevant sections of the "Sterile Compounding Competency" Assessment, which may include any or all of the following sections:

        i. ***"Part 1:" Garbing and Hand Hygiene with Gloved Fingertip Test***

ii. ***"Part 2:" Aseptic Manipulation Competency Assessment with Media-Fill Test*** (media-fill test, gloved fingertip and thumb sampling, surface sampling)

c. Request for microbial identification of the CFUs recovered from sampling

d. Re-evaluation of pharmacy employee(s)' cleaning procedures

e. Re-evaluation of Environmental Services' cleaning procedures

f. Evaluation of primary and secondary engineering controls to ensure they meet required specifications

g. Potentially conducting microbial air/surface sampling of the compounding area(s) for potential contamination

2. Repeated failures (e.g. 2 or more consecutive failures) may result in assessment of assigned duties and possible reassignment vs. further training and evaluation.

3. The DP may consult with external laboratory microbiologist, Infection Control, or the Director of Laboratory to determine a plan of action/correction for each positive result as deemed appropriate.

4. Results of the evaluation and corrective actions, in the event of failure, must be documented and maintained to provide a record and long-term assessment of personnel competency in the employee's departmental personnel file.

G. **Failure of ONLY** the ***"Part 2:" Aseptic Manipulation Competency Assessment*** (media-fill test, gloved fingertip and thumb sampling, surface sampling) triggers personnel re-evaluation and corrective action(s) listed in Section F above, in addition to reassignment of duties as below, as per 16 CCR § 1736.2(d):

1. Compounding personnel who fail will be ***removed from all IV compounding duties***, re-education and re-testing performed by the Designated Person (DP), instead of an Assigned Trainer.

2. Direct oversight personnel who fail may continue to ***provide only direct oversight for no more than 30 days***, while results are pending. Staff will undergo re-education and re-testing performed by the Designated Person (DP), instead of an Assigned Trainer.

H. Document training and successful completion of competency assessment at a minimum must include:

1. Name of person evaluated

2. Evaluation date and time

3. Media and components used including manufacturer, expiration date, and lot number

4. Samples are sent out to an external laboratory for incubation and enumeration at 30-35°C for at least 48 hours, followed by 20-25°C for at least 5 additional days. The external laboratory is responsible for documentation of:

a. Starting temperature for each interval of incubation

b. Dates of incubation

c. Results and identification of the observer

d. Personnel reading and documenting the results

5. Microbial identification of the colony-forming units (CFU) may be requested from the external laboratory by the DP as part of the corrective action plan

6. "Sterile Compounding Competency" Assessment and all supporting documentation of evaluation and corrective actions, in the event of failure and/or repeated failures, will be kept in the employee's departmental personnel file.

I. As per 16 CCR § 1736.2 (c), additional aseptic manipulation competency assessment(s) may occur for staff member(s) involved in an occurrence where the quality assurance program (see Policy for Quality Assurance in Pharmaceutical Compounding) yields an unacceptable result, that may indicate microbial contamination of compounded sterile products due to poor practices.

Non-Sterile Compounding Competency Training Program

A. The "Non-Sterile Compounding" Competency training program includes didactic review of:

1. Quality assurance and quality control procedures
2. Container closure and equipment selection
3. Component selection and handling

B. Competency of skills for performing non-sterile manipulations is demonstrated in: Non-Sterile Compounding Competency Assessment

1. Hand Hygiene
2. Garbing
3. Cleaning and sanitizing
4. Handling and transporting components and compounded non-sterile products (CNSPs)
5. Measuring and mixing
6. Proper use of equipment and devices selected to compound CNSPs
7. Documentation of the compounding process

C. Initial Training for New Employees must be directly observed by the DP or Assigned Trainer(s) before compounding CNSPs independently.

D. Ongoing Training and competency assessment is performed at least every 12 months.

E. Document training and successful completion of competency assessment.

F. The "Non-Sterile Compounding Competency" Assessment will be kept in the employee's departmental personnel file.

RELATED LINKS:

~~Attachment A.~~ Sterile Compounding Competency Assessment

~~Attachment B.~~ Non-Sterile Compounding Competency Assessment

Procedure for Garbing and Hand Hygiene Competency Assessment (Gloved Fingertip Test ~~and Surface Sampling~~)

~~Procedure for Media Fill Test~~Procedure for Aseptic Manipulation Competency Assessment (Media Fill Test)

~~Procedure for Handling of Positive Cultures from Pharmacy Monitoring~~Procedure K. Handling of Positive Cultures from Pharmacy Monitoring

REFERENCES:

A. TJC Standards HR.01.06.01, HR.01.07.01
B. CMS CoP § 482.11(a)(c), 482.23(c), 482.25(a)(b)
C. USP General Chapter <797>. Pharmaceutical Compounding – Sterile Preparations
D. USP General Chapter <1163>. Quality Assurance In Pharmaceutical Compounding
E. Title 16 California Code of Regulations Articles 4.5~~, 7 and 7.5~~ § 1735, ~~1751~~Article 4.6 § 1736, Article 4.7 § 1737

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	03/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19992859**

Origination	03/2004
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Compounding of Medications

POLICY STATEMENT:

To establish policies and procedures for compounding of medications. This includes procurement, processes for compounding drugs, storage and handling, recordkeeping requirements, beyond-use dating and labeling, facilities and equipment cleaning and maintenance, personnel training and evaluation, and quality assurance.

CCRMC compounds drugs or drug mixtures with the goal of providing consistent preparation of safe and effective products using the best available resources and techniques following applicable state and federal law, rules and regulations and standards set forth in USP <795>, <797>, and <800>.

Quality assurance shall be an integral component of medication compounding.

Any changes to the process or the Policy and Procedure manual will be relayed to the staff assigned to compounding duties.

The Designated Person (DP), Pharmacist II, is responsible for all requirements of the USP 797, USP 800, and USP 795.

GUIDELINES:

A. DEFINITIONS:

1. ***Compounding*** is performing any of the following processes:
    a. Altering the dosage form or delivery system of a drug
    b. Altering the strength of a drug

c. Combining components or active ingredients

d. Preparing a compounded drug product from chemicals or bulk drug substances

2. Compounding does NOT include:

    a. Reconstituting a drug pursuant to the manufacturer's directions

    b. Tablet splitting, crushing, capsule opening, or addition of flavoring agent(s) to enhance palatability.

3. ***Active pharmaceutical ingredient (API) or Bulk drug substance:*** means any substance that, when used in the manufacturing of a compounded drug preparation, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

4. ***Beyond use date (BUD)***: means the date, or date and time, after which administration of a compounded sterile preparation (CSP) shall not begin, shall not be dispensed, and shall not be stored (other than for quarantine purposes). The date is determined from the date or time the preparation is compounded. Refer to Policy for Expiration Dates, Procedure E. Assigning Beyond-Use Dates (BUDs).

5. ***Category 1 Compounded Sterile Product (CSP):*** a CSP that is assigned a BUD of 12 h or less at controlled room temperature or 24 h or less refrigerated without any required sterility testing that is compounded with aseptic manipulations under the least controlled environmental conditions in accordance with all applicable requirements for Category 1 CSPs in USP Chapter <797>, which includes, but is not limited to the following:

    a. In an ISO Class 5 Primary Engineering Control (PEC) following aseptic technique.

        1. The ISO Class 5 PEC may be in an ISO Class 7 or better buffer room with an ISO Class 8 or better ante room OR an unclassified segregated sterile compounding area (SCA)

        2. SCA must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow. The area within 1 meter of the PEC should be dedicated only for sterile compounding.

    b. Using only sterile starting ingredients or by using some or all nonsterile starting ingredients.

        1. If sterile starting components are used, the sterility must be maintained during compounding to produce a CSP

        2. If one or more non-sterile starting components are used, the sterility of the compound must be achieved through a sterilization process (e.g., terminal sterilization in the final sealed container) or sterilization filtration

6. ***Category 2 Compounded Sterile Product (CSP):*** a CSP that is assigned a BUD of greater than 12 h at controlled room temperature or greater than 24 h refrigerated that is compounded under more environmental controls and testing than Category 1 CSPs, in accordance with all applicable requirements for Category 2 CSPs in USP Chapter <797>, which includes, but is not limited to the following:

    a. In an ISO Class 5 PEC located in an ISO Class 7 or better buffer room with an ISO Class 8 or better ante room (i.e. cleanroom suite)

b. Using only sterile starting ingredients or by using some or all nonsterile starting ingredients.
    1. If sterile starting components are used, the sterility must be maintained during compounding to produce a CSP
    2. If one or more non-sterile starting components are used, the sterility of the compound must be achieved through a sterilization process (e.g., terminal sterilization in the final sealed container) or sterilization filtration. This is not performed at CCRMC.
    3. Sterility testing may also be performed and passed and affect the maximum BUD

c. Assigned a maximum BUD as follows:
    1. Aseptically processed without sterility testing
        a. Using only sterile starting components:
            i. Controlled room temperature: 4 days
            ii. Refrigerated: 10 days
            iii. Frozen: 45 days
        b. Using one or more non-sterile starting components:
            i. Controlled room temperature: 1 day
            ii. Refrigerated: 4 days
            iii. Frozen: 45 days
    2. Aseptically processed with sterility testing performed and passed
        a. Controlled room temperature: 30 days
        b. Refrigerated: 45 days
        c. Frozen: 60 days
    3. Terminally sterilized without sterility testing
        a. Controlled room temperature: 14 days
        b. Refrigerated: 28 days
        c. Frozen: 45 days
    4. Terminally sterilized with sterility testing performed and passed
        a. Controlled room temperature: 45 days
        b. Refrigerated: 60 days
        c. Frozen: 90 days

7. ***Category 3 Compounded Sterile Product (CSP):*** a CSP that may be assigned a BUD exceeding the limits for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in USP Chapter <797>, which includes, but is not limited to the following: undergo sterility testing, supplemented by endotoxin testing when applicable,

and have more requirements for personnel qualification, use of sterile garb, use of sporicidal disinfectants, frequency of environmental monitoring, and stability determination. CCRMC does not compound Category 3 CSPs.

8. ***Immediate-use compounded sterile product (CSP):*** Compounded Sterile Product (CSP) prepared outside of an ISO Class 5 environment for direct and immediate administration. Administration shall begin no later than 4 hours following the start of the compounding process. These CSPs are not subject to the requirements for Category 1, 2, or 3 CSPs. See Procedure for Immediate-Use Compounding
9. ***Equipment***: means items that must be calibrated, maintained or periodically certified (includes filters, but does not include syringes, needles, spatulas, etc).
10. ***Integrity:*** means the retention of potency until the beyond use date noted on the label, so long as the preparation is stored and handled according to the label directions.
11. ***Potency:*** means the "active ingredient strength within +/- 10% of the labeled amount (or the range specified in the general chapter of the most current edition of USP37-NF32). Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility" are exempt from this definition. "For those exempt, the range shall be defined in the master formula." [1735.1(y)]
12. ***Quality:*** means the absence of harmful levels of contaminants (filth, decomposed substances, active ingredients other than those noted on the label), and the absence of inactive ingredients other than those listed on the master formula document.
13. ***Strength:*** means the amount of active ingredients per unit of compounded drug product.

B. COMPOUNDING LIMITATIONS AND REQUIREMENTS

1. The Pharmacy Department will prepare compounded drugs in situations where drugs not commercially available, are widely used based on literature reports, and where there exists a formula for the preparation of these products. The following reasons for ordering and preparing compounded drugs include, but may not be limited to:
    a. The drug required is not manufactured in the prescribed strength.
    b. The prescriber requests a different form of the drug to improve patient compliance with prescribed drug therapy (for swallowing or taste purposes, etc.).
    c. The prescribed drug needs to be combined in forms not available from the manufacturer to improve patient response to prescribed drug therapy.
    d. The patient is allergic to inactive ingredients (dye, lactose, etc.) in the manufactured form of the drug.
2. A valid prescription must be received prior to compounding products, unless not having a limited supply of compounded product would jeopardize the continuity of care for an identified population based on a documented history of prescriptions for that patient population.
3. The bulk drug substance (the chemical that becomes the drug's active ingredient) qualifies for use in compounding when:
    a. It is found in an FDA-approved drug list and is approved for Pharmacy compounding.
    b. It is listed in a book of widely used drug substances published by the United States

Pharmacopeia and National Formulary (USP-NF).

c. It has been properly stored and is in date.

d. It has been obtained from a reliable supplier.

4. The following products may NOT be compounded:
    a. Previously marketed drug that was found to be unsafe or ineffective and has been removed from the market.
    b. If the prescriber has ordered a compounded drug that is either found to be unsafe or ineffective and removed from the market or is listed in the FDA's regulations as difficult to compound, the prescriber will be contacted for revision of the order.
    c. Drug preparations that are a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the storage and the specific medical need in the pharmacy record for 3 years from the date of receipt of the documentation.
5. All staff performing compounding activities will be required to successfully pass an initial and annual competency assessment of aseptic technique, which includes a didactic portion and review of current policies and procedures. (See Policy for Compounding Competency Assessment).
6. A drug product will not be compounded until there is a written ***master formula*** record that includes at least the following elements:
    a. The name, strength, and dosage form of active ingredients to be used
    b. Identities and amounts of all ingredients (including inactive); if applicable relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility)
    c. Type and size of container closure system(s)
    d. The complete instructions for preparing the compound, including equipment, supplies, a description of compounding steps, and any special precautions.
    e. Physical description of the final CSP.
    f. Maximum allowable beyond-use date (BUD) and the rationale or reference source justifying its determination.
    g. Instructions for storage and handling of the compounded drug preparation.
    h. The quality review required at each step of the compounding process.
    i. Quality Control (QC) procedures (e.g., pH testing, filter integrity testing).
    j. Post-compounding processes or procedures required, if any, and any other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity; sterilization method, such as steam, dry heat, irradiation, or filter).
    k. The master formula for a drug product that is not routinely compounded by the

pharmacy may be recorded on the prescription document or compounding record itself

l. The master formula for a drug product that is not routinely compounded will be later added to the master formula

7. All chemicals, bulk drug substances, drug products and other components for compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength. (See Policy for Drug Procurement, Storage & Inventory Control, Policy for Drug Storage Temperatures – Pharmacy Department Only, Policy for Room Temperature Monitoring for Drug Storage Areas).
8. Compounded drug products are assigned a beyond-use date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. (See Procedure A. Sterile Compounding of Medications, Procedure E. Assigning Beyond-Use Dates (BUDs), and Policy for Expiration Dates).
9. For each compounded product, the ***pharmacy compounding record*** shall include:
    a. The master formula record
    b. A compounding record/log consisting of a single document containing all of the following:
        i. Name, Strength, and dosage form of the CSP
        ii. Date and time of preparation of the CSP
        iii. Assigned internal identification number (e.g., prescription, order, or lot number)
        iv. The identity of the staff member who compounded the product
        v. The identity of the pharmacist reviewing the final product
        vi. Name, weight or volume, and strength of each component
        vii. The manufacturer, expiration date and lot number of each ingredient
            i. Required for CSPs prepared for more than one patient
            ii. Required for CSPs prepared from non-sterile starting ingredients
            iii. Sterile products that are compounded on a one-time basis for administration within 72 hours to an inpatient are exempted from this requirement. However, if this information is not recorded, the product may NOT be reused if it is returned to the pharmacy.
        viii. The quantity of each component used in compounding (e.g., weight, volume, strength, activity, etc.)
        ix. The total quantity compounded
        x. Final yield (e.g., quantity, containers, number of units)
        xi. The beyond-use date and storage requirements of the final product
        xii. Results of QC procedures (e.g., visual inspection, filter integrity testing, pH testing)

c. Documentation of quality reviews and required post-compounding process and procedures (if any).

d. If applicable, calculates made to determine and verify quantities and/or concentrations of components.

10. All compounds will be properly ***labeled*** with the following:

    a. The name and telephone number of the compounding pharmacy and dispensing pharmacy (if different)

    b. The generic name of the principal active ingredients and the strength, volume OR weight of each active ingredient, dose of each ingredient, and concentration as appropriate. For admixed IV solutions, the intravenous solution utilized shall be included

    c. Instructions for use, handling, and administration (i.e. route). For admixed IV solutions, the rate of infusion shall be included

    d. Beyond-use date and storage requirements

    e. The date compounded or issued

    f. The lot number, pharmacy reference number, or prescription number

    g. The name of the patient and medical record number

    h. The patient location

    i. The name of the prescriber, if applicable

    j. The prescription number

    k. The dispense quantity or final volume

    l. Auxiliary warnings, as appropriate

    m. For hazardous agents, the label states "Chemotherapy Agent – Handle and Dispose of Properly" or "Hazardous Agent – Handle and Dispose of Properly"

    n. A statement that the product has been compounded by the pharmacy

    o. Initials of the compounding personnel

    p. Initials of the checking pharmacist

    q. Any compounded drug preparation dispensed to a patient shall additionally include on label:

    r. Address of the pharmacy

    s. Condition or purpose for which the drug was prescribed if indicated on the prescription

    t. If a pharmacist dispenses a prescribed drug by means of a unit dose medication system for a patient in a skilled nursing, immediate care, or other health care facility, the requirement will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration

11. If the product is packaged in unit-dose containers that are too small to accommodate all of the

above information, it shall be labeled with at least the following and not subject to the font size requirements:

a. Name of the active ingredients
b. Concentration or strength
c. Volume or weight
d. Pharmacy reference number (Rx #) or lot number
e. Beyond-use date

C. FACILITIES AND EQUIPMENT:

The pharmacy department maintains written documentation regarding the calibration and maintenance of the facilities and equipment necessary for safe and accurate compounded drug products. (See Policy for Maintenance and Calibration of Weighing Balance, Policy for Maintenance of Sterile Compounding Facilities and Equipments).

D. TRAINING AND COMPETENCY ASSESSMENT:

The pharmacy follows a program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. (Refer to Policy for Quality Assurance in Pharmacy, Policy for Compounding Competency Assessment)

E. RECORD KEEPING:

In addition to records required by section 1735.3 the pharmacy maintains at least the following records, which are in a readily retrievable form, within the pharmacy for at least three (3) years from the date the record was created. If only recorded and stored electronically or in any other computerized form, the records are maintained as specified by B&PC 4070 subsection I CCR1751.1[c]

1. Documents of training and competency evaluations of employees in sterile drug preparation policies & procedures
2. Results of hand hygiene and garbing assessments with integrated gloved fingertip testing
3. Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests
    a. Records of training and competence are retained for three (3) years beyond the period of employment.
4. Results of viable air and surface sampling
5. Biannual video of smoke studies in all ISO Class 5 certified spaces.
6. Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:
    a. Controlled room temperature

b. Controlled cold temperature

c. Controlled freezer temperature

7. Certification(s) of the sterile compounding environment(s)
8. Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas
9. Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment)
10. Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients
11. Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results

F. QUALITY ASSURANCE

1. There is a written, documented, ongoing quality assurance program (Policy for Quality Assurance in Pharmacy) maintained by the pharmacy that monitors personnel performance (Policy for Compounding Competency Assessment), equipment and facilities (Policy for Maintenance of Sterile Compounding Facilities and Equipments).
2. In the event any components of a compounded product are recalled, the recall policy and procedure will be followed (Policy for Medication Recall)
3. **Annual review of all policies and procedures** relating to compounding with special emphasis on current literature, best practices, changes in rules and regulations, etc.
    a. Policies and procedures shall be immediately available to all personnel involved in compounding activities. All personnel (including new hires) involved in sterile compounding must read the policies and procedures before compounding sterile drug preparations. All personnel (including new hires) involved in sterile compounding must read additions, revisions, and deletions to the written policies and procedures. Each review must be documented by a signature and date. This review will be performed by the Pharmacist-in-Charge and/or Pharmacy Administration and will be approved by the Patient Care Policy and Evaluation Committee (PCP &E) i.e. P&T. Whenever policies are updated, they are uploaded online onto our electronic learning module. Staff are held accountable for the review of the policies online and must acknowledge the review via eSignature.
    b. In addition, staff will be in-serviced via mandatory weekly staff meetings.
4. **Self-Assessments and/or gap analyses** are to be done as they become available through outside sources, plus the self-assessments published by the California Board of Pharmacy are required to be completed by the Pharmacist-in-Charge by July 1st of every odd year or whenever the Pharmacy changes PIC or owner.
5. **Initial and annual o**r semi-annual **competency assessment** of all staff compounding drug

products (see Policy for Compounding Competency Assessment)

6. **Procurement and quality of ingredients (see Policy for Procurement of Medications)**
7. **Methodologies for formulation and compounding:**
    a. A master formula must be prepared in writing prior to compounding
    b. Only reputable sources will be used to research and prepare the master formula
    c. All measuring of liquids will be done with pharmaceutical-grade graduate, cylinder, or syringe in a size appropriate to the volume being measured
    d. All measuring of bulk solid ingredients (e.g. powders) will be done with a properly calibrated, maintained, and certified pharmaceutical-grade scale (see Policy for Maintenance and Calibration of Weighing Balance).
8. **Environmental maintenance and monitoring:**
    a. By Pharmacy Department:
        1. Daily cleaning of compounding aseptic isolators (CAI) and compounding aseptic containment isolators (CACI)
        2. Monthly cleaning of drug storage bins
        3. Monthly surface sampling inside and outside CAI/CACI
        4. Daily monitoring of refrigerator and freezer temperatures
    b. By Environmental Services:
        1. Daily cleaning of counter tops and supply carts
        2. Monthly cleaning and disinfecting with a sporicidal agent the exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools and after any unanticipated event that could increase risk of contamination
    c. By Engineering:
        1. Monitoring of room temperature in medication storage areas
        2. Monitoring of differential pressures and humidity in sterile compounding areas
    d. By Nursing:
        a. Monitoring of temperatures in medication refrigerators/freezers in the patient care areas
    e. By outside vendor(s):
        1. At a minimum, semi-annual certification of CAI(s)/CACI(s)
        2. At a minimum, semi-annual air and surface sampling for particulate and microbial contamination
9. **Assurance of integrity, potency and strength:**
    a. **Quality** will be assured by:

1. The procurement processes
2. Proper storage conditions
3. By the pharmacist's verification of the ingredients and compounding process to be used
4. Visual inspection and other final quality checks by pharmacist
5. Periodic qualitative/sterility analysis of compounded products on at least an annual basis.

b. **Potency and strength** will be assured by
    1. The pharmacist's verification of the mathematical calculations
    2. The accurate measurement of the ingredients
    3. Periodic quantitative analysis of compounded products on at least an annual basis.

c. **Integrity** will be assured by
    1. Assigning the correct beyond-use date, based on literature, the master formula, and USP specifications
    2. Periodic qualitative/sterility analysis of compounded products on at least an annual basis.

d. **Below or above minimum standard**
    1. ***CCRMC compounded products*:** In the event that the results reflect above or below minimum standards, the staff responsible for making the compound is to be retrained and resampling to occur to assure optimal qualitative/sterility analysis.
    2. ***503B Compounding Pharmacies compounded products:*** In the event that the results reflect above or below minimum standards, fact finding is to be conducted. This includes communication with the compounding pharmacy as well as the qualitative analysis resource to rule out errors per their end.

RELATED LINKS:

Procedure for Immediate-Use Compounding

Procedure A. Sterile Compounding of Medications
Procedure B. Aseptic Technique
Procedure C. Hand Hygiene for Sterile and Non-Sterile Compounding
Procedure D. ~~for~~ Garbing for Sterile and Non-Sterile Compounding
Procedure E. Assigning Beyond-Use Dates

Policy for Non-Sterile Compounding
Policy for Antineoplastic and Hazardous Drug Handling

Policy for Expiration Dates

Policy for Compounding Competency Assessment

Policy for Drug Procurement, Storage & Inventory Control

Policy for Drug Storage Temperatures – Pharmacy Department Only

Policy for Room Temperature Monitoring for Drug Storage Areas

Policy for Maintenance and Calibration of Weighing Balance

Policy for Maintenance of Sterile Compounding Facilities and Equipments

Policy for Procurement of Medications

Policy for Medication Recall

Policy for Quality Assurance in Pharmacy

REFERENCES:

A. TJC Standards MM 04.01.01, MM 05.01.07
B. CMS CoP § 482.23(c), 482.25(a)(b)
C. Business & Professions Code 4076
D. USP General Chapter <797>. Pharmaceutical Compounding – Sterile Preparations
E. USP General Chapter <800>. Hazardous Drugs – Handling in Healthcare Settings
F. Title 16 California Code of Regulations ~~Articles~~Article 4.5~~, 7 and 7.5~~ § 1735, ~~1751~~1735.12, ~~1751~~Article 4.6 § 1736, 1736.18, Article 4.7 § 1737, Article 2 § 1707.5

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19955824**

Origination	09/2013
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Controlled Substance Diversion Prevention

POLICY STATEMENT:

To define the controlled substance diversion prevention program at CCRMC, the organization shall establish a multidisciplinary team to develop and oversee a Controlled Substance Diversion Prevention Program (CSDPP). The team shall include representatives from: Pharmacy Administration, Nursing Administration, Medical Staff, Safety & Performance Improvement, and Risk Management. Human Resources, Security/Law Enforcement, and County Counsel will be included as necessary. The team will be chaired by Pharmacy Administration

The CSDPP shall have a plan that includes prevention, monitoring, and investigation.

The organization shall have controls in place that meet all DEA and California Board of Pharmacy requirements for controlled substances and for any other medication deemed by CSDPP to have a high potential for diversion.

GUIDELINES:

Controlled substance (CS): Any medication defined by the DEA as a Scheduled

A. Prevention:

1. **Employees:**
    a. Background checks are performed on all new hires, including fingerprinting. New hires are not permitted to work until the background check has come back clean.
    b. All employees are required to wear a picture ID badge when working.

c. A record is maintained of all providers' pictures and signatures.

d. Sharing of system passwords is prohibited. This includes ccLink, the automated dispensing machines, door codes, etc.

2. **Ordering CS:**

   a. The preferred method of ordering CS is using The DEA's CSOS (Controlled Substance Ordering System). This is an online system that eliminates the need for a paper 222 form. CSOS requires that the Director of Pharmacy register staff members authorized to order controlled substances. Those staff members must, in turn, register with the DEA to obtain a secure CSOS digital certificate.

   b. The paper process using the DEA's 222 Order Form shall remain as a back-up process. The 222 forms are retained by General Purchasing and selected buyers are authorized, via Power of Attorney, to sign these forms. (See Policy for Purchasing Records - Controlled Substances and Policy for Purchasing Agents).

3. **Receiving and checking in of CS:**

   a. The Pharmacy Department has a process in place to minimize the potential for diversion within the department (See Policy for Controlled Substances - Pharmacy).

   b. If CS are received by Materials Distribution, the product is delivered to Pharmacy the same day.

   c. Any discrepancy between the invoice and product actually received is communicated to the Pharmacy Administration and the wholesaler or manufacturer is contacted within 2 business days.

4. **Storage of CS:**

   a. The Pharmacy Department has a secure process in place for the storage of CS inside the department (see Policy for Controlled Substances - Pharmacy).

   b. CS are stored in a locked location (e.g., automated dispensing machines (ADMs), vault, or locked cabinet/drawer/box at all times.

   c. CS are never left unattended.

   d. Patient-specific CS to be administered are stored in the ADMs.

   e. Upon admission, patient's own CS medications are sent home with a family member. (See Policy for Patient's Own Medication – Storage & Destruction).

   f. Camera surveillance is used in the inpatient pharmacy.

5. **Movement of CS within the Hospital and Clinics:**

   a. There is a secure process in place for the distribution and control of CS within the organization. (See Policy for Drug Distribution: Controlled Medications, Policy for Controlled Substances in the Surgery Department, Policy for Controlled Substances, Removal and Wasting: Automated Drug Delivery Systems)

   b. Tamper-evident packaging is utilized for CS prepared by Pharmacy.

   c. CS are dispensed in single use, unit-dose packaging, to the greatest extent possible.

6. **Inventory of CS:**
    a. Two authorized pharmacy staff will perform a monthly inventory of the narcotic vault. Any discrepancies will be investigated and reconciled. If a discrepancy cannot be reconciled, it will be reported to Pharmacy Administration no later than the next business day.
    b. The CS stored within an automated dispensing machine are inventoried every shift by Nursing staff. Any discrepancies are to be researched and reconciled. If a discrepancy cannot be reconciled, it will be documented in SERS.
    c. Pharmacy dept. is responsible for the inventory of all CS every odd year
    d. Partial doses of CS are to be wasted, per policy. (See Policy for Controlled Substances, Removal and Wasting: Automated Drug Delivery Systems).
    e. CS waiting for pick up by the reverse distributor shall be stored in the narcotic vault, per policy. (See Policy for Pharmaceutical Waste Management).
    f. All sites use the blind count process when removing/adding CS
    g. The bar-code for all medications is to be scanned whenever medications are removed from or refilled into the automated dispensing machine.
7. **Record-keeping of CS:**
    a. There is a process in place to accurately maintain the required records for the purchase and sale of all CS. (See Policy for Purchasing Records - Controlled Substances, Policy for Pharmaceutical Waste Management).
8. **Waste/Destruction of CS:**
    a. There is a process in place for the secure destruction and waste of CS. (See Policy for Controlled Substances, Removal and Wasting: Automated Drug Delivery Systems, Policy for Pharmaceutical Waste Management).
    b. Empty CS containers are securely discarded (See Policy for Pharmaceutical Waste Management).
    c. Expired, unusable CS are logged into the narcotic vault from the originating location (See Policy for Controlled Substances, Removal and Wasting: Automated Drug Delivery Systems). On a regular basis, these items are turned over to the reverse distributor, per policy and procedure (See Policy for Pharmaceutical Waste Management).
9. **Automated Dispensing Machine Access:**
    a. A UAF is submitted to authorized Pharmacy staff for all new hires or terminations who have or need access to the ~~ADCs~~ADDS. These changes are acted upon within 1 business day of receipt. No less frequently than once a year, the access list is verified with the appropriate department.
    b. Passwords automatically expire every 60 days.
    c. Users who do not access the machine within 90 days are automatically eliminated from the user database.
    d. Access to CS is restricted to healthcare professionals who may administer CS within

their scope of practice (See Policy for Access to Automated Drug Delivery Systems (ADDS)).

e. Unused CS cannot be returned to the ADM, it must be placed in the return bin. Pharmacy reconciles the CS found in the return bin against the ADM computer printout. Any discrepancies are researched and reconciled. If a discrepancy cannot be reconciled, Pharmacy Administration is notified (See Policy for Controlled Substances, Removal and Wasting: Automated Drug Delivery Systems).

10. **Culture:**
    a. Senior leadership clearly urges staff to speak up when they become aware of any issue relating to CS diversion. Information provided is considered confidential and CCRMC takes reasonable steps to protect the identity of the reporting person.
    b. Staff receives annual education about how to recognize employee diversion through SICRR (Safety, Infection Control and Regulation Review).
    c. Staff is provided with several ways to inform leadership about potential diversion: In person with his/her supervisor; voice message to supervisor or Pharmacy Administration; Patient Safety Hotline (925-370-5190).
    d. CSDPP members are encouraged to attend seminars about drug diversion and are provided the time and resources to attend.
    e. Resources are available for impaired healthcare providers (e.g., Employee Assistance Program, Health Professionals Services Program)

11. Prescribing:
    a. CS are prescribed only by licensed authorized prescribers with a valid DEA registration or institutional DEA.
    b. A valid order exists for all CS administered.
    c. CS are not prescribed by a prescriber for him/herself or immediate family members.
    d. Patient-specific CS orders are electronically generated. Schedule II – V prescriptions to be filled in the retail setting are either electronically transmitted to the patient's pharmacy-of-choice or printed on secure paper via a secure printer.
    e. The paper for Schedule II prescriptions is stored securely in locked printers. Only Nursing Administration, Pharmacy Administration, and their designees have knowledge of the password to unlock the printer.
    f. Range orders with more than one variable are not permitted. (See Policy for Range Orders for Medications).

12. **Administration**:
    a. Medications, including CS, are to be administered within 30 minutes of removal from the ADM.
    b. If a CS is drawn up in a syringe and not immediately administered, it is properly labeled with the drug name, concentration, date, time, and initials of the preparer and appropriately secured.
    c. Waste and return of CS must be managed as soon as possible.

B. Detection:

1. **Purchasing monitor:** the purpose is to reconcile all CS received by the Pharmacy Department against the monthly purchasing history from the vendor.
2. **Automated dispensing machine activity review:**
    a. On a monthly basis, a 'Dispensing Practices' report is generated by the automated dispensing machine. For those users whose withdrawal of CS exceeds their peers by a defined standard deviation, detailed transaction reports are generated and researched. Findings are reported to Pharmacy and Nursing Administration.
    b. On a daily basis, Pharmacy reviews unreconciled CS dose reports, comparing the ADM transaction against the orders and the medication administration record. Any discrepancies are entered into SERS for follow-up.
    c. Discrepancies in count are to be researched and resolved within 24 hours of creation. A pharmacist reviews the discrepancy report on a daily basis. Any unacceptable resolutions are communicated to Nursing Administration for further investigation.
    d. **Random audits** of ADM CS activity vs medication administration records are conducted on a routine basis. Findings are reported to Pharmacy Administration for appropriate action.
3. **Inventory:** All CS in the Pharmacy are inventoried on a monthly basis. Any count discrepancies are investigated and reconciled. If a discrepancy cannot be reconciled, Pharmacy Administration is notified (See Policy for Controlled Substances - Pharmacy).

C. Investigation:

1. Activation of the CSDPP team: In the event a diversion is suspected:
    a. The Director of Pharmacy (DOP) shall be notified immediately.
    b. DOP will perform an initial investigation.
    c. DOP will assemble a team, if warranted, comprised of the appropriate individuals (e.g. Nursing Administration, HR, Risk Management, Employee Health, law enforcement, etc).
    d. Team will perform a thorough investigation and a decision will be made as to the course of action. Action taken may include one or more of the following:
        i. Removing the employee from patient care
        ii. Counseling, suspension, termination
        iii. Referral to an employee assistance program
        iv. Legal prosecution
    e. A final case report will be prepared and filed.
    f. The Director of Pharmacy Services shall report to the Board of Pharmacy within 14 days of the receipt or development of information regarding any licensed individual

employed by or within the pharmacy who has committed diversion of any CS, theft, or has been impaired (physical, chemical, mental)

g. Other appropriate authorities will be notified (e.g., DEA, Board of Nursing, CEO, CNO, etc. (See Policy for Reporting Diversion of Controlled Substances).

2. If there is suspected diversion, a data mining software program may be used for more detailed analysis of withdrawal practices within the automated dispensing machines.

D. Reporting:

1. CCRMC shall fulfill all reporting requirements for the diversion or loss of CS.
    a. The Director of Pharmacy shall report to the California Board of Pharmacy within thirty (30) days of discovery of any CS loss, including their amount and strength. (See Policy for Reporting Diversion of Controlled Substances).
        i. If cause of loss is theft, diversion, or self-use, the report shall be made within fourteen (14) days of discovery.
    b. The Director of Pharmacy shall report any CS theft or significant loss to the DEA within one (1) business day of discovery.
    c. The Director of Pharmacy shall report any abuse or loss of CS to Hospital Administration, including the CEO. (See Policy for Reporting Diversion of Controlled Substances).

REFERENCES:

A. CMS CoP § 482.11(a), 482.13(c), 482.21(a)(b)(c)(d), 482.23(c), 482.25(a)(b) TJC Standard HR.01.06.01, HR.01.07.01, LD.01.02.01, LD.01.03.01, LD.01.05.01, LD.02.03.01, LD.03.01.01, LD.03.02.01, LD.03.06.01, LD.04.01.01, LD.04.01.05, LD.04.01.07, MM.01.01.03, MM.03.01.01, MM.05.01.11, MM.06.01.01, MM.07.01.03, MM.08.01.01, PC.01.02.05, RC.01.04.01, RC.01.04.01, RC.01.05.01, RI.01.01.01

B. California Board of Pharmacy 2019 law 4059.5, 4104, 4106.5

C. H&S code 4104

D. Pharmacy Policy for Purchasing Records - Controlled Substances

E. Pharmacy Policy for Purchasing Agents

F. Pharmacy Policy for Access to Automated Drug Delivery Systems (ADDS)

G. Pharmacy Policy for Controlled Substances - Pharmacy

H. Pharmacy Policy for Controlled Substances, Removal and Wasting: Automated Drug Delivery Systems

I. Pharmacy Policy for Controlled Substances in the Surgery Department

J. Pharmacy Policy for Patient's Own Medication – Storage & Destruction

K. Pharmacy Policy for Reporting Diversion of Controlled Substances

L. Pharmacy Policy for Drug Distribution: Controlled Medications

M. Pharmacy Policy for Pharmaceutical Waste Management

~~**APPROVALS:**~~

~~Patient Care Policy and Evaluation Committee: 7/2022~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19946859**

Origination	04/2001
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Controlled Substances, Removal and Wasting: Automated Drug Delivery Systems

POLICY STATEMENT:

The purchase, storage, distribution, and accounting of controlled drugs will be done in accordance with all federal and state laws and standards of professional practice, to maintain optimal quality control over these high-risk substances and to prevent diversion. The Pharmacy Department is responsible for compliance with this policy. (See Policy for Drug Distribution: Controlled Medications)

All controlled substances dispensed for inpatients are processed through an automated drug delivery system (ADDS). An electronic transaction record for all controlled substances will be maintained by the hospital. All controlled drug records will be maintained for the period required by law and be readily retrievable.

~~Automated Drug Delivery System (ADDS):~~

Automated Drug Delivery System (ADDS): means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability

~~Automated Unit Dose System (AUDS):~~

Automated Unit Dose System (AUDS): an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

~~Automated Patient Dispensing System (APDS):~~

Automated Patient Dispensing System (APDS): an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

GUIDELINES:

A. Perpetual Inventory:

1. A perpetual inventory record of all C-II drugs stored in the main Pharmacy Department will be maintained.
2. Each dispensing and each drug administration transaction will be recorded separately; therefore, there should be two (2) transaction records for each dose given to a patient.
    a. When the nurse retrieves the dose from the controlled drug stock inventory in the automated drug delivery system, the record of dispensing will be made on the automated drug delivery system.
    b. Once removed from the ADDS, controlled substances are to be administered within 30 minutes.
    c. The dose administered will also be recorded by the nurse on the patient's medication administration record (MAR).
    d. Documentation includes patient's name, date, time, amount of medication given, remaining balance and the name of the staff member removing the medication.
3. The automatic drug delivery system will prompt the user to complete an inventory count and enter the number when a controlled substance is removed. If the count is incorrect per the system, the user will be prompted to perform a recount. If the recount remains incorrect, a discrepancy is created and tracked by the ADDS.

B. Controlled Substance Discrepancies

1. Controlled substance discrepancies will be reported to the Charge Nurse immediately.
2. Controlled substance discrepancies must be resolved by the change of shift. Nursing staff will run a Discrepancy Report, which will list the name(s) of person(s) who last had access to the controlled substance.
3. Resolution of each discrepancy must be documented in the automatic drug delivery system and witnessed by a second nurse.
4. End of shift check will be performed by the Charge Nurse. The Charge Nurse will run a Discrepancy Report at the end of each shift to verify that all transactions were performed correctly.
5. A cycle count inventory of all controlled substances stored in the ADDSs is done every day by nursing staff.
6. Noncompliance is reported to the Chief Nursing Officer/Nursing Director for follow-

up and possible disciplinary action.

7. A report listing all unresolved discrepancies will automatically be emailed to each unit's NPM daily. The Pharmacy will review the reasons for appropriateness/ acceptability. Any unacceptable explanations will be returned to the unit for further investigation or clarification.
8. When an error occurs in the inventory count, which cannot be explained on investigation, the error is to be reported in SERS. These reports will be reviewed by the Medication Safety Advocates. The unresolved discrepancy must be documented in the automatic drug delivery system.
9. The Pharmacy Department will refill controlled substances into the automated drug delivery system daily during normal business hours based on inventory printouts. The Pharmacy Department will verify the actual count of the controlled substance at this time and enter it into the system.

C. Return of Controlled Substances at the Automated Units
    1. Intact packaging
        a. The nurse shall return any controlled substance that is removed in error, with the packaging unit still intact, to the "Narcotic Return Bin". This action will require two nurse electronic signatures. This action must be completed as soon as possible.
        b. The Pharmacy dept. will empty these containers in a timely fashion. All removed products will be returned to the main narcotic vault per pharmacy policy and procedures.
    2. Non-intact packaging:
       Any controlled substance that is removed in error and the packaging is no longer intact, is not suitable for return and reuse. These packages must be wasted in accordance with the "Wasting Procedure" delineated below. This method does require two signatures as mentioned below.

D. Wasting of Controlled Substances:
    1. If the controlled substance is not administered and it is not in its original packaging, the nurse must waste the controlled substance. The waste option is used on the automated drug delivery system.
    2. A second nurse must witness the wasting of the controlled substance and electronically co-sign in the automated drug delivery system. The nurse will use the waste option of the automated drug delivery system if all or part of a control substance must be wasted. This must be witnessed by a second nurse/physician and co-signed in the automated drug delivery system. The amount used is entered into the system.

E. Medication-filled syringes: Will not be put into the sharps container.

F. Destruction of Controlled Substances: See Policy for Pharmaceutical Waste Management

G. Reporting Diversion and Loss of Controlled Substances:
    1. Policy for Controlled Substance Diversion Prevention

2. Policy for Reporting Diversion of Controlled Substances
3. Policy for Licensed Employee – Theft or Impairment

RELATED LINKS:

Policy for Drug Distribution: Controlled Medications

Policy for Pharmaceutical Waste Management

Policy for Controlled Substance Diversion Prevention

Policy for Reporting Diversion of Controlled Substances

Policy for Licensed Employee – Theft or Impairment

REFERENCES:

A. TJC Standard MM.03.01.01, MM.05.01.11
B. CMS CoP § 482.11(a), 482.23(c), 482.25(a)(b)
C. Uniform Controlled Substances Act of 1970
D. California Pharmacy Law
E. Title 16 Business and Professions Code, Chapter 9, Division 2, Article 2 § 4017.3, Article 7 § 4119.11, Article 24 § 4427
F. Health and Safety Code 126

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 7/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19969630**

Origination	10/2007
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval

Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Drug Procurement, Storage & Inventory Control

POLICY STATEMENT:

This policy establishes guidelines for the acquisition, storage, and inspection of drugs as part of inventory control. The Pharmacy Department is responsible for control of medications within CCRMC. Policies and procedures are designed to ensure the safe and accurate dispensing of medications throughout the hospital. These policies will be approved by the Pharmacy and Therapeutics Committee.

GUIDELINES:

Acquisition

A. The Pharmacy Department is responsible for the acquisition of pharmaceuticals for CCRMC. The Pharmacist is responsible for specification as to quality, quantity and source of supply all drugs used in the hospital.
B. Special consideration is given to the current ASHP Guidelines for Selecting Pharmaceutical Manufacturers and Suppliers.
C. Only those medications approved by the Patient Care Policy & Evaluation Committee for use will routinely be stocked and stored.
D. Practical decisions about the source of multi-vendor (generic equivalent) drugs are deferred to the purchasing group and the competitive bid structure.
E. Medications for distribution to patient care units are provided in the most ready-to-administer form available, in prepackaged patient unit doses whenever possible.
F. All medications and chemicals used to prepare medications are accurately labeled with contents, expiration dates and appropriate warnings.

G. The number of drug concentrations is limited and standardized throughout the organization.

Storage

A. Medications are stored under proper conditions as stated by the medication manufacturer to assure stability of that medication.

B. Medications are stored in a secure manner.

C. The Pharmacy Department is locked at all times. Access is limited to Pharmacy Department personnel under the direct supervision of a Pharmacist.

D. External Use drugs in liquid, tablet, capsule or powder form are segregated from drugs for internal use.

E. Drugs are stored in an orderly manner in well-lighted cabinets, shelves, drawers, or carts of sufficient size to prevent crowding.

F. Corrugated/cardboard boxes must be stored away from and are not allowed in the sterile compounding spaces in the pharmacy department.

G. Medication rooms on patient care units used for storage of floor stock medications will remain locked. Access is limited to licensed nursing personnel.

H. All high-risk drugs and drugs with a higher potential for dispensing error due to look-alike/ sound-alike names, will be stored with a secondary caution/alert label, thereby alerting staff for the necessity of taking additional dispensing precautions.

    a. High-risk drugs are those drugs listed by category and specifically in the High Alert Medication Management policy and procedure (see Policy for High Risk/High Alert Medication Management).

        i. Concentrations of high-risk drugs are standardized and strictly limited throughout the organization.

        ii. Commercially prepared premixes of high-risk drugs will be procured whenever possible.

        iii. Single-dose containers will be used when possible.

    b. Look-alike, sound-alike drugs are those drugs listed in the Look-Alike, Sound-Alike Medication Management policy and procedure (see Policy for Look-Alike, Sound-Alike Medication Management).

    c. Refrigerators/freezers intended for drug storage will be monitored to ensure the correct temperature range (See Policy for Drug Storage Temperatures – Pharmacy Department Only).

    d. In addition, the room temperature of drug storage areas in the inpatient pharmacy will also be monitored (See Policy for Room Temperature Monitoring for Drug Storage Areas).

Inspection

A. All drug storage areas within the hospital will be inspected at least monthly by the Pharmacy Department.

B. A report of inspection will be maintained by the Pharmacy Department. Reports of

discrepancies will be shared with the supervising professional of the unit involved.

a. Expired, damaged and/or contaminated medications will be removed from drug storage areas within CCRMC during the Pharmacy inspection and will be returned to the Pharmacy Department for proper disposal.

b. All opened multi-dose vials, when expired or found without a labeled expiration date, will be removed from all drug storage areas within CCRMC and returned to the Pharmacy Department for proper disposal.

c. Expired, damaged and/or contaminated medications will be stored in an isolated area in the Pharmacy Department that has been designated for the storage of such unusable drugs. The drugs shall remain there until proper disposal or pick up can be made.

RELATED LINKS:

Policy for High Risk/High Alert Medication Management

Policy for Look-Alike, Sound-Alike Medication Management

Policy for Drug Storage Temperatures – Pharmacy Department Only

Policy for Room Temperature Monitoring for Drug Storage Areas

REFERENCES:

A. TJC Standard MM.03.01.01

B. CMS CoP § 482.23(c), 482.25(a)(b)

C. Title 22 § 70263

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19969595**

Origination	01/2012
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Drug Shortages

POLICY STATEMENT:

When the pharmacy department is unable to obtain drug product through legal channels, patient therapy may be compromised. This policy describes the process for evaluating drug shortages, managing scarce resources, and minimizing impact on patient care.

A drug shortage is a supply issue that affects how the pharmacy department prepares or dispenses a product or influences patient care when prescribers must choose an alternative therapy because of supply problems.

The Pharmacy Department, under the auspices of the Patient Care Policy and Evaluations Committee (PCP&E), is responsible for investigating and providing information about potential drug shortages that may affect patients at CCRMC Hospital and Clinics. The Pharmacy Department, after consultation with Chiefs of Services and/or other appropriate departments, will develop a strategy for handling the shortage. The plan, which may include, but is not limited to restricting use or rationing limited supplies and use of alternate therapy all of which will be presented to PCP&E for approval.

GUIDELINES:

A. Pharmacy Administration and/or Clinical staff routinely screen for shortages through national databases and the pharmacy group purchasing organization. In addition, staffs who identify a real or potential drug shortage will notify Pharmacy Administration.

B. Pharmacy Administration or the designee will investigate potential drug shortages by contacting manufacturers of the product and/or our wholesaler (Cardinal Health) to determine current availability and will purchase supplies of the drug product to the greatest extent possible.

C. Pharmacy staff will maintain a spreadsheet ("DRUG SHORTAGES") containing the following information and will routinely report to the Medication Safety Committee and Patient Care Policy and Evaluations Committee:

1. Drug involved in shortage
2. Date of notification
3. Notifying entity
4. Manufacturer(s) involved
5. Package size
6. Legend status
7. Reason for shortage
8. Available alternatives
9. Estimated availability date
10. Implications for patient care, if applicable
11. Safety implications, if applicable
12. Alternative agents and/or management strategies, if applicable
13. Latest notification/update
14. Latest CCRMC review date
15. CCRMC action
16. Current status (Green = no shortage at CCRMC, Yellow = periodic availability problems, Red = serious availability problems, actions in place)

D. If the supply situation meets the definition of a drug shortage, Pharmacy Administration will develop a management strategy, which may include:

1. Restricting or rationing supplies, in cooperation with the clinicians most affected by the shortage.
2. Contacting alternate licensed suppliers (see ~~policy # 3105~~Policy for Procurement of Medications)
3. Recommending alternate therapy options
4. Obtaining therapeutic substitution protocols/privileges obtained from the Patient Care Policy and Evaluations Committee (PCP&E) for pharmacists

E. PCP&E will approve the management strategy.

F. Pharmacy Administration will/may notify pharmacy personnel, affected clinicians, and administrators about drug shortages and management strategies via any/all of the following:

1. Ongoing reports to the Medication Safety Committee and PCP&E
2. iSite folder with link to FDA website
3. E-mails
4. Memos

5. Screen-savers
6. Phone calls, pages, etc.

G. Information provided will include the following, as applicable:
    1. Products affected
    2. Reason for shortage
    3. Estimated date of product availability
    4. Rationing or restriction strategies
    5. Other specific management strategies, such as removing product from automated dispensing cabinets (ADCs) and centralizing distribution, or repackaging doses in pharmacy to conserve product
    6. Recommendations for alternative agents, if appropriate

H. Pharmacy Administration or the designee will monitor the status of the drug shortage until the supply situation no longer meets the definition of drug shortage. Pharmacy Administration will provide information about the resolution of a drug shortage via reports, email, memos, screen savers, iSite, etc.

REFERENCES:

A. https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
B. https://www.ashp.org/drug-shortages/current-shortages
C. Fox ER, Tyler LS, Managing Drug Shortages: Seven Years' Experience at One Health System. Am J Health-Syst Pharm. 2003; 60:245-253.
D. American Society of Health-System Pharmacists. ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems. Am J Health-Syst Pharm. 2009; 66:1399-1406.
E. TJC MM.02.01.01
F. CMS CoP § 482.23(c), 482.25(a)(b)

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date

Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19756653**

Origination	12/2006	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	01/2026		
Next Review	1 year after approval		

Policy for Drug Storage Temperatures – Pharmacy Department Only

POLICY STATEMENT:

All medications will be stored appropriately and at the proper temperature. Refrigerators and freezers are fitted with continuous wireless temperature monitoring probes and are monitored automatically.

GUIDELINES:

Appropriate temperatures for drug storage are defined as follows.

A. **Freezer:** A place in which the temperature is maintained thermostatically between -25ºC and -10ºC (-13ºF and 14ºF).

B. **Cool**: Any temperature between 8ºC and 15ºC (46ºF and 59ºF). An article for which storage in a cool place is directed may, alternatively, be stored and distributed in a refrigerator, unless otherwise specified by the individual monograph (e.g., when cold storage is indicated for an article, it may be stored in a cold place like a refrigerator)

C. **Refrigerator:** A cold place in which the temperature is maintained thermostatically between 36ºF and 46º F.

D. **Controlled Room Temperature:** A temperature maintained thermostatically that encompasses the usual and customary working environment of 68ºF to 77ºF; that results in a mean kinetic temperature (MKT) calculated to be not more than 77ºF; and that allows for excursions between 59ºF and 86ºF that are experienced in pharmacies, hospitals, and warehouses. Provided that the MKT remains in the allowed range, transient spikes up to 104ºF are permitted as long as they do not exceed 24 hours. Spikes above 104ºF may be permitted if the manufacturer so instructs. Articles may be labeled for storage at "controlled room

temperature" or at "up to 77ºF", or other wording based on the same mean kinetic temperature. The mean kinetic temperature is a calculated value that may be used as an isothermal storage temperature that simulates the non-isothermal effects of storage temperature variations. An article for which storage at Controlled Room Temperature is directed may, alternatively, be stored and distributed in a cool place, unless otherwise specified in the individual monograph or on the label.

E. ~~**Incubator Temperature:** 30ºC to 35ºC for tryptic soy agar (TSA) media. 26ºC to 30ºC for malt extract agar (MEA) or other fungal media.~~

Table 1. Acceptable Temperature Range	Degrees Celsius	Degrees Fahrenheit
Refrigerator temperature		36°F to 46°F
Freezer temperature (may vary per drug-specific freezer)	-25°C to -10°C	-13ºF to 14ºF
Controlled room temperature		68ºF to 77º F with brief deviations between 59ºF to 86ºF

CCRMC has standardized all drug storage units to read temperatures in degrees Fahrenheit.

Temperature ranges may be customized to the specific contents of a refrigerator or freezer.

Only drugs requiring refrigeration will be stored in the refrigerator. Only drugs requiring freezing will be stored in the freezer.

All medications dispensed by Pharmacy that require refrigeration will have the appropriate storage conditions marked &/or the appropriate storage label attached.

Food items are not to be stored in the same refrigerator/freezer with drugs, except for those that are taken with medication only (i.e. fruit juices). These must be identified as such.

Temperatures are monitored via central temperature monitoring system (e.g. Viewpoint®), which is calibrated annually.

If applicable, Vaccines for Children (VFC) Program vaccine storage locations have at least one backup continuous temperature monitoring device.

During Pharmacy operational hours/days:

A. Pharmacy personnel are responsible for monitoring the temperatures of the refrigerators/ freezers in the pharmacy via central temperature monitoring system at least daily or twice daily for VFC storage locations, if applicable.

B. In the event of an excursion, corrective actions are to be taken and documented upon resolution, as needed, for any out-of-range readings.

Outside of Pharmacy operational hours/days:

A. In the event of an excursion, central temperature monitoring system will notify the Medical Center Supervisor.

B. The Medical Center Supervisor shall contact the On-Call Pharmacist for access to the appropriate pharmacy location for investigation and resolution of the temperature excursion.

An excursion is defined as the storage temperature being out of range (see table 1 for acceptable temperature range) for one hour (60 minutes) or more. The Engineering Department is to be contacted to obtain a backup storage unit for storage of the medications removed from the problematic unit. Medications will be moved to the backup unit within 1 ½ hour (90 minutes).

If the temperature excursion exceeds 1 ½ hour (90 minutes), all medications must be isolated and labeled "DO NOT USE," and maintained in the appropriate original storage environment, until the drug manufacturer can be contacted for information on the extended stability of each product.

RELATED LINKS:

~~VFC Refrigerator Temperature Log (Fahrenheit)~~VFC Refrigerator Temperature Log (Fahrenheit)

Non-VFC Refrigerator Temperature Log

Non-VFC Freezer Temperature Log

Freezer Temperature Log for Cervidil

Procedure for Central Temperature Monitoring System Alerts

Viewpoint Mesa Labs User Manual DV1561vD-ViewPoint-User-Manual3.pdf (mesalabs.com)

REFERENCES:

A. TJC Standard MM.03.01.01, ~~EC~~PE.~~02.04.03, MM.03~~05.01.01
B. California Pharmacy Law
C. CMS CoP § 482.13(c), 482.23(c), 482.25(a)(b), 482.41(a)(c)
D. USP General Chapter <797>. Pharmaceutical Compounding – Sterile Preparations
E. USP <659> Packaging and Storage Requirements
F. Title 16 California Code of Regulations Articles 4.5~~, 7 and 7.5~~ § 1735~~, 1751~~
G. Title 22 Article 3 § 70263

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19470272**

Origination	04/2001
Last Approved	N/A
Effective	Upon Approval
Last Revised	12/2025
Next Review	3 years after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Emergency Medication Supply – Location & Quantity

POLICY STATEMENT:

Emergency medications and supplies, for use in medical emergencies only, shall be immediately available at each patient care unit or service area. Emergency drugs for resuscitation shall be stored in portable containers and sealed by a pharmacist. Emergency medications contained in the crash carts and kits will be provided in the most ready-to-administer form available, in age-specific doses (where applicable, i.e., neonatal and pediatric care areas) and in-patient unit doses when possible. The automated dispensing machines contain additional stock of certain emergency medications in kits (see Policy for Malignant Hyperthermia Cart and Kit Contents – Emergency Medication Supply, Policy for Anaphylaxis/Infusion Reaction Emergency Medication Supply, Policy for Anesthesia and Pediatric Rapid Sequence Intubation (RSI) Kits – Emergency Medication Supply). PCP&E (Patient Care Policy & Evaluation), Code Blue and MEC (Medical Executive Committee), whose members include licensed independent practitioners, nursing and pharmacy staff will determine and approve the contents of the crash carts and auxiliary emergency medication boxes, utilizing current specialty criteria, recommendations, and guidelines.

To coordinate the maintenance of crash carts with Medical staff, Nursing, Central Sterilization, and Pharmacy staff to ensure that crash carts will be in a constant state of readiness and available on all patient care units and service areas at all times and are monitored on a monthly basis.

GUIDELINES:

A. Crash Carts: There are three (3) different types of crash carts in the hospital patient care areas:
    1. Adult crash carts and Anesthesia Airway kits will be available in all areas where adult patients may be seen. (See Policy for Crash Cart, Adult - Medication Tray Contents)
    2. Pediatric crash carts and Rapid Sequence Response kits (RSI) will be available in all areas where pediatric patients may be seen. (See Policy for Crash Cart, Pediatric - Medication Tray Contents)
    3. Neonatal crash carts will be available in all areas where neonates may be seen. (See Policy for Crash Cart, Neonatal – Medication Content)

B. Malignant Hyperthermia carts will be available in the operating room areas. (See Policy for Malignant

Hyperthermia Cart and Kit Contents – Emergency Medication Supply)

1. Malignant Hyperthermia Kits (chilled 0.9% normal saline and regular insulin) will be stored in several refrigerators located in different automated dispensing machines throughout the hospital noted below (See Policy for Malignant Hyperthermia Cart and Kit Contents – Emergency Medication Supply)

C. Intubation medication kits, the Anesthesia Airway Kits and Pediatric Rapid Sequence Intubation (RSI) kits, are stocked in the automated dispensing machines noted below (See Policy for Emergency Medication Supply – Location & Quantity)

D. ~~Anaphylaxis kit/box stocked and maintained by pharmacy department are stored in the locations noted below (See Policy for Anaphylaxis/Infusion Reaction Emergency Medication Supply)~~

Anaphylaxis kit/box stocked and maintained by pharmacy department are stored in the locations noted below (See Policy for Anaphylaxis/Infusion Reaction Emergency Medication Supply)

	CRASH CARTS PAR	MALIGNANT HYPERTHERMIA (MH) CARTS PAR	INTUBATION KIT PAR					
LOCATION	**Adult Cart**	**Pediatric Cart**	**Neonatal Cart**	**MH Cart**	**MH Kit**	**Anesthesia Airway Kit**	**Rapid Sequence Intubation (RSI) Kit**	**Anaphylaxis Kit**
2B-OR	1			1	2			
2C-PACU	1				1	1	1	
3A-Radiology special procedures	1					1		
3A-DI CT Scan Room	1	1				2		
3-ECHO Room	1							
3B-ED	2	1			1	4	1	
3B-ED (Fast Track)	1					4	1	
3C-CSU	1	1				1	1	
3D-CCU	2					2		
3E-IMCU	1				1	2		
4A-MS	1				1	2		
4B-MS	1					1		1
4B-MS2						1		
4C-PSY	1					1		
4D-PSY	1					1		

	CRASH CARTS PAR	MALIGNANT HYPERTHERMIA (MH) CARTS PAR	INTUBATION KIT PAR					
5A-OR	1		2	1	2			
5A-PN	1		1			2		
5B-NUR			1					
5C-CP/MS	1				1	2		
5D-MS	1					1		
Building I (Infusion Clinic)	1					1		1
~~**Building I (Ante-Partum)**~~	~~1~~							
CT Mobile Van	1	1				2	2	
Total	~~23~~22	**4**	**4**	**2**	**9**	**31**	**6**	**2**

INPATIENT PHARMACY BACK UP SUPPLY								
	CRASH CART BACK UP TRAYS PAR			**MALIGNANT HYPERTHERMIA (MH) BACK UP TRAY PAR**		**INTUBATION KIT PAR**		
SUPPLY OF BACK UP TRAYS/ KITS/BOX (not carts)	**Adult Cart**	**Pediatric Cart**	**Neonatal Cart**	**Medication tray for carts**	**MH Kit**	**Anesthesia Airway Kit**	**Rapid Sequence Intubation (RSI) Kit**	**Anaphylaxis Box**
Inpatient Pharmacy	6	2	1			6	3	
Inpatient Pharmacy Night locker	2	2	3	1	1	1	1	
Infusion Pharmacy								1
Total	**8**	**4**	**4**	**1**	**1**	**7**	**4**	**1**

STERILE PROCESSING DEPARTMENT (SPD) BACK UP SUPPLY				
	CRASH CARTS PAR	**MALIGNANT**	**INTUBATION KIT PAR**	

STERILE PROCESSING DEPARTMENT (SPD) BACK UP SUPPLY								
				HYPERTHERMIA (MH) PAR				
SUPPLY OF BACK UP CARTS	**Adult Cart**	**Pedi Cart**	**Neonatal Cart**	**MH Cart**	**MH Kit**	**Anesthesia Airway Kit**	**Rapid Sequence Intubation (RSI) Kit**	**Anaphylaxis Box**
Sterile processing department (backup carts)	**1**	**1**	**1**	**n/a**	**n/a**	**n/a**	**n/a**	**n/a**

E. There are written policies and procedures establishing the contents of the crash carts, procedures for use, restocking and sealing of the emergency carts after use. (See Nursing Policies No. 204, 205, and 207)

F. Maintaining and inspecting crash carts is a shared responsibility between Nursing, Central Sterilization, and Pharmacy Departments. (See Policy for Crash Cart Medications - Maintenance)

RELATED LINKS:

Policy for Emergency Medication Supply

Policy for Emergency Medication Supply – Location & Quantity

Policy for Crash Cart Medications - Maintenance

Policy for Crash Cart, Adult - Medication Tray Contents

Policy for Crash Cart, Pediatric - Medication Tray Contents

Policy for Crash Cart, Neonatal – Medication Content

Policy for Malignant Hyperthermia Cart and Kit Contents – Emergency Medication Supply

Policy for Anaphylaxis/Infusion Reaction Emergency Medication Supply

Policy for Anesthesia and Pediatric Rapid Sequence Intubation (RSI) Kits – Emergency Medication Supply

Policy for Crash Cart Readiness

Procedure for Crash Cart Exchange Program

REFERENCES:

A. TJC Standard MM 01.01.03, MM.03.01.01, MM.03.01.03, PC.02.01.11

B. Title 22, California; Standards: 1; Elements: 1 Article 263 70263- Pharmaceutical general service.

C. CMS CoP § 482.12(f), 482.23(c), 482.25(a)(b), 482.55

APPROVALS:

Patient Care Policy and Evaluation Committee: 9/2023
Medical Executive Committee:
Joint Conference Committee:

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	01/2026
	Shideh Ataii: Director Of Pharmacy Svcs	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19981330**

Origination	04/2004
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Expiration Dates

POLICY STATEMENT:

All conventionally manufactured pharmaceuticals dispensed by pharmacy shall be clearly marked with the expiration date.

When pharmaceuticals are received from the vendor, the expiration date will be checked. No product that has expired will be accepted nor incorporated into inventory for dispensing. It will be returned to the vendor for credit or replacement.

Products with expiration dates consisting of only the month/day and year are presumed to be in date until the last day /~~hourof~~hour of the month/day in which they expire.

If the expiration date is not assigned by the manufacturer, an expiration date of 1 year shall be assigned for sterile products and an expiration date of 3 years shall be assigned for non-sterile products as per USP 797 and USP 795, respectively.

For assigning Beyond-Use Dates (BUDs) to compounded products, sterile and non-sterile, refer to Procedure E. Assigning Beyond-Use Dates (BUDs)

GUIDELINES:

An **expiration date** identifies the time during which a conventionally manufacturer product, active ingredient, or excipient can be expected to meet the requirements of a compendial monograph, if one exists, provided it is kept under the prescribe storage conditions. The expiration date limits the time during which the conventionally manufacturer product, active pharmaceutical ingredient (API), or excipient may be dispensed or used. Expiration dates are assigned by 503b pharmacies, and

manufacturers of conventionally manufactured products based on analytical and performance testing of the sterility, chemical and physical stability, and packaging integrity of the product. Expiration dates are specific for a particular formulation in its container and at the stated exposure conditions of illumination and temperature.

If an expiration date is stated only in terms of the year and the month, then the intended expiration date is the last day of the stated month. If the expiration date is stated in terms of year, month, and day, then the intended expiration date is the last hour of the stated day.

The **beyond-use date (BUD)** is the date or hour and the date, after which a compounded preparation must not be used, stored, or transported. The date or time is determined from the ate the preparation was compounded.

The following summary table is to be used to determine appropriate expiration and beyond-use dates for various products, sterile and non-sterile.

Table 4. Beyond-Use & Expiration Dating for All Product Types

ITEM	BEYOND-USE / EXPIRATION DATE**
Chemicals without manufacturer's expiration date	1 year from date of receipt
Compounded, non-sterile nonaqueous oral liquids	90 days
Compounded, non-sterile nonaqueous other dosage forms (e.g., capsules, tablets, granules, powders, topicals, suppositories, and troches or lozenges)	180 days
Compounded, non-sterile non-preserved aqueous dosage forms (e.g., emulsions, gels, creams, solutions, sprays, or suspensions)	14 days
Compounded, non-sterile preserved aqueous dosage forms	35 days
Immediate-use CSP	4 hours
Category 1 CSP	Less than or equal to 12 hours at room temperature, less than or equal to 24 hours in refrigerator
Category 2 CSP – aseptically processed **without** sterility test prepared from 1+ ***nonsterile*** starting components	1 day at room temperature, 4 days in refrigerator, 45 days in freezer
Category 2 CSP – aseptically processed **without** sterility test prepared from only ***sterile*** starting components	4 days at room temperature, 10 days in refrigerator, 45 days in freezer
Category 2 CSP – aseptically processed **with** sterility test performed and passed	30 days at room temperature, 45 days in refrigerator, 60 days in freezer
Category 2 CSP – terminally sterilized **without** sterility test	14 days at room temperature, 28 days in refrigerator, 45 days in freezer

Category 2 CSP – terminally sterilized **with** sterility test performed and passed	45 days at room temperature, 60 days in refrigerator, 90 days in freezer
Inpatient-specific medication	Expiration date from manufacturer as labeled on individual package
Inpatient-specific unit-of-use packaging (creams, inhalers, etc)	Expiration date from manufacturer as labeled on individual package
Single-dose vial	12 hours if kept in CAI or CACI. Immediately after use, within 4 hours, if not kept in CACI or CACI Date and puncture time should be cited on the container
Multi-dose vial (excluding vaccines)	28 days from 1st puncture Vaccines: refer to individual manufacturer package inserts
Outpatient-specific prescription	Expiration date from manufacturer as labeled on individual package
Unit-dosed meds repackaged from bulk packages (except Re-Packager)	1 year from repackaging date (Re-Packager: 6 months from repackaging date)
Non-unit dosed meds repackaged from bulk container (e.g. KOH, ETOH)	180 days (6 months) from compounding date

** unless individual components or manufacturer cites earlier date

RELATED LINKS:

Procedure E. Assigning Beyond-Use Dates (BUDs)

REFERENCES:

A. TJC Standard MM.03.01.01, MM05.01.01, MM.05.01.07, MM05.01.09, MM.05.01.11, MM05.01.17, MM.05.01.19, ~~EC.02.01.01~~
B. CMS CoP § 482.11(a), 482.13(c), 482.23(c), 482.25(a)(b), 482.41(a)(c)
C. Title 16 California Code of Regulations Articles 4.5, ~~7 and 7.5~~ § 1735, ~~1751~~1736
D. Business and Professions Code 4076
E. Extemporaneous compounding references
F. Drug/chemical manufacturers
G. USP General Chapter <797>. Pharmaceutical Compounding – Sterile Preparations
H. USP General Chapter <795>. Pharmaceutical Compounding – Non-Sterile Preparations
I. USP General Chapter <7>. Labeling

~~**APPROVALS:**~~

~~Patient Care Policy and Evaluation Committee: 2/2025~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19756560**

Origination	09/2003	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	01/2026		
Next Review	1 year after approval		

Policy for Handling of Suspected IV Contamination

POLICY STATEMENT:

In the event an IV preparation is suspected of contamination or of producing an infection/reaction in a patient, the IV preparation will be tested for microbial contaminants.

GUIDELINES:

In the event an IV is suspected of contamination or of producing a reaction in a patient:

A. The IV will be discontinued immediately
B. The cannula or catheter will be removed and saved for culturing
C. Infection Control and the provider will be notified
D. The IV bag and tubing are placed in a zip-locked bag and returned to Pharmacy after completing an online SERS.

Infection Control will send the bag, tubing, and cannula/catheter to the Lab for culturing.

The results will be noted on the SERS.

If the bag cultures positive for contamination, Pharmacy will work with Infection Control to track down the source of the contamination. Based on their findings, either employee or department education may be warranted. Completion of the education will be documented on the SERS.

The completed SERS is forwarded to the Medication Safety Advocates for discussion at the Medication Safety Committee.

REFERENCES:

A. TJC Standard IC.01.03.01, IC.02.02.01, MM.05.01.07, ~~MM.05.01.11,~~ MM.06.01.01~~, MM.07.01.03~~

B. CMS CoP § 482.13(c), 482.21(d), 482.23(c), 482.25(a)(b)

C. Infection Control Policies

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19992897**

Origination	10/2007	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	02/2026		
Next Review	1 year after approval		

Policy for Hazardous Materials and Waste Training

POLICY STATEMENT:

Employees shall be inserviced at orientation, annually and as needed to recognize and evaluate hazardous drugs to properly handle and control exposure to them.

GUIDELINES:

Employee Responsibilities:

A. Obey established safety rules.
B. Use personal protective equipment as required.
C. Inform your supervisor of:
    1. Any symptoms of overexposure that may possibly be related to hazardous chemicals
    2. Missing labels on containers
    3. Malfunctioning safety equipment
    4. Any exposure **immediately**
    5. Any damaged containers or spills **immediately**

Training:

A. This procedure outlines the hospital policy for training personnel required to handle hazardous chemicals.
B. Scope of training for personnel will include, as a minimum, the following areas:

1. The Hazard Communication/Right to Know Law
2. Symptoms associated with overexposure to hazardous materials; what to do if overexposed to hazardous materials
3. Physical and health risks associated with hazardous chemicals
4. First aid treatment
5. How to read Material Safety Data Sheets; location where MSDS information is available
6. How employee can determine the existence or release of a hazardous chemical, labeling of hazardous chemicals
7. Procedures to follow to reduce or prevent exposure to hazardous chemicals
8. Use of personal protective equipment; location, availability, type, use and limitations
9. Standard operating procedures
10. Radiation hazards
11. Biosafety (infectious agents)
12. Carcinogen handling procedures
13. Chemical handling, storage and disposal
14. Compressed gas handling and storage
15. Hazards of chemicals to workers involved in non-routine tasks, such as in the cleaning, maintenance, and repair of equipment
16. Hazards associated with chemicals contained in unlabeled pipes in the work area
17. Emergency procedures
18. How to identify what and where hazardous chemicals are found in the work area

Training Program:

A. To develop specific training for individual jobs, the following guidelines shall be used:
   1. List all jobs and associated occupations that handle hazardous chemicals.
   2. Identify any areas where an industrial hygiene or occupational health evaluation may be needed
   3. Perform the training
   4. Document all personnel training

B. Review training procedures periodically, especially prior to performing non-routine tasks.

RELATED LINKS:

Policy for MSDS – How to Read

REFERENCES:

A. TJC Standards EC.01.01.01, EC.03.01.01, HR.01.04.01, HR.01.05.03, HR.01.06.01
B. CMS CoP § 482.11(a), 482.13(c), 482.23(c), 482.25(a)(b, 482.41(a)(b)(c)
C. OSHA Regulations

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19771954**

Origination	03/2004
Last Approved	N/A
Effective	Upon Approval
Last Revised	01/2026
Next Review	1 year after approval

Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for High Risk/High Alert Medication Management

POLICY STATEMENT:

It is the policy of this institution to maintain a list of high risk/high alert medications that require specific safeguards to reduce the risk of errors related to ordering and prescribing, order communication, preparation, storage, distribution and administration.

High risk/high alert medications are drugs that have an increased risk of causing significant harm to a patient when used in error. Because the consequences of an error associated with use of these medications can result in significant patient injury, special precautions will be employed with their overall management throughout the institution.

GUIDELINES:

The Pharmacy Department will outline specific precautions to be undertaken with the management of high alert/high risk medications cited in the references above.

The types of precautions include:

A. Reducing staff access to these medications (e.g., warfarin & fentanyl patch are non-overridable from the ADCs prior to pharmacist review)
B. Putting both generic and brand names on labels when applicable
C. Entering default dosing and frequency parameters in computer drug database
D. Standardizing the ordering, preparation, and administration of these products
E. Employing automated or independent double checks when necessary
F. Restricting access to ordering oncology medications to oncology providers

G. Standardizing availability of medications in patient treatment areas

H. Heparin IV, insulin, PCAs, and chemotherapy require nursing dual sign-off (heparin flush is excluded)

The Director of Pharmacy Services and/or the Medication Safety Committee will monitor publications for national medication error patterns and CCRMC's internal error data to suggest revisions to the Patient Care Policy and Evaluation Committee as needed.

RELATED LINKS:

Medication Safeguards Poster

Policy for Medication Administration and Documentation

Procedure for Chemotherapy and Hazardous Drugs – Administration, Disposal, Exposure and Spills, Extravasation

Policy for Insulin Administration

Procedure for Insulin Administration

Policy for Parenteral Nutrition Total and Peripheral Nutrition Administration

Policy for Patient Controlled Analgesia

Policy for Antineoplastic and Hazardous Drug Handling

Policy for Anticoagulation Program for Inpatients

Policy for Fentanyl Patch: Prescribing & Usage of

REFERENCES:

A. TJC Standards MM 01.01.03

B. CMS CoP § 482.21(a)(b)(c), 482.23(c), 482.25(a)(b)

C. Institute for Safe Medication Practices (ISMP)

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date

Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [GS]	02/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [AL]	02/2026
	Shideh Ataii: Director Of Pharmacy Svcs	01/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19355606**

Origination	04/2001	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	11/2025		
Next Review	3 years after approval		

Policy for Labeling Standards

POLICY STATEMENT:

To state the requirements for medication labels

All medications and drug containers shall be properly labeled with drug labels that are clear, consistent, legible and in compliance with state and federal requirements. There shall be a standard method for appropriately and safely labeling medications dispensed to both inpatients and outpatients. Labeling requirements shall be in general compliance with the current ASHP Technical Assistance Bulletin on Single Unit and Unit Dose Packages of Drugs.

GUIDELINES:

Purchased unit-of-use (unit-dose) medication labels shall include at a minimum:

- Generic and brand drug name
- Dose (the amount included in the unit-of-use package)
- Manufacturer's lot number
- Expiration date if medication not used within 24 hours
- Expiration time if medication expires in less than 24 hours
- Name of manufacturer or repackager

The inpatient prescription label shall be affixed to the container and shall include the following information:

- Name and phone number of the pharmacy

- The patient's name and medical record number
- The patient's location
- Generic and brand name (if applicable) of the drug
- Strength and dose
- Dispense quantity
- The expiration date
- The initials of the person who filled the order
- The initials of the pharmacist who checked the order, if it was filled by a licensed individual other than the pharmacist (e.g. pharmacy technician, pharmacy intern)
- The prescription number
- The date filled and the original date, if applicable
- Auxiliary caution labels or special requirements, as applicable
- The name of the drug the prescriber ordered, if not the same as the generic or brand name of the drug dispensed
- For IV sterile compounded orders prepared by pharmacy, the EPIC (ccLink) generated label includes "Compounded by" on the pharmacist signature line (e.g., as opposed to "Prepared by" which is reflective of what EPIC generates, automatically for non-compounded IV sterile medications such as Add-Vantage etc.)

Intravenous admixture and parenteral nutrition solution labels shall include at a minimum:

- Name and phone number of the pharmacy
- Prescription number
- Patient's name, location, and medical record number
- Bag sequence number
- Date and time due
- Generic and brand name (if applicable) of the drug
- Correct names amounts and concentrations of the ingredients, and IV solution utilized
- Total volume
- Rate of administration
- Preparation date
- Beyond-use date
- Initials of the technician who prepared the admixture
- Initials of the pharmacist checking the admixture
- Special storage requirements or other cautionary statements, as appropriate; all hazardous agents have special label stating "chemo-dispose of properly" or "hazardous- dispose of properly"

Repackaged unit-of-use medication labels shall include at a minimum:

- Generic and brand name (if applicable) of drug

- Dosage form (if special or other than oral)
- Strength
- Strength of dose and total contents delivered (i.e., number of tablets and their total dose), as applicable
- Special storage notes or comments (i.e., refrigerate)
- Internally assigned control number and expiration date or beyond use date
- Name of centralized hospital packaging pharmacy

Prescriptions intended for use outside of the hospital shall be labeled to ensure complete understanding and compliance by the patient/family. These include prescriptions for discharged patients, the self-medication program and pass medications. The minimum requirements include:

- The name, address, and phone number of the dispensing pharmacy
- The prescription number
- The patient's name
- The prescriber's name
- The date filled
- The directions for use
- The generic and brand name (if applicable) of the medication
- The strength and dispense quantity of the medication
- The expiration date of the medication (manufacturer's expiration date)
- Physical description of the dispensed medication as specified by California Law
- The initials of the technician who filled the prescription
- The initials of the pharmacist who filled the prescription, or checked the technician's work
- Federal caution statement
- Number of refills remaining
- Auxiliary labels and cautionary statements, as appropriate

Take-Home Naloxone nasal spray provided to patients under the Naloxone Distribution Project (NDP) by Contra Costa Department of Public Health is excluded from the above labeling requirements. The Board of Pharmacy clarified that naloxone obtained through the NDP and stored separately from the hospital's pharmacy inventory for distribution under a standing order pursuant to Civil Code 1714.22 is not a pharmaceutical that will be used in the healthcare setting and is exempt from Title 22 Cal. Code Regs. 70265, Business and Professions Code 4068, and Business and Professions Code 4076. As the inventory is considered separate from the pharmacy inventory, it does not need to be maintained, stored, or labeled in compliance with Business and Professions Code section 4068.

~~Syringes of medication~~Medication containers that are not immediately administered are labeled with the following:

- Drug name
- Concentration

- Date and time prepared
- Beyond use date
- Initials of the technician or licensed individual who prepared the syringe
- Initials of the pharmacist who checked the syringe

REFERENCES:

TJC Standard MM.05.01.09, NPSG.01.01.01
CMS CoP § 482.12(a)(d), 482.23(c), 482.25(a)(b)
California Pharmacy Law 4076, 4128.5, 1735.4
Naloxone-Distribution-Project-FAQ-020120 (californiamat.org)
CA BRIDGE - GUIDE - Guide to Naloxone Distribution - October 2022 (secureserver.net)

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 4/23~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
	Shideh Ataii: Director Of Pharmacy Svcs	11/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19756713**

Origination	03/2019	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	01/2026		
Next Review	1 year after approval		

Policy for Licensed Employee – Theft or Impairment

POLICY STATEMENT:

It is the responsibility of the Pharmacy to protect the public when a licensed personnel employed by or working in the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

Pharmacy shall report and provide to the Board of Pharmacy, within 14 days of the receipt or development of the following information regarding any licensed individual employed by or with the pharmacy:

1. Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.
2. Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.
3. Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
4. Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.
5. Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
6. Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

The report required shall include sufficient detail to inform the Board of the facts upon which the report is based, including an estimate of the type and quantity of all dangerous drugs involved, the timeframe

over which the losses are suspected, and the date of the last controlled substances inventory.

Upon request of the Board, the pharmacy shall prepare and submit an audit involving the dangerous drugs suspected to be missing. See ~~policy #3612~~Policy for Controlled Substance Diversion Prevention for additional information.

Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

RELATED LINKS:

Policy for Controlled Substance Diversion Prevention

REFERENCES:

A. California Board of Pharmacy B&PC Chapter 9, Division 2, Article 6 §4104

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19223956**

Origination	04/2004
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Look-Alike, Sound-Alike Medication Management

POLICY STATEMENT:

It is the policy of this organization to maintain a list of look-alike, sound-alike drugs (LASA) used in the organization, and to implement measures to prevent errors when ordering, dispensing, or administering look-alike and sound-alike medications.

This list will be approved by PCP&E and reviewed/revised annually.

The Food and Drug Administration and ISMP recommend using "tall man" lettering as one strategy to help prevent medication errors caused by look-alike medication names by drawing attention to dissimilarities in their names. CCRMC shall implement the suggested TallMan lettering for all its medications listed on the FDA and ISMP websites. In addition, CCRMC has added medications to its TallMan lettering pairs, based on data from medication error reports:

GUIDELINES:

A. A list of CCRMC's LASA target drugs will be posted in the Pharmacy~~,~~ and in all med rooms~~, and in physician charting areas~~.

B. TallMan lettering will be used to the greatest extent possible wherever the name of medications on the TallMan lists appear (see attachments), including:

   1. ccLink
   2. Automated dispensing cabinets
   3. Storage areas

C. A secondary "LASA" caution label will be placed on the storage bins in Pharmacy.

D. Distinct packaging and/or labeling is preferred for all LASA meds (vial vs amp, bulk vs UD).

E. If there is any doubt on orders for any of these meds, the provider will be contacted for clarification. Determining indication for use will aid in identifying the correct medication.

F. Special attention will be taken when taking a verbal order. It is suggested that when the pharmacist reads back the order, both the generic and brand name be included and the indication for the medication be requested.

G. Both brand and generic names will appear in ccLink. Default on the Automated Dispensing Cabinets will be the generic names, but brand cross-reference is available.

RELATED LINKS:

Medication Safeguards Poster

REFERENCES:

A. Institute for Safe Medication Practices

B. TJC Standard MM.14.01.01~~.03, MM.01.02.01, MM.03.01.01, MM.04.01.01, MM.05.01.01~~

C. CMS Cop § 482.23(c), 482.24(c), 482.25(a)(b)

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2022, 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Attachments

Medication Safeguards Poster

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19992884**

Origination	03/2024
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Maintenance of Sterile Compounding Facilities and Equipments

POLICY STATEMENT:

All sterile compounding shall be prepared in a Primary Engineering Control (PEC) device that provides an ISO Class 5 air quality environment for sterile compounding. The type of PEC used in the CCRMC Pharmacy Department are Restricted-access barrier systems (RABS), an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS are compounding aseptic isolators (CAIs) and compounding aseptic containment isolators (CACIs). The CAIs and CACIs will be maintained in a clean and safe operational mode. CAIs and CACIs are placed into an area called a Secondary Engineering Control (SEC), which may be a cleanroom suite or a segregated compounding area (SCA), that incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area. CCRMC Pharmacy Department's SECs are all cleanroom suites.

To ensure the PECs meet its design functions, Pharmacy personnel review and document the pass-through chamber and main chamber pressures and change the gauntlet gloves and sleeves according to the manufacturer's recommended frequency.

To ensure the SEC compounding suites meet its design functions, Pharmacy personnel review and document the following environmental controls daily, on days when compounding occurs: (1) the air pressure differential between all adjoining ISO-classified rooms, (2) room temperature, (3) relative humidity.

Cleaning and disinfection of the PECs is performed by trained Pharmacy personnel at the beginning and end of each shift as well as throughout the day, as necessary, on days when compounding occurs.

Cleaning and disinfection of the SECs is performed by trained Environment Services personnel daily, on days when compounding occurs, while compounding is not actively taking place.

Pharmacy and Environmental Services personnel perform hand hygiene and are appropriately garbed upon entry into the SEC compounding suites. Pharmacy staff competency is assessed initially and reassessed semi-annually or annually, depending on their role. Environmental Services staff competency is assessed initially and reassessed annually.

To monitor, maintain and minimize the microbial bioburden in the controlled environments for compounding sterile products, microbial surface sampling is performed monthly and in conjunction with pharmacy personnel ongoing sterile compounding competencies, end-product testing (sterility, endotoxin, and potency testing) is performed at least annually, microbial air sampling is performed semi-annually in conjunction with the certification of the compounding suites.

Pharmacy microbial sampling data is evaluated against appropriate action levels for the type of microbial sampling (i.e., air vs. surface) and ISO classified area. If levels measured exceed the action levels for the ISO classification of the area sampled, the cause must be investigated, and corrective action must be taken. Data collected in response to corrective actions must be reviewed to confirm the actions taken have been effective (i.e., re-sampling). The Designated Person (DP), Pharmacist II, will be notified of any samples exceeding the specified action levels.

GUIDELINES:

A. Compounding Facilities Design Requirements and Monitoring
    1. Hazardous drug compounding shall be performed in an externally vented physical separate room meeting the following requirements:
       Minimum of
        a. 30 air changes per hour (ACPH) **or**
        b. 12 air changes per hour (ACPH) with a BSC or CACI **if**
            i. Products are assigned a BUD of 12 hours or less **or**
            ii. Only non-sterile products are compounded
    2. Maintained at negative pressure 0.01 to 0.03 inches of water column relative to adjacent accessible spaces
    3. Each primary engineering control (PEC) in the room shall also be externally vented
    4. All surfaces in the room shall be smooth, seamless, impervious, and non-shedding
    5. The air pressure differential between all adjacent ISO spaces or areas shall be reviewed and documented on the appropriate log at least daily on the days when compounding is occurring.
        a. The air pressure differential must be between
        b. +0.02 to +0.05 for a positive pressure environment and

c. -0.01 to -0.03 for a negative pressure environment.

6. If the air pressure differential deviates from the ranges specified, the pharmacist and or the management must be notified immediately, and engineering must be contacted to address the issue promptly.
7. The room temperature of the IV compounding rooms must be monitored each day that compounding is performed, either manually or by a continuous recording device. The results must be documented at least once daily.
    a. The room temperature should be maintained at a temperature of 20 degrees C or 68 degrees F or cooler to provide comfortable conditions for compounding personnel attired in the required garb.
    b. The room temperature must also meet acceptable temperature range for storage of pharmaceuticals at room temperature as defined in Policy for Room Temperature Monitoring for Drug Storage Areas.
8. The relative humidity of the IV compounding rooms must be monitored each day that compounding is performed, either manually or by a continuous recording device. The results must be documented at least daily.
    a. The relative humidity should be maintained at 60% or below to minimize the risk of microbial proliferation.

B. Compounding Equipment (Primary Engineering Controls)

1. CAI and CACIs shall have routine maintenance and certification performed every 6 months, or whenever the unit is relocated, to assure proper function of the HEPA filters. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, revised May 20, 2015). Certification records must be retained in the pharmacy for at least 3 years.
2. CAIs are generally used for non-hazardous sterile compounding, set to positive pressure
3. CACIs are used for antineoplastic/hazardous drug compounding, set to negative pressure
4. CAIs and CACIs shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.
5. CAIs and CACIs have a visible pressure gauge. Compounding personnel will check the reading on the pressure gauge of the main chamber and the ante/interchange chamber before compounding. The pressure reading must be within the acceptable range,
    a. **For the CAI (positive pressure):**
        i. >0.05 inches of water gauge for the ante/interchange chamber and
        ii. >0.15 inches of water gauge for the main chamber
    b. **For the CACI (negative pressure):**

i. < -0.25 inches of water gauge for the ante/interchange chamber and

ii. < -0.05 inches of water gauge for the main chamber, but should maintain a pressure of approximately -0.25 inches of water gauge

iii. In both CAI and CACIs, the ante/interchange chamber should be at least 0.05 inches of water gauge lower than the main chamber pressure

6. The CAIs' blower will be kept on throughout the compounding session. Blowers will remain on during interruptions of compounding sessions of less than eight (8) hours. If turned off, the blower must be on for a minimum of 30 minutes before a compounding session takes place.
7. The CACIs' blower should be left on continuously.
8. Recovery time to achieve ISO Class 5 air quality in the main chamber shall be complied with after an event such that the blower is inadvertently turned off.
    a. For both the CAI (positive pressure) and the CACI (negative pressure), the recovery time determination test results were less than 1 minute.
    b. To add a margin of safety, the manufacturer recommends waiting a minimum of 5 minutes to achieve ISO Class 5 air environment within the main chamber.
9. The inner airlock door must be kept closed while the outside door is open. Separate containers of agents used for deactivation, cleaning, and disinfection will be utilized to clean the main chamber and the ante/interchange chamber.
10. When placing items into the ante/interchange chamber, the appropriate pass-through purge or wait time must be observed.
    a. For the CAI (positive pressure): the manufacturer specifies that no wait or purge time is required during the material transfer process.
    b. For the CACI (negative pressure): the manufacturer recommends a minimum of 1-minute pass-through purge or wait time for material removal, and possibly more depending on volatility and quantity of hazardous drugs compounded. However, at CCRMC only one (1) hazardous drug is prepared at a time, therefore the 1-minute pass-through purge or wait time will be followed. All compounding must be ceased prior to the internal transfer chamber door being opened. Additionally, a second operator should not add or remove compounding materials from the transfer chamber while active compounding is being conducted in the main chamber.
11. During the use of both positive pressure and negative pressure compounding aseptic isolators, sterile gloves will be donned over the isolator's gauntlet gloves. In the case of negative pressure compounding aseptic isolator(s) being used for compounding of hazardous drugs, two (2) pairs of sterile chemotherapy-tested gloves shall be donned over the isolator's gauntlet gloves.

RELATED LINKS:

MIP- Record of Inpatient IV Room Temp-Pressure-Humidity
MOP- Record of Outpatient Infusion-Room Temp-Pressure-Humidity
Procedure F. Cleaning of Primary Engineering Controls by Pharmacy
Procedure G. Cleaning of Secondary Engineering Controls (Compounding Suites) by Environmental Services (EVS)
Procedure H. Environmental Surface Sampling
Procedure I. Viable and Non-Viable Environmental Air Sampling
Procedure J. End Product Testing of IV Admixtures
Procedure K. Handling of Positive Cultures from Pharmacy Monitoring

REFERENCES:

A. TJC Standard MM.01.01.03, MM.05.01.07, EC.02.02.01, EC.02.04.01, EC.02.04.03, IC.02.02.01, EC.01.04.01
B. CMS CoP § 482.11(a), 482.13(c), 482.23(c), 482.25(a)(b), 482.41(a)(b)(c), 482.42(a)
C. Title 16 California Code of Regulations Articles 4.5, 7 and 7.5 § 1735, ~~1751~~1736, 1737, 1738
D. USP General Chapter <797>. Pharmaceutical Compounding – Sterile Preparations
E. USP General Chapter <800>. Hazardous Drugs – Handling in Healthcare Settings
F. Pharmagard™ Positive Pressure Recirculating Compounding Aseptic Isolator Model NU-PR797 Operation & Maintenance Manual; Jan 2016, Rev. 1, Series 25
G. Pharmagard™ Total Exhaust Sterile Isolator Model NTE-800 Operation & Maintenance Manual; April 2016, Rev. 2, Series 25

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19355661**

Origination	03/2004
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	3 years after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Medication Orders - Pharmacy

POLICY STATEMENT:

In order to ensure safe administration of medications, a pharmacist will review all prescriptions or orders for medication prior to administration.

GUIDELINES:

A. Pharmacy shall receive an electronic copy of the original physician's order for verification and review prior to administration.

B. A pharmacist will review all orders, checking for:

1. ~~Completeness of the order~~Completeness of the order (medication name, medication dose, medication route, and medication frequency)
2. Correctness of the drug ordered
3. Allergies (including drug, food, latex)
4. Drug incompatibilities
5. Therapeutic duplications
6. Interactions with food or other drugs
7. Appropriateness of dosage, route, frequency, and indications
8. Pertinent lab values
9. Contraindications
10. Variations from CCRMC's criteria for use or CCRMC formulary

C. Any questions or clarification of the order shall be directed to the provider by the pharmacist. The pharmacist will page the provider, attending physician, or house officer and place a clinical intervention attached to the order. In the event all of these avenues fail, the pharmacist will enter a note into the computer system for the provider.

D. Verbal clarification from the provider shall be entered into the patient's electronic medical record and read back to the provider.

E. Drugs will be dispensed only after review of the product and/or the physician's order by a pharmacist.

F. ~~Exceptions are made for a licensed independent practitioner (LIP) controlled environment when the LIP controls the ordering, preparation, and administration of the drug.~~

   1. ~~Such environments include:~~
      a. ~~Emergency Department~~
      b. ~~Pre-& post-operative care~~
      c. ~~Surgery Department~~
      d. ~~Interventional radiology~~
      e. ~~General radiology~~
      f. ~~Labor & delivery~~
      g. ~~GI lab~~
      h. ~~Anesthesiology~~
   2. ~~In such areas, physician-entered orders auto-verify and are reviewed retrospectively by a pharmacist.~~
   3. ~~Other exceptions include STAT or one-time orders, urgent situations when the resulting delay would harm the patient, including situations in which the patient experiences a sudden change in clinical status or sudden onset of symptoms (e.g. nausea, pain, cardiac events, sepsis, fever), or if waiting for a pharmacist to review the order would result in clinical harm to the patient.~~
   4. ~~Drug classes that are available for the above scenarios include:~~
      a. ~~Pain and antipyretic medications~~
      b. ~~Cardiac medications (e.g., antithrombolytics, antiarrhythmics, anticoagulants, antihypertensives, etc)~~
      c. ~~Antiemetics~~
      d. ~~Code medications~~
      e. ~~Antibiotics & other anti-infectives~~
      f. ~~Any other medication required urgently for various clinical conditions~~

   Exceptions are made as per Policy for Automated Drug Delivery Systems – Pharmacist Order Verification and Policy for Automated Drug Delivery Systems - Override and Emergency/STAT Medication Orders

G. A 24-hour supply of the medication will be dispensed unless:

1. The provider indicates a lesser quantity or duration of therapy.
2. The medication has a restriction as to dispense quantity or duration of therapy.
3. The medication comes in a unit-of-use package (inhaler, tube, dropper, etc.).
4. The medication is stocked in the unit's automated dispensing machine.

H. For the pharmacy turn-around time expectations, refer to Pharmacy Policy for Prescribing & Ordering – General Practices.

I. The medication will be delivered to the unit by pharmacy runner on next scheduled delivery, unless a Nursing staff member comes to pick it up sooner or it is a dose not due for at least 4 hours.

J. In the event the Medical Center Supervisor must obtain a medication after hours, the medication removed will be compared against the physician's order.

RELATED LINKS:

Pharmacy Policy for Prescribing & Ordering – General Practices

REFERENCES:

A. TJC Standards MM.03.01.01, MM.04.01.01, MM.05.01.01, MM.05.01.07, MM.05.01.09, MM.05.01.11, MM.06.01.01

B. CMS CoP § 482.23(c), 482.24(c), 482.25(a)(b)

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2022~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19969704**

Origination	03/2004
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Medication Recall

POLICY STATEMENT:

The Pharmacy shall maintain a system whereby drugs subject to recall or discontinuation by the manufacturer or the FDA can be identified, removed from active inventory, and isolated for appropriate action. The actual or potential clinical significance of the recall on patient care will be assessed, and an alternative for drug therapy of recalled drugs or devices will be determined, as appropriate. The system shall include drugs dispensed to both inpatients and outpatients. If the recall is a Class I recall and requires that patients be contacted, that shall be done using dispensing and billing records. Providers will be notified of all Class I recalls via emails, memos, phone conversations or other levels as appropriate.

GUIDELINES:

A. The Pharmacy will be notified of a recall through one or more of the following:
    1. Direct mail from the manufacturer
    2. Direct mail or email from the drug wholesaler
    3. FDA Safety Alert or Recall Notification
    4. Recall bulletin from Materials Management Department
    5. California State Board of Pharmacy

B. Recall definitions:
    1. **Class I recall**: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. Requires notification of all affected or potentially affected patients.

2. **Class II recall**: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
3. **Class III recall**: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
4. **Market withdrawal**: occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation.
5. **Medical device safety alert**: issued in situations where a medical device may present an unreasonable risk of substantial harm. In some cases, these situations also are considered recalls.
6. **Facility complaints related to potential quality problems with compounded sterile product (CSP) and nonsterile compounded product (CNSP)** and any related adverse drug experiences

C. **Staff notification**

1. When a notice is received requiring immediate staff notification: all dispensing staff will be informed via emails or staff meetings/huddle etc.
2. A copy of the recall notice is sent to outpatient pharmacists, so they can check purchasing records
3. When the Pharmacy receives information about a medication recall or discontinuation by the manufacturer or the FDA for safety reasons, all individuals ordering, dispensing and/or administering recalled or discontinued medications are notified.
4. A review of any complaints made to the facility related to a potential quality problem with a CSP or CNSP shall be initiated within **72 hours** of receipt of the complaint.

D. **Product Inventory:**

1. The recalled product will be evaluated for potential distribution sites: In-Patient Pharmacy, Outpatient Pharmacy, Clinics, Automated Dispensing Machines, etc.
2. A purchase history of the medication will prompt an inspection of:
    a. The main pharmacy
    b. All areas of the hospital that may contain the recalled medication(s). Designated staff members will utilize the "Inpatient Medication Recall Inventory Checklist Form" to check each area of the hospital and will complete a walk-through.
    c. Crash Carts and Kits, as applicable
    d. Automated dispensing machines that contain the recalled medication(s), utilizing a product specific Omnicell Inventory Report Listing (nursing units containing the product).
3. When products are used outside the pharmacy and nursing care units, all-staff-memos may be sent to alert other healthcare providers of the recall in question.

E. **Recall Inventory Documentation Log and duties**

1. Once a product has been identified as being purchased from our pharmacy, an "Inpatient Medication Recall Inventory Checklist Form" is completed.
2. Upon notification, the assigned staff member(s) will remove all lots of recalled or discontinued drugs found in inventory in the Pharmacy, patient care areas, and ambulatory care clinic areas.
3. If unable to verify lot number, Pharmacy will retrieve all lots of the recalled medication. The staff member will inventory all applicable sites and note any removed product or that "none" or "zero" affected product was discovered at that unit.
4. The pharmacist will conduct an audit to make certain all recalled product(s) have been removed and sequestered.

F. **Medication Sequestering:**

1. The involved medications will be sequestered until the drug is packaged and returned to the manufacturer or wholesaler, per recall instructions.
2. All sequestered medications from the recall will be placed into a recall tackle box. This will prevent the medications from being reintroduced into the regular stock stream.
3. A record of actions taken will be written on the recall notice and the date the action was taken. Any return information will be stapled to the specific recall notice and filed.

G. **Patient Notification:**

1. For a Class I recall, an electronic medical record search will be conducted for all patients who potentially received the medication. These patients will all be notified via US mail of recall or discontinuation and appropriate action per recall notification.
2. Providers will be informed via memo, email, or fax (as appropriate). All lists and records will be filed for at least 3 years.
3. For sterile and nonsterile compounded drug product recalls, the recipient pharmacy, prescriber, or patient of the recalled drug will be notified as soon as possible within ~~12 hours~~**12 hours** of the recall notice, if BOTH of the following apply:
    a. Use of or exposure to the recalled drug may cause serious adverse health consequences or death
    b. The recalled drug was dispensed, or is intended for use, in this state
4. The recall notice shall be made as follows:
    a. If the recalled drug was dispensed directly **to the patient**, the notice shall be made to the ***patient***
    b. If the recalled drug was dispensed directly **to the prescriber**, the notice shall be made to the ***prescriber***, who shall ensure the patient is notified
    c. If the recalled drug was dispensed directly **to a pharmacy**, the notice shall be made to the ***pharmacy***, ~~who~~which shall notify the prescriber or patient,

as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

H. **Records Maintenance**

1. Six months of recall records will be maintained with-in the pharmacy in binders labeled by record dates.
2. The records may be stored off-site. These files will be readily retrievable.
3. All completed Inventory checklists will be stapled to any Omnicell Inventory sheets. The final reports will be signed and dated by all parties involved, attached to the original recall notice and maintained in the Logbook as above.
4. The review of any complaints made to the facility related to a potential quality problem with a CSP or CNSP shall be documented and dated.

I. **Monitoring and Reporting:**

1. A monthly report will be prepared and presented to Medication Safety Committee, Patient Care Policy & Evaluations Committee, etc. This report shall include:
    a. The number of recall notifications received by the Pharmacy
    b. The number of recalls requiring action
    c. The number of patients affected or potentially affected, including any adverse outcomes for Class I recalls
    d. The location and quantity of recalled product returned
    e. The number of audits performed by the pharmacist and whether or not any deficiencies were identified. If deficiencies were identified, action taken will be noted.
2. If the pharmacy has been advised that a patient has been harmed by a nonsterile compounded product compounded by the pharmacy, the pharmacy reports the event to ~~MedWatch~~ **MedWatch** within ~~72 hours~~ **72 hours** of the pharmacy being advised.
3. Facility compliants
4. For sterile and nonsterile compounded drug product recalls, the ~~Board of Pharmacy~~**Board of Pharmacy** will be notified as soon as possible within ~~12 hours~~**12 hours** of the recall notice, if BOTH of the following apply:
    a. Use of or exposure to the recalled drug may cause serious adverse health consequences or death
    b. The recalled drug was dispensed, or is intended for use, in the state of California
5. In the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength, the **Board of Pharmacy** shall be notified **in writing within 96 hours** of the facility's receipt of a complaint of a potential quality problem involving a **CNSP**.

REFERENCES:

A. TJC Standard MM.05.01.17, EC.02.01.01
B. CMS CoP § 482.11(a), 482.13(c), 482.23(c), 482.25(a)(b), 482.41(a)(c)
C. California State Board of Pharmacy, Addressing the Drug and Device Recalls in Hospitals, January 2010
D. ~~B&PC 4126.9, 4127.8~~Business and Professions Code Article 7 §4126.8, 4126.9, 4127.2, 4127.8, 4005, Article 4.5, 4.6 §1735.12, 1736.18
E. www.fda.gov/Safety/MedWatch/default.htm
F. U.S. Food and Drug Administration

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Attachments

Medication Recall Inventory Checklist

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19226607**

Origination	06/2010
Last Approved	N/A
Effective	Upon Approval
Last Revised	01/2026
Next Review	3 years after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Medication Reconciliation

POLICY STATEMENT:

Contra Costa Regional Medical Center and Health Clinics will implement a patient medication information/ reconciliation process to obtain and document a complete list of a patient's current medications upon admission, including, when possible, the name, dosage, route, frequency and purpose for every scheduled and as-needed medication a patient reports. Patient medication information/ reconciliation shall be conducted by a qualified healthcare staff and is a multidisciplinary process involving the patient/family. Physicians and other healthcare professionals managing the patient's medications (i.e., pharmacists) shall review the patient's medication list in the computer system in order to make decisions about drug therapy and to document any discrepancies and their resolution. The attending physician will make any additions, deletions or corrections to the patient's medication orders. The complete list of the patient's medications will be provided to the patient or the patient's family upon discharge.

During transitions of care pharmacy hours of operation, a pharmacist at the hospital will obtain an accurate medication profile or list for each high-risk patient upon admission ~~of the patient~~and upon discharge under specified circumstances. A trained staff member (intern pharmacist, pharmacy technician) may perform the task of obtaining an accurate medication profile ~~or list~~. If assigned, the trained staff member (intern pharmacist, pharmacy technician) will have records of training and competency assessment.

In the ambulatory care setting, the nurse and the patient will review the patient's current medication list in the computer, using the 'Medications Activity' in the 'Visit Navigator'. Based on the patient's comments, the nurse will flag the medications as 'Taking' or 'Not Taking'. In addition, any patient-reported medications not on the list will be added. The provider has the ultimate authority and

responsibility to review and intervene (e.g., continue, discontinue, or modify) the medications listed.

GUIDELINES:

A medication is any product designated by the Food and Drug Administration (FDA) as a drug, as well as any prescription medications, sample medications, herbal remedies, vitamins, nutriceuticals, over-the-counter drugs, vaccines, diagnostic and contrast agents used on or administered to persons to diagnose, treat or prevent disease or other abnormal conditions, radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives and intravenous solutions (plain, with electrolytes and/or drugs). This definition of medication does not include enteral nutrition solutions (which are considered food products), oxygen and other medical gases.

RELATED LINKS:

Procedure for Medication Reconciliation

REFERENCES:

A. TJC Standards IM.02.01.03, IM.02.02.03, MM.01.01.01, ~~NPSG~~NPG.~~03~~14.~~06~~05.01, PC.04.02.01
B. CMS CoP § 482.23(c), 482.43(d)
C. SB-1254 Hospital pharmacies: medication profiles or lists for high-risk patients (Chapter 697)
D. AB 1503, Section 4118.5 High Risk Patients

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 1/2023~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Attachments

TC training and competency assessment for pharmacy techs and interns.docx

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [GS]	02/2026

Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [AL]	02/2026
	Shideh Ataii: Director Of Pharmacy Svcs	01/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19980089**

Origination	03/2024
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Non-Sterile Compounding

POLICY STATEMENT:

The Designated Person, Pharmacist II, is responsible for performance and operation of the pharmacy and personnel for the ~~preparaiton~~preparation of compounded non-sterile products following the standards in USP 795.

GUIDELINES:

A. Introduction and Scope

1. The following compounded non-sterile preparations (CNSPs) are subject to this policy and USP <795> (current version)
    a. Solid oral preparations
    b. Liquid oral preparations
    c. Rectal preparations
    d. Vaginal preparations
    e. Topical preparations (i.e., creams, gels, and ointments)
    f. Nasal and sinus preparations intended for local application (i.e., nasal sprays and nasal irrigation)
    g. Otic preparations (excluding use in perforated eardrums)
2. The following activities are not subject to this policy or USP <795>:
    a. **Repackaging** of a conventionally manufactured drug product shall be not considered

compounding

b. **Reconstitution**:
    i. Reconstitution of a conventionally manufactured nonsterile product in accordance with the directions contained in the manufacturer approved labeling

c. **Splitting tablets**: Breaking or cutting a tablet into smaller portions

d. **Administration**: Preparation of a single dose for a single patient when administration will begin within 4 hours. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.

B. Personnel Training and Evaluation

1. All personnel who compound or have direct oversight of compounding CNSPs must be initially trained and qualified by demonstrating knowledge and competency before being allowed to perform compounding. Training includes reading the facility's SOPs and ensuring that they are followed. See Policy for Compounding Competency Assessment and Non-Sterile Compounding Competency Assessment
2. Training and competency of personnel will occur before a staff member is allowed to compound non-sterile preparations. Competency shall be assessed by the compounding supervisor, designated person, or an approved trainer.
3. Training and evaluations must be documented.
4. Before beginning to compound CNSPs independently or have direct oversight of compounding personnel, personnel must complete training and be able to demonstrate knowledge of principles and competency of skills for performing nonsterile manipulations as applicable to their assigned tasks.
5. Knowledge and competency must be demonstrated initially and at least every 12 months in at least the following core competencies:
    a. Hand hygiene and garbing
    b. Cleaning and sanitizing the compounding area
    c. Compounding techniques for non-sterile preparations (principles and practice, specific compounding steps, measuring and mixing, inspection of final compounds)
    d. Proper use of equipment and devices selected to compound CNSPs
    e. Documentation of the compounding process (master formulas and compounding records)
    f. Handling and transporting components and CNSPs
    g. Accessing, understanding, and interpreting safety data sheets (SDS)
    h. Read and understand procedures related to compounding duties
    i. Spill management
    j. Handling hazardous drugs (if applicable)

C. Personal Hygiene and Garbing

1. Individuals entering the compounding area must maintain appropriate personal hygiene. Individuals must evaluate whether they have a personal risk of potentially contaminating the compounding environment and CNSP (e.g., personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection). Individuals must report these conditions to the manager or compounding supervisor. Because of the risk of contaminating the CNSP and the environment, the manager or designated person(s) is responsible for evaluating whether these individuals should be excluded from working in compounding areas until their conditions have resolved.
2. Personnel engaged in compounding must maintain appropriate hand hygiene and maintain appropriate cleanliness required for the type of compounding performed.
3. Before entering the compounding area, compounding personnel must remove any items that are not easily cleanable and that might interfere with garbing. At a minimum, personnel must:
    a. Remove personal outer garments (e.g., bandanas, coats, hats, and jackets)
    b. Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing or hand hygiene (e.g., watches or rings that may tear gloves)
    c. Remove earbuds or headphones
    d. The compounding supervisor or designated person may permit accommodations provided that the quality of the environment and CNSP will not be affected.
4. Hand Hygiene – see Procedure C. Hand Hygiene for Sterile and Non-Sterile Compounding
5. To minimize the risk of cross contaminating other CNSPs and contaminating other objects (e.g., pens and keyboards), gloves should be wiped or replaced before beginning a CNSP that has different components.
6. All gloves must be inspected for holes, punctures, or tears and must be replaced immediately if such defects are detected.
7. Garb and Glove Requirements
    a. Gloves must be worn for all compounding activities.
    b. If compounding an HD, appropriate personal protective equipment (PPE) must be worn and disposed of in accordance with USP <800> Hazardous Dugs. See Policy for Antineoplastic and Hazardous Drug Handling

D. Building and Facilities Designated Area(s) for Non-Sterile Compounding

1. The area designated for the compounding of non-sterile preparations is in the main pharmacy.

E. Cleaning and Sanitizing the Non-Sterile Compounding Area

1. Cleaning and sanitizing the surfaces in the nonsterile compounding area(s) must occur on a regular basis at the minimum frequencies specified below.
2. If compounding is not performed daily, cleaning and sanitizing must be completed before initiating compounding. Cleaning and sanitizing must be repeated when spills occur and when surfaces are visibly soiled.
3. Applicable cleaning and sanitizing must be documented daily on days when compounding occurs.
4. Surfaces should be resistant to damage by cleaning and sanitizing agents. Floors in the compounding area should be easily cleanable and should not be porous or particle generating.
5. Cleaning and sanitizing agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues.
6. If cleaning and sanitizing are performed as separate steps, cleaning must be performed first.
7. Cleaning agents for the facility surfaces:
    a. QC 34 high performance ultra concentrated neutral floor cleaner for floors
    b. Ecolab A-456II disinfectant cleaner for counters, walls, and ceiling (dwell time 10 minutes)
    c. Sani-Cloth® Germicidal disposable wipe AF3 (dwell time 3 minutes)
8. Cleaning supplies for compounding equipment: paper towels, brushes, sponges, and cleaning agents with detergents if required for equipment.
9. Purified water or better quality (e.g. sterile water for irrigation, sterile water for injection) shall be used for rinsing equipment and utensils.
10. Minimum frequency for cleaning and sanitizing in non-sterile compounding area(s)
    a. Work Surfaces
        i. At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected
        ii. Between compounding CNSPs with different components
    b. Floors
        i. Daily on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected
    c. Walls
        i. When visibly soiled, after spills, and when surface contamination (e.g., from splashes) is known or suspected
    d. Ceilings

i. When visibly soiled and when surface contamination (e.g., from splashes) is known or suspected

e. Storage shelving

i. Every 3 months, after spills, and when surface contamination (e.g., from splashes) is known or suspected

F. Equipment and Components

1. The equipment and components used for compounding a CNSP must be suitable for the specific compounding process.
2. Equipment surfaces that contact components must not be reactive, additive, or sorptive, and must not alter the quality of the CNSP. Disposable or dedicated equipment may be used to reduce the chance of bioburden and cross-contamination.
3. Equipment must be stored in a manner that minimizes the risk of contamination and must be located to facilitate equipment use, maintenance, and cleaning.
4. Beakers, graduated cylinders, mortar and pestles will remain in the designated area for non-sterile compounding. These items will be cleaned prior to their use and after their use.
5. Equipment and devices used in the compounding or testing of compounded preparations must be inspected prior to use and, if appropriate, verified for accuracy as recommended by the manufacturer at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent.
6. The components use in non-sterile compounding will include finished pharmaceutical ingredients (manufactured tablets, capsules, liquids). When a bulk active pharmaceutical ingredient (API) or lab-grade ingredient for human use is utilized for compounding, the certificate of analysis (COA) must be reviewed and kept on file.
7. For all components that lack a vendor expiration date, the date of receipt by the compounding facility must be clearly and indelibly marked on each packaging system. Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt.
8. All ingredients used in compounding must be manufactured by an FDA-registered facility.
9. Water used for compounding must be purified water or better quality (e.g. sterile water for irrigation, sterile water for injection). Tap water shall not be used for compounding.
10. Before use, compounding personnel must visually re-inspect all components. Each packaging system must be inspected to detect any container breakage, looseness of the cap or closure, or deviation from the expected appearance or texture of the contents that might have occurred during storage.
11. Compounding personnel must ascertain before use that components are of the correct identity based on the labeling and have been stored under required conditions in the facility.
12. If the identity, strength, purity, and quality of components intended for preparation of CNSPs cannot be verified (e.g., containers with damaged or incomplete labeling), the components must be immediately rejected. Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use

before appropriate disposal.

13. All components must be handled in accordance with the manufacturer's instructions or per laws and regulations of the applicable regulatory jurisdiction. The handling must minimize the risk of contamination, mix-ups, and deterioration (e.g., loss of identity, strength, purity, or quality). For each use, the lot must be examined for evidence of deterioration and other aspects of unacceptable quality. Once removed from the original container, any component not used in compounding (e.g., excess after weighing) should be discarded and not returned to the original container to minimize the risk of contaminating the original container.
14. Component spill and disposal
    a. Staff will have access to current chemical hazard and disposal information (e.g. safety data sheets (SDS) on file)
    b. A spill kit for hazardous drugs will be accessible in areas where hazardous non-sterile preparations are compounded and stored.
    c. Training on the use of spill kits is required for staff who perform compounding and must be conducted at least every 12 months as part of the staff's training program.
    d. Waste of drug components must be disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction. Additional handling of hazardous drugs is outlined in USP <800>.

G. Master Formulas and Compounding Records

see Policy for Compounding of Medications

H. Release Inspections and Testing

1. All checks, inspections, and any other required tests to ensure the quality of the CNSP must be detailed in the facility's MFR.
2. At the completion of compounding, before releasing and dispensing, the CNSP must be visually inspected to determine whether the physical appearance of the CNSP is as expected (e.g., color, texture, physical uniformity). Some CNSPs, as noted in their MFR, also must be visually checked for certain characteristics (e.g., emulsions must be checked for phase separation). The CNSP must be visually inspected to confirm that the CNSP and its labeling match the CR and the prescription or medication order. The inspection also must include a visual inspection of container closure integrity (e.g., checking for leakage, cracks in the container, or improper seals).
3. When a CNSP will not be released or dispensed on the day of preparation, a visual inspection must be conducted immediately before it is released or dispensed to make sure that the CNSP does not exhibit any defects (e.g., leakage) that could develop during storage. Any CNSP found to be of unacceptable quality (e.g., observed defects) must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.

I. Labeling

See Policy for Compounding of Medications

J. Beyond Use Dates of Non-Sterile Compounded Preparations

See Procedure E. Assigning Beyond-Use Dates (BUDs)

K. Standard Operating Procedures

1. All personnel who conduct or oversee compounding activities must be trained in the facility's SOPs and be responsible for ensuring that they are followed.
2. One or more person(s) must be designated to ensure that the facility's SOPs are fully implemented. The designated person(s) must ensure that follow-up occurs if problems, deviations, or errors are identified.

L. Quality Assurance and Quality Control

1. See Policy for Quality Assurance in Pharmacy
2. See Policy for Medication Recall

M. CNSP Packaging and Transport

1. Personnel should select and use packaging materials that will maintain the physical and chemical integrity and stability of the CNSPs. Packaging materials must protect CNSPs from damage, leakage, contamination, and degradation, while simultaneously protecting personnel from exposure.
2. The required packaging of the final preparation will be included in the master formula for each preparation.

RELATED LINKS:

Policy for Antineoplastic and Hazardous Drug Handling

Policy for Compounding of Medications

Procedure E. Assigning Beyond-Use Dates (BUDs)

Policy for Quality Assurance in Pharmacy

Policy for Medication Recall

Policy for Compounding Competency Assessment

Non-Sterile Compounding Competency Assessment

REFERENCES:

A. Joint Commission Standards

B. California State Board of Pharmacy Regulations: Section 1735 -1735.8 Note: Authority cited: Sections 4001.1. 4005. 4057. 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051. 4052. 4057, 4076, 4081. 4105. 4126.8 and 4169. 4301, 4306.5 and 4332 of the Business and Profession Code.

C. USP General Chapter <795>. Pharmaceutical Compounding – Non-Sterile Preparations

D. Title 16 California Code of Regulations Articles 4.5 § 1735

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19994063**

Origination	05/2018	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	02/2026		
Next Review	3 years after approval		

Policy for Outsourced Compounding Pharmacy- Quality Assurance

POLICY STATEMENT:

To define when and how outsourced compounded sterile preparations are used at CCRMC and Clinics. This may include injectable drugs including chemotherapeutic agents, eye drops, bladder instillations, etc. or any sterile compound administered to a patient.

To obtain critical medications, when there is no other method to obtain the product or for highly specialized patient clinical condition, CCRMC pharmacy may use an outsourced sterile compounding pharmacy as a source.

In the event an outsourced sterile compounding pharmacy must be used, CCRMC pharmacy will only contract with pharmacies that are licensed sterile compounding pharmacies with the California State Board of Pharmacy AND a Registered Outsourcing Facility as defined by section 503A and 503B of the Federal Food, Drug and Cosmetic Act and CA State Business and Professions Code.

GUIDELINES:

A. Identify an outsourced sterile compounding pharmacy (also known as "503B Pharmacy") that can produce the product(s) required to meet patient care needs.

B. Validate that the pharmacy is licensed by the California State Board of Pharmacy as a licensed "Sterile Compounding Pharmacy," or if the pharmacy is not in California, as a "Nonresident Sterile Compounding Pharmacy." http://www.pharmacy.ca.gov/online/verify_lic.shtml

C. Validate that the 503B pharmacy is a "Registered Outsourcing Facility" as listed by the FDA. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/

PharmacyCompounding/ucm378645.htm

D. Validate that the 503B pharmacy is a registered "Outsourcing Facility" or "Nonresident Outsourcing Facility" with the California State Board of Pharmacy http://www.pharmacy.ca.gov/online/verify_lic.shtml

E. If purchasing controlled substances, validate that the pharmacy has a valid DEA license.

F. If a Form FDA-483 has been issued, review the report (downloadable from the FDA website) and then validate with the outsourced sterile compounding pharmacy that all of the observations identified in the report have been rectified.

G. The 503B pharmacy must provide a copy of their last quarterly quality assurance report for review before any products are obtained from them. Quarterly reports are to be reviewed for any outsourced sterile compounding pharmacy that is actively providing sterile products to CCRMC. A pharmacy representative provides a summary of these quarterly reports on a regular basis to the Medication Safety Committee.

H. If there is ever any uncertainty as to the quality of products produced by the outsourced sterile compounding pharmacy, they will not be used.

I. Documentation of all licenses and registration will be printed and maintained for any outsourced sterile compounding pharmacies used.

J. Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy, (e.g. a 503A pharmacy) shall report the contractual agreement to the Board of Pharmacy within 30 days of commencing that compounding as per Business and Professions Code 4123

REFERENCES:

A. CA State Board of Pharmacy B&PC 4123, 4034, 4129, 4303.1

B. FDA Registered Outsourcing Facilities https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities

C. DEA

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date

Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19980202**

Origination	03/2004	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	02/2026		
Next Review	3 years after approval		

Policy for Patient's Own Medication – Storage & Destruction

POLICY STATEMENT:

To provide guidelines for the storage of patient's own medications (POM) during hospitalization and their destruction, if unclaimed within thirty (30) days of discharge.

Medications that have been brought in by patients at admission will be sent home with the family whenever possible. During their stay and after their discharge, the medications will be itemized, bagged, and stored in the Pharmacy Department in a specified location according to a specific procedure.

GUIDELINES:

Home medications brought in will be itemized and sealed in a white numbered patient medicine envelope and taken to pharmacy for storage.

The pharmacy dept. does not store any patient's own medication in the form of a Controlled Substance (CI-CV)

If the pharmacy is closed, the bag will be placed in the medication vault in the Nursing Office. Pharmacy will empty the vault every morning.

The medications will be logged into the patient's medication log with the date, name of patient and serial number of the bag. A treatment team sticky note will be placed in the patient's electronic chart.

If the patient, patient's representative, or nurse picks up the bag from Pharmacy on discharge, the bag is logged out to whoever picks it up. The bag is verified by a pharmacist before being signed out.

If patient is admitted to the Psychiatric Emergency Department (PES) with patient's own medication(s),

PES staff may store the POM in a sealed numbered POM envelope and place in a secure area in the medication room. The POM is returned to the patient by the nurse upon discharge from PES.

Patient's medication may only be destroyed upon the physician's order or if the medication is not claimed within thirty (30) days of discharge.

Medications will be destroyed following pharmacy policies and procedures for destruction of medications.

~~Regarding the storage and destruction of patient's own medication of patients with confirmed or suspected COVID-19 infection, please refer to Policy for Medication Management in the State of Emergency (Covid-19).~~

RELATED LINKS:

Policy for Drug Distribution: Controlled Medications

~~Policy for Medication Management in the State of Emergency (Covid-19)~~

REFERENCES:

A. TJC Standard MM.03.01.05, MM.06.01.03
B. CMC CoP § 482.23(c), 482.25(a)(b)
C. Title 22, § 70263 q11(a)(b)

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2022~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19940497**

Origination	03/2004	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	02/2026		
Next Review	3 years after approval		

Policy for Pharmacist Order Verification

POLICY STATEMENT:

To ensure safe ordering and dispensing of medications.

~~A pharmacist will review all prescriptions or orders for medication prior to administration. Exceptions are made for a licensed independent practitioner (LIP) controlled environment when the LIP controls the ordering, preparation, and administration of the drug. Such environments include:~~

- ~~Emergency Department~~
- ~~Pre-operative patients~~
- ~~Labor & delivery- from delivery thru post-recovery period~~
- ~~GI and Radiology- for contrast media via protocol and other procedural medications~~

~~Other exceptions include: STAT or one-time orders; and urgent situations when the resulting delay would harm the patient, including situations in which the patient experiences a sudden change in clinical status or sudden onset of symptoms (e.g. nausea, pain, cardiac events, sepsis, fever); if waiting for a pharmacist to review the order would result in clinical harm to the patient.~~

~~All such exceptions as described above will result in orders being reviewed by a pharmacist retrospectively.~~

~~Drug classes that are available for the above scenarios include:~~

- ~~Pain and antipyretic medications~~
- ~~Cardiac medications (e.g. antithrombolytics, antiarrhythmics, anticoagulants, antihypertensives, etc.)~~

- ~~Antiemetics~~
- ~~Code medications~~
- ~~Antibiotics and other anti-infectives~~
- ~~Reversal agents /rescue medications~~
- ~~Any other medication required urgently for various clinical conditions~~

Exceptions are made as per Policy for Automated Drug Delivery Systems – Pharmacist Order Verification and Policy for Automated Drug Delivery Systems - Override and Emergency/STAT Medication Orders

This policy applies to Pharmacy and Nursing.

GUIDELINES:

A pharmacist will review all orders, checking for:

- Completeness of the order
- Appropriateness of the drug order, dosage, route, frequency, and indications
- Real or potential allergies or sensitivities (including drug, food)
- Drug incompatibilities
- Therapeutic duplications
- Real or potential interactions between the prescribed medication(s) and other medications or food
- Current or potential impact as evidenced by laboratory values
- Contraindications
- Variations from CCRMC's criteria for use
- Applicable black box warning

Any questions or clarification of the order shall be directed back to the provider by the pharmacist for provider clarification in the computer system.

If verbal clarification is obtained by the pharmacist from the provider, the order shall be entered into the computer by the pharmacist, read back to the provider, and the new order entered as a Verbal with Readback: Cosign.

Drugs needing to be dispensed from the Pharmacy will be dispensed only after review of the order. A 24 hour supply will be dispensed unless:

- The provider indicates a lesser quantity or duration of therapy.
- The medication has a restriction as to dispense quantity or duration of therapy.
- The medication comes in a unit-of-use package (inhaler, tube, dropper, etc)
- The medication is stocked in the unit's automated dispensing machine.

An independent double-check will be performed by a second pharmacist for parenteral nutrition orders, chemotherapy orders, and neonatal orders for medications dispensed by Pharmacy. In the event a second pharmacist is not available, the double-check may be performed by a nurse.

The following are the expected turn-around times for orders, once they are received in pharmacy. This includes entry into the computer and delivery to the floor:

- 'STAT' orders: immediately. They are to receive the highest priority.
- CAP and sepsis antibiotic orders: immediately
- 'Urgent' orders: within 1 hour
- 'Routine" orders: within 1.5 hours.
- 'Non-urgent' orders: within 2 hours

If the medication is not stored in the ~~ADM~~ADDS, the first dose of the medication will be delivered to the unit and the subsequent doses will be dispensed through cartfill and IV delivery before the next scheduled due time.

When the Pharmacy is closed, an after-hours order entry service will review all orders entered into the computer system by providers. This will release the order to the floor and the order will appear on the automated dispensing machine. If the medication is not available on the floor, the Medical Center Supervisor (MCS) will be contacted to check alternative ~~ADMs~~ADDS for medication availability by referring to the pharmacy provided ~~ADM~~ADDS item stock list. If the medication is not available on any of the ~~ADMs~~ADDS on the floors, the MCS will gain access to the Night Locker to obtain the medication. If the medication is not available in the Night Locker, the on-call pharmacist will be contacted.

REFERENCES:

~~TJC Standard MM.04.01.01, MM.05.01.01, MM.05.01.07, MM.05.01.11, MM.05.01.09, PC.02.01.03 (2022)~~
~~CMS CoP § 482.11(a), 482.23(c), 482.24(c), 482.25(a)(b), 482.28(b)~~

~~APPROVALS:~~

~~Clinical Practice Committee: 6/22~~
~~Patient Care Policy & Evaluation Committee: 3/22~~
~~Medical Executive Committee: 4/22~~

A. TJC Standard MM.04.01.01, MM.05.01.01, MM.05.01.07, MM.05.01.11, MM.05.01.09, PC.02.01.03
B. CMS CoP § 482.11(a), 482.23(c), 482.24(c), 482.25(a)(b), 482.28(b)

Approval Signatures

Step Description	Approver	Date

Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19762601**

Origination	09/2003
Last Approved	N/A
Effective	Upon Approval
Last Revised	03/2019
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Pharmacy Hazard Communication Program

POLICY STATEMENT:

Pharmacy has developed a local Hazard Communication Program to protect the health and safety of staff. The program is intended to provide information about chemical hazards and other hazardous substances and the control of these hazards through container labeling and MSDS training.

It is our policy that no container of hazardous substance will be released for use until the following label information is verified:

A. Container is clearly labeled as to contents
B. All appropriate hazard warnings are noted
C. The name and address of the manufacturer is present

GUIDELINES:

Employee Information and Training:

Employees will be oriented to the following:

A. Overview of the requirements contained in the Hazard Communication Regulation, including their rights under the regulation
B. Inform employees of any operation(s) in their work area where hazardous substances are present
C. Location and availability of the written Hazard Communication Program
D. Physical and health effects of the hazardous substances

E. Methods and observation techniques used to determine the presence or release of hazardous substances in the work area

F. How to lessen or prevent exposure to these hazardous substances through usage of control, work practices and personal protective equipment

G. Steps the department has taken to lessen or prevent exposure to these substances

H. Emergency and first aid procedures to follow if employees are exposed to a hazardous substance

I. How to read labels and review MSDS to obtain appropriate hazard information

Hazardous Non-Routine Tasks:
Periodically, employees may be required to perform hazardous, non-routine tasks. Prior to starting work on such projects, each affected employee will be given information about any hazards to which they may be exposed during the activity.

The information will include:

A. Specific hazards

B. Protective/safety measures which must be utilized

C. Measures the department has taken to lessen the hazards include ventilation, respirators, presence of other employees, and emergency procedures.

RELATED LINKS:

A. Overview of the Hazard Communication Regulation

REFERENCES:

A. TJC Standards EC.01.01.01, EC.03.01.01, HR.01.04.01, HR.01.05.03, HR.01.06.01

B. CMS CoP § 482.11(a), 482.13(c), 482.23(c), 482.25(a)(b, 482.41(a)(b)(c), 482.42(a)(b)

C. OSHA Regulations

D. USP <800> Hazardous Drugs – Handling in Healthcare Settings

APPROVALS:

Patient Care Policy and Evaluation Committee: 3/2024
Medical Executive Committee:
Joint Conference Committee:

OVERVIEW OF THE HAZARD COMMUNICATION REGULATION

The Hazard Communication Regulation is intended to ensure that both employers and employees are aware of the dangers associated with hazardous substances within their workplace.

The following information is a review of the specific requirements of a hazard communication program, including labeling and Material Safety Data Sheets (MSDS)

WRITTEN HAZARD COMMUNICATION PROGRAM

Written programs that outlines how we will provide information and control staff's exposure to hazardous substances. The plan is available for review at all times.

READING LABELS AND MSDS

A product label on both the original and secondary containers should be reviewed prior to working with any unknown material. Each label has important pieces of information that staff should be familiar with:

- The identity of the hazardous substance
- Hazard warnings

The label on the original container will also state the name and address of the manufacturer.

The label should act as a visual reminder of the information presented in training sessions and of the information found in more detail on the MSDS.

It is essential for staff safety that the Hazard Warnings be read and any/all warnings are followed. Any questions should be referred to the supervisor or to the CCRMC Safety Officer.

Material Safety Data Sheets (MSDS) are the primary means of learning about hazards of the medications and chemicals stored in Pharmacy. The manufacturers and importers are responsible for preparing and providing MSDS upon request.

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19974957**

Origination	09/2015
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	3 years after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Prescribing & Ordering – General Practices

POLICY STATEMENT:

CCRMC will develop, implement and maintain policies and procedures to support prescribing and ordering of drugs that ensure the safe, clear and legal use of drugs. Best practice, external and internal data and the risks of medication(s) are considered when developing medication policies and procedures.

The healthcare organization shall educate the medical staff and other healthcare professionals regarding the organization's medication policies and procedures and to provide guidelines and definitions for providers when ordering/prescribing medications

GUIDELINES:

All orders for medication and treatment must be complete, legible, and appropriate. Providers should input orders through computerized physician order entry. The prescribing practitioner will be contacted for clarification of any orders staff members feel are not complete, legible, or appropriate.

To be considered complete, all medication orders shall include the generic and/or brand name of the drug, the dosage and strength, the quantity or duration (as appropriate), the route and frequency of administration, the time and date the order was placed, and the prescriber's signature/authorization (electronic or handwritten). The patient's name must be documented or written on the prescription.

The use of the terms **"renew", "repeat"** and **"continue"** in reference to previous orders are not acceptable.

If the patient's age and weight and any known allergies or lack thereof is not documented in the medical record at the time the order is written, the prescriber shall obtain these facts and document them with the order.

Medication orders shall not use apothecary units of measure.

Dosage measurements recorded as a unit less than one (1) will have a leading zero. Dosages measured in whole numbers will not use a trailing zero.

A. **Definitions**: When used with medication orders:
    1. "**Hold**" status is not permitted once the order has been active. If a provider wishes to temporarily stop a medication, the order is to be discontinued and then reordered when the provider wants to resume therapy.
    2. "**Stat**" means within 15 minutes. Nurses are authorized to remove medication from the ADDS, if available, as an acceptable override.
    3. "**Now**" means within one (1) hour
    4. Orders sent to Pharmacy as "**Routine**" are to be processed within two (2) hours
    5. **Standing orders** means a group of orders that commonly apply to all or almost all patients of a like category and reflect generally accepted medical therapies. Standing orders are written documents/order sets containing medical directives for the provision of patient care in selected stipulated clinical situations. Standing orders must be approved by the medical *and* nursing staff for use in this facility. Standing orders may be revised in accordance with the necessity to individualize the orders to the needs of the specific patient to which the orders have been applied. As standing orders related to this policy and procedure, standing orders may contain orders for the dispensing, administration and monitoring of patient effects of medication.
    6. **Signed and held orders** New prewritten (held) medication orders that become active upon release

B. **Medication Profiles:** All relevant medical information is available in the EHR on all patients. The information contained includes age, gender, current medications, pertinent diagnosis & conditions, pregnancy and lactation status, allergies and sensitivities. Relevant lab values can be reviewed in the EHR along with the height and weight (when necessary). In the event a concern is identified, i.e. drug-drug interaction, dosage modification based on renal function or age, drug-food interactions; the inpatient medication profile information is accessible through the EHR. The pharmacist providing clinical services will examine the medication profile to facilitate continuity of care and to supplement monitoring of adverse drug reactions.

C. **Intervention**: Any orders requiring clarification will be logged as an intervention.

D. **Abbreviations**: Medication orders shall not contain abbreviations and symbols included on the "unacceptable medication abbreviation/symbols list."

E. **Diagnosis**: There must be evidence of a diagnosis, condition or indication for use in the medical record for each medication ordered by the patient's licensed independent practitioner.

F. **Transfer Orders**: When a patient is transferred to a higher level of care or to the operating room, all existing orders for patients shall be reviewed for appropriateness by either discontinuing or continuing the medication (i.e. transfer medication reconciliation).
    1. Orders shall be reconciled by the provider within twelve (12) hours of transfer. The transfer medication reconciliation process can be generated from the computer

system.

2. All transfer orders are verified by a pharmacist.

G. **Generic Substitution**: For drug entities for which there are multiple sources and a competitive bid opportunity exists, the Pharmacy Department, in collaboration with the hospital's purchasing group, will determine the source of medications. The Patient Care Policy & Evaluation Committee may, at its discretion, determine the source for selected drugs and such information will be disclosed in the formulary. The physician may elect to not allow generic substitution by so stating in writing on the initial order.

H. **PRN:** Orders for "as needed" or "PRN" medications shall specify the indication(s) for use and be specific for dose and dosage frequency.

I. **Standard Administration Times:** All medication will use CCRMC-defined standard administration times, unless pharmacy has assigned medication properties dictate otherwise.

1. See Policy for Standard Administration Times for Medications

J. **Therapeutic Substitution**: In limited, low risk, high volume cases certain drugs or products may be substituted for different drugs or products. Examples of such items are liquid antacids and multivitamins. The Patient Care Policy & Evaluation Committee shall authorize such substitution and shall make the medical and nursing staff aware in the formulary and other publications. *See Attachment A.*

1. Pharmacist may select a different form of medication with same active chemical ingredients based on availability (i.e. syringe to vial, vial to IVPB, tablet to capsule, tablet or capsule to oral solution)
2. Pharmacist may change dispense quantity on discharge prescriptions to comply with discharge medication policy (See Policy for Patient Discharge Medications)
3. Pharmacist may correct the auto stop date/time pursuant to Policy for Automatic Stop Orders.
4. Pharmacist may discontinue duplicated medications.
5. Pharmacist may change administration time of medications when clinically appropriate.

K. **Medication Related Devices**: A medication related device is a special device used to deliver medication to the patient (such as a nebulizer). The medication related device must be present to allow the patient to receive the medication in the manner intended.

1. To further clarify, a medication related device such as a nebulizer is required to provide the medication in the *manner* the LIP (Licensed Independent Practitioner) desires.
2. All medication related devices must be specifically ordered by the LIP, i.e., _____ mg of albuterol via handheld nebulizer.

L. **Verbal Orders**: Verbal (direct or telephone) orders are only permissible in emergent situations or when the provider is not able enter the order personally.

1. Verbal orders are to be entered immediately and read back to the provider for confirmation of correctness.

2. Verbal orders for drugs may be taken by a pharmacist or licensed nurse, as well as RT and PT within the scope of their practice, and as approved by the institution. (See Policy for Verbal and Written Orders - General). Verbal orders must be cosigned by the physician ordering the medication within 24 hours.
3. All verbal and/or telephone orders for medications shall include the following criteria:
    a. Date and time the order is prescribed verbally or via telephone
    b. The name of the individual prescribing the drug and his/her licensure (i.e., MD, DPM)
    c. The generic and/or brand name of the drug
    d. Drug dosage (strength or concentration)
    e. Quantity and/or duration, as appropriate
    f. Route drug is to be administered
    g. Frequency of administration
    h. Age and weight of the patient if this is not known, or in clinical circumstances where this is appropriate
    i. Known allergies (if this has not been determined prior to the time of the verbal/telephone order)
    j. Specific indications for use, as appropriate
    k. Name and level of licensure of the individual receiving and documenting the order. Verbal or telephone orders will not be accepted for chemotherapies.

M. **Investigational medications**: Patients may receive investigational medications while admitted to the hospital. These medications may be part of a CCRMC-sponsored investigational protocol or from an outside source. (See Policy for Investigational Drugs/ Review Committee/ Board)

N. **Signed and held orders**: Licensed independent practitioner may order appropriate sign and held medication orders that become active upon release

O. Compounded medications: The Pharmacy will prepare compounded drugs in situations where drugs are not commercially available, are widely used based on literature reports, and where there exists a formula for the preparation of these products. (See Policy for Compounding of Medications)

P. Discharge medications: CCRMC does not routinely provide discharge medications for patients except in specific situations. (See Policy for Patient Discharge Medications)

Q. **Drug Shortages**: Drug shortages are dealt with as proactively as possible through the following measures:
    1. Alternate suppliers
    2. Alternative therapy options
    3. Therapeutic substitution protocols/privileges obtained from the Patient Care Policy

& Evaluations Committee (PCP&E). See Policy for Drug Shortages

4. Drug shortages are communicated to medical staff and other healthcare providers via:
    a. Ongoing reports to the Medication Safety Committee and PCP&E
    b. E-mails
    c. Memos
    d. Screen-savers
    e. Phone calls, pages, etc.

R. **Recalls**: When Pharmacy learns of a drug recall: (See Policy for Medication Recall)
    1. Product inventory is taken and any recalled product is isolated for appropriate action
    2. Staff are notified
    3. Patients are contacted for all class I recalls
    4. If all product is affected, a therapeutic alternative is selected and ordered

S. **Laboratory Monitoring:** The Patient Care Policy & Evaluation Committee has authorized pharmacists to write orders for all necessary laboratory tests which may include but not limited to the following:
    1. **Fasting Blood Glucose, Hgb A1C, and Cholesterol Panel for Atypical Antipsychotics:** Ordered on all hospitalized patients taking atypical antipsychotics and not having these lab tests in the past 3 months
    2. **Phenytoin levels Upon admit OR with a dose change:** Levels on Day 0, day 3, Day 7, day 14, Day 21, Day 28 and weekly thereafter. *Note* if there is a drug-drug interaction, dose/metabolic change that can affect Phenytoin plasma concentrations, Phenytoin level monitoring will restart at day 0 as listed above.
    3. **Serum creatinine levels**: Ordered as needed for medications that require renal dose adjustment and/or pursuant to Policy for Monitoring and Dosage Adjustment: Vancomycin and Gentamicin
    4. **Pro-time/INR:** in patients who are being anti-coagulated when appropriate
    5. **Medication serum levels:** Vancomycin (peak and/or trough), aminoglycosides (peak and/or trough), phenytoin (see above), valproic acid, lithium, carbamazepine, phenobarbital, digoxin
    6. **CBC or CBC with differential:** patients on heparin or LMWH (i.e. enoxaparin) or clozapine (to obtain WBC and ANC)
    7. **aPPT: for patients on heparin IV**

T. **Chemotherapy:** Only oncology providers are granted access to the oncology treatment group in the physician order entry system and, as such, are the only providers who have access to enter new orders or renew orders for oncology medications.
    1. To avoid drug wastage and medications errors, pharmacist will do the following:
    2. Ordered chemotherapy or biologics doses may be rounded up or down by **10% for**

palliative therapy and **5% for curative therapy** by the pharmacist during the verification process without prior authorization of the ordering physician.

3. For patients who may not be a good candidate to dose rounding, physicians must notify pharmacists (i.e. do not modify the dose)

RELATED LINKS:

~~Attachment A. CCRMC Pharmacy Therapeutic Substitution List~~

Policy for Standard Administration Times for Medications

Policy for Patient Discharge Medications

Policy for Automatic Stop Orders

Policy for Verbal and Written Orders - General

Policy for Compounding of Medications

Policy for Drug Shortages

Policy for Medication Recall

Policy for Investigational Drugs/ Review Committee/Board

Policy for Monitoring and Dosage Adjustment: Vancomycin and Gentamicin

REFERENCES:

A. TJC Standards MM.01.01.01, MM.02.02.01, MM.03.01.01, MM.04.01.01, PC.02.01.03, MS.03.01.01
B. Standard Administration Times Policy
C. CCRMC Policy # 544: Medication Reconciliation
D. CMS CoP § 482.11(a), 482.12(a)(c)(f), 482.23(c), 482.24(c), 482.25(a)(b), 482.28(b), 482.55

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 4/23~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Attachments

A: CCRMC Pharmacy Therapeutic Substitution List

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19756511**

Origination	09/2003	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	01/2026		
Next Review	1 year after approval		

Policy for Procurement of Medications

POLICY STATEMENT:

All pharmaceuticals; including drugs, biologicals, chemicals, related to the practice of pharmacy, that are procured by the Pharmacy Department, shall meet the criteria as set forth in the United States Pharmacopeia or National Formulary or Federal Drug Administration requirements for drugs or found in the current literature as an extemporaneously used formula with valid cause.

The selection, distribution, and safe and effective use of drugs at CCRMC shall be established by the combined efforts of the Pharmacy Director, Pharmacy Department, medical staff, and hospital administration.

These policies will be approved by the Patient Care Policy & Evaluation (PCP&E) Committee.

The drug supply shall contain that type and quantity of drugs necessary to meet the needs of the categories of patients that are serviced at CCRMC as determined by the Patient Care Policy & Evaluation (PCP&E) Committee.

The Pharmacy Director and pharmacy staff shall be responsible for maintenance and the supply as well as assuring that all drugs are properly labeled and stored.

Factors to consider in purchasing a generic or brand name drug:

- Bioavailability of drug
- Reputation of manufacturer
- Contract or non-contract price
- Availability (local or distant)

- PCP&E recommendations

GUIDELINES:

A. Ordering:

1. Orders will be made by the Pharmacy Director or his/her designee. Orders are prepared as often as needed and sent using the wholesaler's computerized ordering system. Certain medications may be ordered directly from the manufacturer.
2. The Pharmacy maintains accounts with the following supplier: Wholesaler: Cardinal Health (inpatient and outpatient)
3. If the wholesaler is out of stock, alternative sources are:
    a. Direct: drug manufacturers, licensed reputable secondary suppliers
    b. Medline: manufacturer and distributor of healthcare products and solutions
    c. In emergency situations, medications may be obtained, borrowed and returned, from any local hospital or pharmacy
    d. 503A and 503B registered outsourcing facilities when needed
4. Schedule II medications shall be ordered online via DEA Controlled Substance Ordering System (CSOS) by a pharmacist registered/authorized to do so. If CSOS is not available, then the required DEA form 222 shall be utilized.

B. Receiving:

1. After the product is delivered directly to the Pharmacy or via Materials Management, the order will be checked against the packing slip and invoice. The Pharmacy copy of the purchase order is then checked against the packing slip/invoice. While verifying that the order is correct, and all items arrived, any discrepancy should be noted and relayed to the appropriate person for resolution.
2. Each item will have the cost of purchase recorded on the package. The items will then be incorporated into the inventory. Utilize the wholesaler sticker if provided.
3. If the items received were not accompanied by an invoice, and thus unavailable for pricing, they will be put aside until an invoice is obtained and the items are able to be priced and placed into inventory.
4. Receipt of a Schedule II drug shall be checked against the original DEA order form or CSOS document and notations of the date and quantity received should be made on the space provided by the Pharmacist.
5. Upon receipt of a hazardous drug, the exterior shipping container shall be inspected for damage or breakage (e.g., visible stains from leakage, sounds of broken glass, etc.). Unpacking shall be performed in an area neutral/normal or negative pressure relative to surrounding areas, to facilitate containment. Unpacking shall be performed by personnel wearing appropriate personal protective equipment (PPE), including, but not limited to chemotherapy gloves.

C. Invoices:

1. A copy of all invoices will be kept in the Pharmacy Department filed according to supplier. A copy of each invoice will be forwarded to Accounts Payable.
2. A copy of an invoice containing Schedule II drugs shall be stapled to the Pharmacy Department copy of the DEA order form or CSOS document and the narcotic vault receipt and kept in a separate file.
3. Copies of invoices containing drugs in Schedules III, IV and V shall be kept in a separate file.

D. Damaged Goods, Short-dated Items and Delivery Errors will be reported to the vendor and compensatory action will be taken to correct shortages and return any items that were received but not ordered.

E. Outdated medications will be returned through CCRMC's contracted pharmaceutical waste management company. Outdated medications may also be returned directly through the manufacturer after conferring with the company representative.

F. Shortages:
    1. Drug shortages are dealt with as proactively as possible through the following:
        a. Alternate reputable suppliers (See Ordering Section)
        b. Alternate therapy options
        c. Therapeutic substitution protocols/privileges obtained from the Patient Care Policy and Evaluations Committee (PCP&E) for pharmacists
    2. Drug shortages are communicated to medical staff and other health care providers via:
        - Ongoing reports to the Medication Safety Committee and PCP&E
        - E-mails
        - Memos
        - Screensavers
        - Phone calls, pages, etc.

G. Large Volume Parenterals:
    1. The Pharmacy Technician assigned to IV compounding will note the quantity of large volume parenterals on hand in the Pharmacy. Based upon this inventory, the Pharmacy Technician will send a requisition to Materials Management who will then fill the order from existing stock and deliver to Pharmacy. Medline also supplies large volume parenterals and other supplies via a Medline Cart situated in the Inpatient Pharmacy and Outpatient Pharmacy. PAR levels are set for each item and assessed daily by Medline staff for restocking daily as needed. PAR levels can be adjusted as needed with Medline Management and/or Materials Management to meet demand.
    2. Certain premixed IV preparations are ordered directly or from the wholesaler. These products are to be ordered on an as-needed basis and in sufficient quantity to meet demand.

3. All shipping cartons should be inspected immediately upon receipt for:
    - Water marks
    - Signs of excessive abuse in handling (crushed or broken cartons)
4. Damaged cartons should be separated from the remainder of the shipment for inspection by a Pharmacist. The damaged carton should be returned to Materials Management who will attempt to obtain prompt replacement by the manufacturer.
5. Stock shall be rotated with the earliest expiration dated items to be used first.

REFERENCES:

A. TJC MM.02.01.01

B. CMS CoP § 482.23(c), 482.25(a)(b)

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19948562**

Origination	03/2016
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Quality Assurance in Pharmacy

POLICY STATEMENT:

The Department of Pharmacy Services strives to provide services and pharmaceutical products of the highest quality. This is achieved through a multi-pronged approach, beginning with the interview/hiring process, and continues through staff orientation, ongoing training, competency assessment, use of external resources and references, process monitors, spot audits, etc.

GUIDELINES:

A. **Staff members**:

1. The Pharmacy Department's emphasis on quality begins with the interview/hiring process. Clinical skills and experience are assessed with a set of standardized questions. Only candidates with an optimal skillset are considered for employment.
2. After hire, a new employee receives an extensive orientation to the department, including policies and procedures. In addition, the employee's skills are assessed with baseline testing (e.g. math skills; hazardous materials, etc.)
3. All new hires must complete an online didactic course in aseptic compounding, read pertinent county policies, pass 3 soy broth challenges in appropriate environments (e.g. negative and/or positive pressure containment primary engineering control (PEC)) and pass an aseptic technique competency assessment prior to being allowed to compound sterile products. (See Policy for Compounding Competency Assessment)
4. The county's probationary period allows for on-the-job assessment of skills and competency and early intervention with education and training when necessary.

5. On an annual basis, all staff members must successfully pass a 'Safety and Infection Control Regulation and Review (SICRR)'. Staff members involved with aseptic compounding must repeat the entire aseptic compounding training and competency assessment annually.
6. Staff education and development is ongoing.

B. Internal and external resources and references used include, but are not limited to:
    1. Institute for Safe Medication Practices
    2. Center for Disease Control
    3. The Joint Commission
    4. California Board of Pharmacy
    5. Federal Drug Agency
    6. Drug Enforcement Administration
    7. Professional journals (e.g. AHA/ACC, ASHP, NEJM, Medscape, Journal Watch, Medical Letter, Medical Letter Guidelines, Pharmacists' Letter, AJHP, National Guidelines Clearing House, JAMA, Lancet, Chest, BOP, FDA, MedAlert Circulation, TJC Perspectives, etc)
    8. California Department of Public Health
    9. Local pharmacy directors' group
    10. Online queries (listserve, etc.)
    11. CCRMC drug formulary
    12. Master compounding formula record
    13. Various gap analysis tools, self-assessments

C. Process monitors are in place using tools within ccLink and VigiLanz to name a few for all aspects of the medication management process. They include, but are not limited to:
    1. ~~Medication error data collection and analysis~~Medication error data collection and analysis
        a. For purposes of Automated Drug Delivery System (ADDS), a “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in 16 CCR Section 1716, excluding corrections corrected prior to furnishing the drug to the patient or patient's agent or any variation allows by law. Examples of medication errors related to the use of an ADDS, include, but are not limited to, the following:
            i. A drug removed from the ADDS that is the wrong drug, strength, quantity or contains incorrect directions for use.
            ii. The nurse removes the wrong drug from the ADDS.
            iii. An ADDS that packages the drug in plastic pouches containing 2 tablets and should only contain one tablet as prescribed.
    2. Adverse Drug Reaction data collection and analysis

3. Antibiotic stewardship
4. Turn-around-time
5. Alaris pump
6. Override
7. Rescue medications
8. Medication shortage
9. Physician order review and validation by pharmacist
10. Audit of pharmacy dispensing practices
11. Inpatient prescriptions
12. Repackaging
13. Sterile product preparation involves several monitors some of which are listed below:
    a. Air quality testing
    b. PEC testing and certification
    c. Surface sampling
    d. Media-fill testing
    e. End-product testing
    f. Final product inspection
    g. Product potency validation
    h. Qualitative and quantitative checks

D. Specific monitors and programs using different technologies and software including but not limited to VigiLanz, ccLink (EHR), Alaris pump are in place to achieve quality assurance in the pharmacy department in relation to medication management.

E. For quality assurance for outsourced compounding pharmacies refer to Policy for Outsourced Compounding Pharmacy- Quality Assurance.

F. Quality Assurance reports of medication errors related to the use of automated drug delivery system (ADDS) will be internally reported using the online Safety Events Reporting System (SERS).
    1. A quality assurance review of the error is performed and documented, including investigation of the source of the event, findings, and recommendations for initiation of system improvement, and/or staff re-education as needed.
    2. In addition, quality assurance reports will be shared with the California State Board of Pharmacy at the cycle required by the licensing status:
        a. Unlicensed ADDS: at annual review of facility license via email to ADDS@dca.ca.gov or with the renewal application
        b. Licensed ADDS: within 30 days of completion of quality assurance review via email to ADDS@dca.ca.gov or mail

G. Quality Assurance for contracted services:

1. Staff hired through Contracted Services are held to the same standards as noted in letter A. above
2. The staff hired through the Contracted Service are expected to:
    a. Have a current California Board of Pharmacy Licensure and in good standing with the BOP (Contracted service is expected to check the above)
    b. Staff are to conduct themselves in a professional manner and adhere to all departmental policies including but not limited to being punctual and professional (Contracted service will be contacted for any deviation from this practice)
    c. Staff are expected to adhere to all Medication Management and Medication Safety Standards. Any medication errors are documented in SERS and tabulated.
    d. Staff are expected to complete all required departmental competencies in a timely manner. Any deviations from the above will be communicated to the Contracted Service.

RELATED LINKS:

Policy for Compounding Competency Assessment

Policy for Outsourced Compounding Pharmacy- Quality Assurance

REFERENCES:

A. TJC MM.01.01.01, MM.01.01.03, MM.01.02.01, MM.03.01.01, MM.03.01.03, MM.04.01.01, MM.05.05.01, MM.05.01.07, MM.05.01.09, MM.05.01.11, MM.05.01.13, MM.05.01.17, MM.05.01.19, MM.06.01.01, MM.06.01.05, MM.07.01.03, MM.08.01.01, PI.01.01.01, PI.02.01.01, PI.03.01.01, LD.03.02.01, LD.03.05.01, LD.03.06.01, LD.04.04.01

B. CMS CoP § 482.11(a), 482.12(b)(d)(f), 482.21(a)(b)(c)(d)(e), 482.23(c), 482.25(a)(b), 482.41(c), 482.42(b), 482.54(b), 482.55

C. CA Pharmacy Law § 4125, 4198, 1711, 1716, 1735.8, 1751.3, 1751.7

D. ~~CCRMC Pharmacy Policies and Procedures~~

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19955805**

Origination	02/2009	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	07/2025		
Next Review	1 year after approval		

Policy for Reporting Diversion of Controlled Substances

POLICY STATEMENT:

All known or suspected diversion of controlled substances will be reported to the appropriate authorities, in accordance with County policies and state and federal regulations.

This policy provides guidelines for reporting drug diversion of controlled substances to the appropriate authorities.

GUIDELINES:

A. Known or suspected diversion must be reported immediately to the department head. The department head is responsible for investigating the incident and notifying the Director of Pharmacy.

B. The Director of Pharmacy Services can and will report all thefts by all disciplines to the DEA and the California Board of Pharmacy.
    1. Affected Department Heads will be notified
    2. Information will be provided to affected Department Heads to report to other regulatory agencies as appropriate (e.g. Board of Registered Nursing, Medical Board, etc.)

C. Reporting a Loss
    1. Definition of Significant Loss
        a. Any loss of a controlled substance, regardless of amount, attributed to employee theft
        b. A trend or pattern of losses repeated over a period of time using software

and technology

c. Losses where the aggregate amount discovered in that category, on or after the same day of the previous year, that equals or exceeds the following, as defined by the Board of Pharmacy Title 16 CCR 1715.6:

i. 99 dosage units – for tablets, capsules, or other oral medications

ii. 10 dosage units – for single-dose injectable medications, lozenges, film (such as oral, buccal, and sublingual), suppositories, or patches

iii. 2 dosage units – for multiple-dose injectable medications/vials, medications administered by continuous infusion, or any other multi-dose unit/container not previously described above.

2. Reporting to the Board of Pharmacy (BOP)

a. The report must be made no later than thirty (30) days after the date of the discovery of the significant loss defined in section (1) above.

b. The report shall specify the identity, amounts, and strengths of each controlled substance lost, and date of discovery of the loss, for all loses that have made the report necessary.

c. Any loss due to theft, diversion, or self-use of a licensed individual employed by or with the pharmacy shall be made within 14 days of discovery as per B&PC section 4104.

3. Reporting to the Drug Enforcement Agency (DEA)

a. Notice of the theft or significant loss must be provided in writing directly to the local DEA Diversion Field Office within one (1) business day upon discovery.

b. The DEA registrant must keep a copy of the notice for its records.

c. The DEA registrant must complete a DEA form 106 (Report of Theft or Loss of Controlled Substances).

RELATED LINKS:

DEA Form 106: https://apps.deadiversion.usdoj.gov/webforms/dtlLogin.jsp

Board of Pharmacy Online Portal for Reporting Theft or Loss of Controlled Substances: Report Drug Loss - California State Board of Pharmacy

REFERENCES:

A. TJC Standards MM.01.01.03, MM.05.01.11, EC.02.01.01, LD.04.01.11

B. CMS CoP § 482.11(a), 482.13(c), 482.23(c), 482.25(a)(b), 482.41(a)(c)

C. California Board of Pharmacy Law Health and Safety Code 4104, CC&R Title 16 §1715.6

D. DEA Pharmacist's Manual https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046)(EO-DEA154)_Pharmacist_Manual.pdf

E. Diversion Control Division | Reporting

F. DEA Notification: CFR, Title 21, Sec 1301.76(b)

Attachments

Tally of Cumulative CII to CV Losses

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19756519**

Origination	12/2006	Owner	Shideh Ataii: Director Of Pharmacy Svcs
Last Approved	N/A	Area	Pharmacy
Effective	Upon Approval		
Last Revised	01/2026		
Next Review	1 year after approval		

Policy for Room Temperature Monitoring for Drug Storage Areas

POLICY STATEMENT:

The room temperature of all areas in the Inpatient Pharmacy where medications are stored will be monitored. Acceptable controlled room temperature is between 68-77 degrees F (+/- 9 degrees F), with allowed deviations between 59-86 degrees F.

GUIDELINES:

Controlled Room Temperature: A temperature maintained thermostatically that encompasses the usual and customary working environment of 68º to 77ºF; that results in a mean kinetic temperature (MKT) calculated to be not more than 77ºF; and that allows for excursions between 59ºF and 86ºF that are experienced in pharmacies, hospitals, and warehouses. Provided that the MKT remains in the allowed range, transient spikes up to 104ºF are permitted as long as they do not exceed 24 hours. Spikes above 104ºF may be permitted if the manufacturer so instructs. Articles may be labeled for storage at "controlled room temperature" or at "up to 77ºF", or other wording based on the same mean kinetic temperature. The mean kinetic temperature is a calculated value that may be used as an isothermal storage temperature that simulates the non-isothermal effects of storage temperature variations. An article for which storage at Controlled Room Temperature is directed may, alternatively, be stored and distributed in a cool place, unless otherwise specified in the individual monograph or on the label.

The room temperature of all drug storage areas in the Inpatient Pharmacy and Outpatient Pharmacy are measured via continuous wireless temperature monitoring probes and recorded automatically. If the temperature falls outside the acceptable range (68-77 °F), an alarm/alert is generated in the software

and sent to the Medical Center Supervisor (MCS) and Engineering.

The MCS will respond by notifying the on-call Pharmacist. Subsequently thereafter, Engineering will troubleshoot the reason for the excursion and make necessary adjustments to return the temperature to acceptable range (68-77 °F) for that drug storage area.

REFERENCES:

A. TJC Standards MM.03.01.01~~, EC.02.04.03, MM.03.01.01~~
B. CMS CoP § 482.13(c), 482.23(c), 482.25(a)(b), 482.41(a)(c)
C. USP 32/NF 17
D. Title 22 Article 3 § 70263
E. USP General Chapter <797>. Pharmaceutical Compounding – Sterile Preparations
F. Title 16 California Code of Regulations Articles 4.5~~, 7 and 7.5~~ § 1735~~, 1751~~

~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19223828**

Origination	09/2003
Last Approved	N/A
Effective	Upon Approval
Last Revised	11/2025
Next Review	3 years after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Standard Administration Times for Medications

POLICY STATEMENT:

To standardize administration times for inpatient medications to provide for consistent medication administration throughout the hospital and consistency of information in the various computer systems

The administration times for medications will be standardized, as much as possible. Certain oral and injectable drugs (digoxin, warfarin, antibiotics and other anti-infectives) have specific administration times based on their pharmacokinetics, or should be cycled from the time of the first dose. Certain situations (especially pediatric patients or patients in CCU, IMCU) do not lend themselves to the established times. Pharmacy will customize the administration times to fit the situation.

Certain medications should be cycled from the time the first dose is administered. Those medications include: heparin drips, vancomycin, enoxaparin treatment, aminoglycosides, ganciclovir,pentamidine, and phenytoin.

GUIDELINES:

Medications ordered with a 'sig' of letters only will be administered while the patient is awake at the following times:

Directions	Standard Times
AC (before meals)	0730—1130--1630
Daily	1000
Daily with food	0800
BID	1000--1800

BID before meals	0730-1700
TID	0600 – 1400 - 2200
TID before meals	0730 --1130-1630
QID	0600 – 1200 – 1800 - 2200
HS	2200
4C Psychiatry will utilize the following standard times for these three sigs only	
BID	1000 - 2100
TID	1000 – 1500 – 2100
QID	1000 – 1400 – 1800 - 2100

Medications ordered with a 'sig' using numbers are to be administered around the clock at the following times:

Directions	**Standard Times**
Q24H	0600 or 1000 or 1800 or 2200
Q12H	0600 - 1800 or 1000 - 2200
Q8H	0200 -1000 - 1800 or 0600-1400-2200
Q6H	0400-1000-1600-2200…or…0600-1200-1800-2400
Q4H	0200-0600-1000-1400-1800-2200
Q2H	0200-0400-0600-0800-1000-1200-1400-1600…etc

There are certain medications that have special administration times:

Directions	**Special Administration Times**
Amphotericin	1200
~~Digoxin~~	~~1400~~
Dofetilide	0600-1800
Heparin prophylaxis	1000 - 2200
Insulins (ANY)	To be given at normal administration times: e.g. BIDAC, QHS, etc
Methadone	1000
Statins (Pravachol & Simvastatin)	1800
Warfarin	1800

Medication administration times for scheduled medications should be within the following window:

- 1 hour for time-critical scheduled medications (30 min before and after scheduled time)
- Medications prescribed for daily, weekly or monthly administration may be within 2 hours before or after the scheduled dosing time, for a total window that does not exceed 4 hours.2

hours for all other medications prescribed (1 hr before and after the scheduled time)

Medications that are not eligible for scheduled dosing times may include, but are not limited to:

- Stat doses
- Now doses
- First time or loading doses
- One-time doses, or doses specifically timed for a procedure
- Drugs prescribed on as needed basis (prn doses)

Time-critical scheduled medications:
Time-critical scheduled medications are those for which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect.

Accordingly, scheduled medications identified below must be administered within **thirty minutes** before or after their scheduled dosing time, for a total window of 1 hour. Excluded are firstdose or loading dose.

- Gentamicin IV
- Tobramycin IV
- Vancomycin IV
- Phenytoin IV

The Intravenous administration of piggybacks:

- Follow dosing from Standard Administration Schedule Reference for CCRMC. Find the ordered frequency pie. Look inside the pie circle for the time the dose was administered and that is the time slot interval it will be assigned to.
- If a pre-op or intra-operative dose is the first dose, time interval assignment will be based upon that initial dose.
- If the antibiotic is to treat CAP or sepsis, the first dose must be administered within one (1) hour of being ordered.
- If there are other extenuating circumstances, Nursing should send an in-basket message, requesting the desired administration times, or by calling Pharmacy
- If a patient's therapy is interrupted and a dose becomes more than one (1) hour late, Pharmacy should be contacted for instructions on how to bring the therapy back on schedule.
- If multiple antibiotics are ordered on the same schedule, Nursing should send an in-basket message, requesting the desire time schedule for each medication. At times, multiple medications may not follow the clock and may need to be staggered to allow for proper medication administration. Nursing will need to contact Pharmacy in this regard.
- Once a schedule has been established, all attempts should be made to maintain that schedule.

  Getting doses on schedule:
  Other than the above scenarios, medications can be brought on schedule within one dose. See the attached chart for instructions.

REFERENCES:

TJC Standard MM.03.01.01, MM.04.01.01 (2022)
CMS CoP § 482.13(c), 482.23(c), 482.24(c), 482.25(a)(b)

~~APPROVALS:~~

~~Clinical Practice Committee: 6/2022~~
~~Patient Care Policy & Evaluation Committee: 3/2022~~
~~Medical Executive Committee: 4/2022~~

Attachments

Standard Medication Administration Schedule Reference for CCRMC

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	01/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	12/2025
	Shideh Ataii: Director Of Pharmacy Svcs	11/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19947419**

Origination	10/2007
Last Approved	N/A
Effective	Upon Approval
Last Revised	02/2026
Next Review	1 year after approval
Owner	Shideh Ataii: Director Of Pharmacy Svcs
Area	Pharmacy

Policy for Standing Orders

POLICY STATEMENT:

It is the policy of this institution to allow standing orders. Standing orders must meet specified criteria and must be approved by the medical staff. Standing orders are written documents containing medical directives for the provision of patient care in selected stipulated clinical situations. Standing orders are generally developed by the professional members of a healthcare entity. Standing orders are a group of orders that commonly apply to all or almost all patients of a like category, relating to routine care or standard treatment measures for common problems or conditions. Standing orders may also address emergency measures, which may be required in life-threatening situations to stabilize a patient's condition or prevent more serious complications, injury or death. Implementation of standing orders in emergency situations when a physician is not available requires critical decision-making by nurses who are competent in the recognition, understanding and interpretation of the patient's condition. Therefore, standing orders must also be approved by the nursing staff. Standing orders are to be considered a starting point in placing orders and should be individualized to the needs of each patient.

GUIDELINES:

Standing orders must:

A. Reflect generally accepted medical practices and therapies
B. Be consistent with the legal scope of nursing practice in the state in which they will be applied to the patient
C. Be approved for use in this institution through the appropriate medical staff and nursing processes

D. Be authorized and countersigned by the appropriate physician(s).

E. Be individualized as appropriate to the needs and condition of the specific patient to which the order(s) are being applied

F. Be entered into the computer system and verified with the physician prior to being implemented

G. Be reviewed by both the medical and nursing staffs on an as needed basis for revisions as necessary

H. Be implemented by a nurse or other licensed healthcare provider whose training and experience qualifies her or him for the duties and responsibilities outlined in the standard orders

I. The patient must be assessed for appropriateness of implementing the standing order. In the event that a change in the order is deemed necessary for the well-being of the patient, the ordering physician shall be notified. Orders shall be modified by the physician.

REFERENCES:

A. TJC Standard MM.04.01.01

B. TJC Standard MM.16.01.01

C. CMS CoP § 482.23(c), 482.24(c), 482.25(a)(b)

APPROVALS:

~~Patient Care Policy and Evaluation Committee: 3/2024~~
~~Medical Executive Committee:~~
~~Joint Conference Committee:~~

Approval Signatures

Step Description	Approver	Date
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari	Pending
	Shideh Ataii: Director Of Pharmacy Svcs	02/2026

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19345633**

Origination	N/A
Last Approved	N/A
Effective	Upon Approval
Last Revised	N/A
Next Review	1 year after approval
Owner	Yvonne Hollister: Utilization Review Supv
Area	Psychiatry

Inpatient Psychiatry 2025 Utilization Management Plan

POLICY STATEMENT:

Utilization Review (UR) at Contra Costa Regional Medical Center (CCRMC) is conducted to ensure compliance with State and Federal regulations on the care, treatment, and authorization for payment requirements for mental health beneficiaries who are admitted to an inpatient psychiatric unit.

GUIDELINES:

A. **UTILIZATION MANAGEMENT COMMITTEE**
CCRMC's Utilization Management Committee (UMC) is a medical staff committee. The UMC develops and oversees implementation and operation of the utilization management plan relating to the care of patients, and clinical support services. The UMC makes utilization decisions as required under the plan, analyzes utilization profiles, and evaluates the effectiveness of the UM program. Physician members of the committee act as the physician advisors required by the UM plan. The UMC meets at least quarterly and reports to the Medical Executive Committee (MEC).

1. **Composition (CFR Title 42 section 456.206):**
The Utilization Management Committee (UMC) includes:
    a. A Chairperson, appointed by the Medical Staff President.
    b. At least two (2) additional staff physicians, one of whom is knowledgeable in the diagnosis and treatment of mental disorders.
    c. Other staff physicians or physician leaders representing different departments in the Hospital/Health System.
    d. At least one (1) representative from Administration, without a vote.

e. Representative from Social Services, without a vote.

f. Representative from Nursing, without a vote.

g. Representative from Finance, without a vote.
All physician members have voting rights on UM medical issues. A quorum, at minimum, three physicians, is required to make UM medical decisions.
The Chair of the UMC serves as a member of the Medical Executive Committee (MEC) and reports from the UMC are submitted to the MEC, and thence to the Board of Supervisors via the Joint Conference Committee (JCC).

2. **Committee Functions:**
The functions of the UMC are carried out by the Committee as a whole or are delegated to the Physician Reviewer (PR). Day-to-day functions are delegated to UM Department staff, which include Registered Nurses.

The Committee is charged with the following functions:

a. Review the Inpatient Psychiatry Utilization Management Plan and update it annually.

b. Using a Concurrent Utilization Review process, review and approve medical necessity, continued stay, and administrative day criteria.

c. Ensure that the Psychiatric UR process is in compliance with state, federal and accreditation requirements.

d. Provide oversight for Medical Care Evaluation Studies.

e. Monitor and facilitate the appropriate use of clinical support and ancillary services.

f. Recommend changes in hospital policies, procedures or medical staff practices where indicated as a result of analyses finding patterns of under or over utilization.

g. Refer quality of care issues noted during review to the appropriate Manager or Clinical Service Director.

h. Maintain complete and accurate minutes of all Utilization Management Committee meetings.

i. Report UM activities to the MEC.

3. **Confidentiality (CFR Title 42, Section 456.213)**
All worksheets, minutes of meetings, findings, recommendations, reports and Medical Care Evaluation (MCE) studies shall be considered confidential in compliance with HIPAA regulations and all applicable laws, regulations, and guidelines.

The Utilization Management Committee's administrative files shall be kept confidential and disclosed only in accordance with applicable state laws, and as required for regulatory surveys by the State Department of Health Care Services or

The Joint Commission, as applicable.

All Utilization Management Committee members, consultants, and guests will agree to maintain confidentiality of the issues and patients discussed.

4. **Committee Meetings**
   The UMC meets quarterly or more frequently if the Chair determines that a meeting is necessary. Other hospital staff members (including physicians, pharmacists, etc.) may attend the UMC meetings at the invitation of the Committee Chair. The UMC reports to the Medical Executive Committee (MEC).
5. **Committee Members – Potential Conflicts of Interest (CFR Title 42, Section 456.206)**
   Physicians and non-physicians do not perform review nor make UM decisions on patients to whom they have provided health care services, or cases in which they have significant involvement or financial interest. If potential for conflict of interest is identified, another qualified reviewer is designated. UM staff and reviewers make decisions based on clinical appropriateness of care and services; and are not offered incentives or compensation for a specific outcome, such as approval or denial of care or services.
6. **Record Keeping**
   a. The UMC maintains the following records:
      i. Minutes from quarterly UMC meetings.
      ii. Reports that are shared with the UMC on various topics.
      iii. Reports related to Medical Care Evaluation (MCE) studies.
   b. The Utilization Review Department also maintains records of initial and continued stay utilization reviews for each admission. These are in electronic files from the Concurrent Utilization Review Software module. UM reviews will be maintained for a minimum of 10 years (AB-1688 Community Health Services: California Mental Health Planning Council).

B. **UTILIZATION MANAGEMENT STAFF**
The Medical Director of the Hospital is the responsible party to ensure operational support is provided for the Utilization Management program. The Medical Director is responsible for determining qualified personnel to perform needed services. Qualified personnel include Utilization Management Nurses, Social Workers and Discharge Planners.

UM Nursing is responsible for the initial and continued stay review of patients treated on inpatient psychiatric units. Clinical chart reviews include notes in the Electronic Medical Record. Reviews are documented in the Concurrent Utilization Review software module.

Social Workers and Discharge Planners are integral members of the Inpatient Psychiatry Treatment Team. They also carry out important Utilization Management functions. They attend morning multidisciplinary rounds meetings and initial and weekly patient care conference meetings for the individualized interdisciplinary treatment plan. Social Workers and Discharge Planners facilitate transition/discharge plans, including any referrals, placements, or any other

needed follow up after discharge.

C. **UTILIZATION REVIEW PROCESS**

1. **Patient Information Required for UR (CFR Title 42, Section 456.211)**
   UM Nursing will include the following information found in the medical record for review and document findings in the Change Healthcare system.
   a. Patient identification by medical record number.
   b. Name of treating physician.
   c. Admission and dates of application for and authorization of Medicaid benefits if application is made after admission.
   d. The plan of care.
   e. Medical information explaining justification for admission / continued stay, diagnoses, information and plan of care.
   f. Initial and subsequent continued stay review dates.
   g. Reasons and plan for continued stay, if the attending physician believes continued stay is necessary.
   h. Other supporting information the UM Nurse believes appropriate to be included in the record.

2. **Psychiatric, Medical, and Social Evaluations, and Certification of Psychiatric Necessity (CFR Title 42: 456.160 and 456.170)**
   a. Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must make a medical evaluation of each applicant's or beneficiary's need for care in the hospital; and appropriate professional personnel must make a psychiatric and social evaluation.
   b. Each medical evaluation must include:
      i. Diagnoses
      ii. Summary of present medical findings
      iii. Medical history
      iv. Mental and physical functional capacity
      v. Prognoses, and:
      vi. A recommendation by a physician concerning:
         1. Admission to the mental hospital; or
         2. Continued care in the mental hospital for individuals who apply for Medicaid while in the mental hospital.
   c. CCRMC Inpatient Psychiatry Units meet this requirement within 24 hours of admission through a Psychiatric H&P by the attending psychiatrist, admission documentation including psychosocial assessment, psychiatric history, and collateral contacts by social services staff, and a Medical H&P by the consulting medical physician from the Department of Hospital

Medicine (DHM).

In our hospital, the admitting psychiatrist in most cases is the psychiatrist who evaluates the patient in the Psychiatric Emergency Services (PES) unit prior to admission to the inpatient psychiatry service. The PES psychiatrist writes evaluation notes and admission orders. After admission to an Inpatient Psychiatry Unit, the inpatient psychiatrist conducts an initial psychiatric evaluation that is documented in the Psych H&P Note; and adds orders as appropriate. In addition, other roles in the treatment team (RN, Social Worker/Mental Health Clinical Specialist, Occupational Therapist) carry out and document admission assessments/evaluations.

3. **Initial Individual Written Plan of Care (CFR Title 42: 456.180; 441.155): Interdisciplinary Treatment Plan**
    a. Before admission or the initial authorization request to the MHP, the physician will establish an initial written plan of care for each patient. The plan of care must include:
        i. Diagnoses, symptoms, complaints, and complications indicating the need for admission
        ii. A description of the functional level of the individual
        iii. Objectives
        iv. Any orders for:
            1. Medications
            2. Treatments
            3. Restorative and rehabilitative services
            4. Activities
            5. Therapies
            6. Social services
            7. Diet
            8. Special procedures recommended for the health and safety of the patient
        v. Plans for continuing care, including review and modification to the plan of care
        vi. Plan for discharge
    b. In CCRMC Inpatient Psychiatry Units, these requirements are met by the initial Interdisciplinary Treatment Plan that is completed within 3 business days of admission, along with admission orders that are in the medical record.

        The individualized interdisciplinary treatment plan is formulated based on evaluation/ assessment by multiple roles, including the psychiatrist, social

worker/mental health clinical specialist, and occupational therapist, along with input from the consulting medical physician (from the Medical H&P note), as well as care plans by the Registered Nurses involved in the patient's care.

The initial interdisciplinary treatment plan is based on a patient care conference that is carried out by the 3rd business day after admission. The interdisciplinary treatment plan is discussed daily during interdisciplinary rounds meetings, and in weekly patient care conferences, with updates documented as indicated.

The interdisciplinary treatment plan is documented in the initial and subsequent Patient Care Conference group notes, and includes the following:

i. Diagnosis
ii. A description of the functional level of the beneficiary
iii. Specific observable and/or specific quantifiable goals/treatment objectives related to the beneficiary's mental health needs and functional impairments resulting from the qualifying mental health diagnosis/diagnoses
iv. Interventions that are consistent with the qualifying diagnoses and which include the proposed frequency and duration for each of the interventions
v. Plans for continuing care, including review and modification to the interdisciplinary treatment plan
vi. Discharge Plan
vii. Documentation of the beneficiary's degree of participation in and agreement with the plan
viii. Documentation of the physician's establishment of the initial interdisciplinary treatment plan

4. **Determination of Bed Day Status**
Determination of bed day status includes: Acute days for initial and continued stay, administrative days, and denied days due to lack of medical necessity. UM nurse performs evaluation for determination of bed day status each business day (non-holiday).
    a. Acute day status meets criteria for medical necessity. This includes initial day of admission and for continued stay.
    b. Administrative day status meets criteria if the beneficiary previously met criteria for acute day stay, and, no bed is available at a lower level, crisis residential type unit.
    c. Denied Day status is met when the beneficiary does not meet criteria for either acute or administrative day status.

5. **Initial Review of Medical Necessity Criteria (CCR: Title IX, Chapter 11, Section 1820.205 & CFR: Title 42, 456.232)**
   The UM nurse reviews the medical record to determine if the beneficiary meets medical necessity for acute care admission. The review occurs within 24-36 hours (non-holiday) of admission. Medical necessity criteria include all of the following:
   a. The beneficiary will have a valid ICD-10 psychiatric diagnosis as listed in one of these diagnostic groups from CCR: Title IX, chapter 11, Section 1820.205 and in BHIN 20-043 dated July 8th, 2020. Note per Draft BHIN 25-XXX re SB 1238 Medi-Cal Reimbursement, the diagnosis groups will be updated soon to include Severe Substance Use Disorder (SUD) in alignment with the implementation of SB-43, which changes the definition of Grave Disability (GD) for adults on Lanterman-Petris-Short (LPS) involuntary holds and LPS Conservatorships for mental health, severe SUD, or both MH and Severe SUD. Contra Costa County will implement SB-43 starting on January 1st, 2026.

      The current diagnostic groups are:
      i. Pervasive Developmental Disorders
      ii. Disruptive Behavior and Attention Deficit Disorders
      iii. Tic Disorders
      iv. Elimination Disorders
      v. Cognitive Disorders (only Dementias with Delusions or Depressed Mood)
      vi. Substance Induced Disorders, only with Psychotic, Mood, or Anxiety Disorder
      vii. Schizophrenia and Other Psychotic Disorders
      viii. Mood Disorders
      ix. Anxiety Disorders
      x. Somatoform Disorders
      xi. Dissociative Disorders
      xii. Eating Disorders
      xiii. Intermittent Explosive Disorder
      xiv. Adjustment Disorders
      xv. Personality Disorders

   b. The beneficiary will also meet the following criteria:
      i. The beneficiary cannot be safely treated at a lower level of care.
      ii. The beneficiary requires acute inpatient services, as a result of a mental disorder, due to either a) or b) subgroup below.
         1. Has symptoms or behaviors due to a mental disorder

that (one of the following):

a. Represent a current danger to self or others, or to significant property destruction.

b. Prevent the beneficiary from providing for, or utilizing food, clothing or shelter.

c. Present a severe risk to the beneficiary's physical health.

d. Represent a recent, significant deterioration in ability to function.

2. Requires admission for one of the following:

a. Further psychiatric evaluation.

b. Medication management that can reasonably be provided only if beneficiary is hospitalized.

c. Other treatment that can reasonably be provided only if the beneficiary is hospitalized.

iii. Determination of medical necessity.
The UM nurse will determine medical necessity or lack of medical necessity from the medical records. When the medical records reflect lack of medical necessity, the UM nurse will:

1. Discuss findings with attending psychiatrist.

2. If the attending physician does not agree, a secondary review request is made.

3. The UM Nurse will refer for secondary review to the Chief of Psychiatry, or designee.

6. **Continued Stay Review for Medical Necessity Criteria (CCR: Title IX, chapter 11, section 1820.205 & CFR: Title 42, 456.233-456.236)**
The UM Nurse will perform continued stay reviews for medical necessity on or before the expiration of each assigned continued stay review date. The UM nurse will determine continued stay necessity from the medical records.

a. For continued stay necessity, the beneficiary will meet one of the following criteria:

i. Continued presence of indications which meet the medical necessity criteria specified above in section C, subsection 5, a & b.

ii. Serious adverse reaction to medication, procedures, or therapies requiring continued hospitalization.

iii. Presence of new indications which meet medical necessity criteria specified above in section C, subsection 5, a & b.

iv. Need for continued medical evaluation or treatment that could only have been provided if the beneficiary remained in a psychiatric inpatient hospital.

b. When records review reflects lack of continued stay necessity, the UM nurse will:

i. Discuss findings with attending psychiatrist.

ii. If the attending physician does not agree, a secondary review request is made.

iii. The UM Nurse will refer for secondary review to the Chief of Psychiatry, or designee.

7. **Administrative Day Criteria (CCR Title IX, chapter 11, 1820.230)**
The UM Nurse requests a level of care change from Acute to Administrative Day(s) when the following criteria are met:

a. The beneficiary initially met medical necessity criteria for acute care hospitalization.

b. Continued stay criteria are no longer met, however, the beneficiary continues to have specialized placement needs but remains in the hospital because of a lack of available beds at an appropriate lower level of care facility.

c. If there are five or fewer appropriate level of care facilities in Contra Costa County, the Mental Health Plan can waive the requirement of contacting five facilities each week.

d. Social workers and discharge planners document in medical record date of attempts, which facility contacted & status of placement attempt at each facility.

8. **Admission and Continued Stay criteria – Medicare / private / managed care insurance**

a. Interqual (IQ) criteria will be used for admission and continued stay reviews.

b. Reviews will be documented in the Change Healthcare UR Module.

c. Concurrent reviews are performed based on the patient's severity of illness and intensity of services. Initial and continued stay authorization requests are required for private insurance and managed care plans. Medicare does not require authorization requests.

d. Medicare patients will be issued a letter "Important Message from Medicare" within two days of admission and no later than four hours before discharge. The letter will be explained, and a signature is obtained from the patient or his/her representative, by registration staff or utilization review representative only if the attending physician of record determines that the patient is physically, mentally, and emotionally capable of receiving such a notice. The original is placed in the patient's chart, and a

copy is given to the patient. If the patient and/or representative refuses to sign the letter, "patient refused to sign" is documented on the letter and the UR representative will sign and date the form and provide the patient with a signed copy.

9. **Secondary Review Process (CFR Title 42, 456.237, CMS CoP 482.30: Utilization Review)**
   Secondary reviews are conducted by the Chief Psychiatrist or another designated Psychiatrist when the initial or continued stay review does not meet criteria for medical necessity, and the attending psychiatrist disagrees. A secondary review results in the following:
   a. The secondary reviewer agrees with the denied day due to lack of medical necessity. The attending psychiatrist will document same in the medical record. If the secondary reviewer disagrees with the denied day, the UM Nurse will request authorization for acute days from the MHP.

10. **Authorization Requests (BHIN N0: 22-017 section I-II)**
    Authorization requests for initial and continued stays are made concurrently for patients with private insurance or a county MHP. Authorization requests will be made based on the UR criteria and attending physician assessment or the results of the secondary review process.
    a. **Authorization Requests to MHP:**
       i. BHS/County MHP: The initial admission notification starts the process for authorization requests for Medi-Cal beneficiaries. Every business day, and on Mondays for admissions from Friday evening to early Monday morning, the Inpatient Psychiatry UR RN notifies the BHS UR Department of all new admissions. The BHS UR RN has access to the Electronic Medical Record with all of the information required.
       ii. The initial authorization request includes the patient's admission orders, Psych H&P note (which also serves as the initial plan of care until the first interdisciplinary treatment plan has been completed within three days of admission), and a completed face sheet, along with a request to authorize the patient's treatment.
       iii. Initial Authorization Request Response - The MHP will review and respond to the authorization request within 72 hours of receipt.
       iv. Continued Stay Authorization Request - before the end of the initial authorization period, or a subsequent authorization period, the hospital shall submit a continued-stay- authorization request for a specified number of days to the responsible county MHP.
       v. Continued Stay Authorization Response - The responsible MHP shall issue a decision on the continued-stay-authorization request within 24 hours of receipt of the request and all

information reasonably necessary to make a determination.

b. **The MHP remains responsible** to cover the cost of each day of an inpatient hospital stay, at the applicable rate for acute psychiatric inpatient hospital services, until the requirements in paragraph a) or b) have been met:

    i. The existing treatment authorization expires and the hospital discharges the beneficiary (or the beneficiary's level of care in the hospital is downgraded to administrative day level while awaiting transfer), pursuant to a plan of care that is agreed upon by the MHP and the beneficiary's treating provider; or

    ii. The MHP denies a hospital's continued stay authorization request and the hospital discharges the beneficiary (or the beneficiary's level of care in the hospital is downgraded to administrative day level while awaiting transfer), pursuant to a plan of care that is agreed upon by the MHP and the beneficiary's treating provider.

c. **Adverse Decisions (BHIN N0: 22-017 section III, CFR Title 42 section 456.237-456.238)**

    i. A decision to modify an authorization request shall be provided to the treating provider(s), initially by telephone or facsimile, and then in writing by a physician.

    ii. If a MHP denies a hospital's authorization request, the MHP must work with the treating provider to develop a plan of care.

    iii. A MHPs denial of an authorization request and a consultation between the treating provider and the MHP may result in one of the following outcomes:

        1. The MHP and the hospital treating provider agree that the beneficiary shall continue inpatient treatment at the acute level of care, and the denial is reversed.

        2. The MHP and the hospital treating provider agree to discharge the beneficiary from the acute level of care and a plan of care is established prior to the beneficiary transitioning services to another level of care.

        3. The MHP and the hospital treating provider agree to discharge orders and plan of care is established; however, appropriate outpatient or step-down facility bed is not available and the beneficiary remains in the hospital, on administrative day level of care.

        4. The MHP and treating hospital provider do not agree on a plan of care and the beneficiary, or the treating provider on behalf of the beneficiary, appeals the decision to the MHP.

11. **Discharge Planning**
    Discharge planning is an integral interdisciplinary process that begins soon after admission. Social Workers and Discharge Planners are involved in daily rounds, team meetings, and other interdisciplinary meetings. Appropriate discharge plans are made in consultation with these team members.

D. **PERFORMANCE IMPROVEMENT REVIEW**
Performance improvement monitoring is performed concurrently and retrospectively. Results are reported to the Utilization Management Committee. Monitoring may include performance improvement & regulatory compliance activities.

E. **MEDICAL CARE EVALUATION STUDIES (CFR Title 42: Chapter 4: 456.241-245)**
Medical care evaluation studies are chosen to improve the overall care provided to the beneficiary. Studies will address improving the treatment of psychiatric and medical conditions, or improving beneficiary and staff safety.

F. **ANNUAL REVIEW, REVISIONS, AND APPROVALS**
The Utilization Management Committee (UMC) reviews and revises as appropriate the Inpatient Psychiatry Utilization Management Plan annually. The plan is approved by the UMC. It is then presented to the Medical Executive Committee (MEC) – along with a brief summary of any key changes—for approval. Then the Plan is added to the Consent Agenda for the Joint Conference Committee (JCC).

REFERENCES:

A. **Behavioral Health Information Notice 20-043, 2020 International Classification of Diseases, Tenth Revision (ICD-10) Included Code Sets Effective October 1st, 2019, remaining in effect until new guidance is issued, dated July 8th, 2020.**

B. **Behavioral Health Information Notice (BHIN) 22-017, Concurrent Review Standards for Psychiatric Inpatient Hospital and Psychiatric Health Facility Services, dated April 15th, 2022.**

C. **California Code of Regulations: Title 9, Chapter 11 - Specialty Mental Health Services, Subchapter 2, Article 2, Section 1820.205: Medical Necessity Criteria for Reimbursement of Psychiatric Inpatient Hospital Services.**

D. **California Code of Regulations, Title 22 Health Care Services, Section 51159 – Utilization Controls.**

E. **Centers for Medicare and Medicaid Services (CMS) Conditions of Participation (CoP) Appendix A, Section 482.30: Utilization Review.**

F. **Code of Federal Regulations (CFR): Centers for Medicaid and Medicare Public Health: Mental Health Title 42, Chapter IV, Subchapter C, Part 456, Subpart D; and Section 441.155.**

G. **The Joint Commission (TJC) Standards 2025: PC 02.01.01; LD 04.01.01, elements 17-18.**

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	12/2025
Utilization Management Committee	Jeff Chiu: EMERG MED EXEMPT	12/2025
	Yvonne Hollister: Utilization Review Supv	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19515049**

Origination	04/1995
Last Approved	N/A
Effective	Upon Approval
Last Revised	07/2022
Next Review	3 years after approval

Owner	Kristina Serrano: Mental Health Prog Manager
Area	Psychiatry

Policy for Discharge Planning/After-Care Plan for Inpatient Psychiatry

POLICY STATEMENT:

An after-care plan is completed for every patient before discharge. The Treatment Team involves the patient/ family/ guardian in discharge planning and after care needs.

GUIDELINES:

A. Discharge Planning:
Discharge planning begins at admission and continues throughout the patient's hospitalization. Discharge planning is a multi-disciplinary process and includes the patient, and, as appropriate, family/guardian. The psychiatrist determines the discharge disposition with input from the Treatment Team, including the MHCS/SW and Discharge Planner.

B. After Care Referrals, Resources, and Placements:
Community referrals and appointments for services after discharge are provided based on individual needs, eligibility, and availability. Placements for short or longer-term psychiatric care after discharge are made according to individual patient needs, eligibility requirements, and available beds and services. See Attachment A for guidelines regarding placements and referrals.

C. Written After Care Plan: After Visit Summary (AVS):
Upon discharge, each patient and the patient's conservator, guardian, or other legally authorized representative receives a copy of the After Visit Summary (AVS). The AVS is reviewed with the patient/family/guardian. The patient may also designate another person to receive a copy.

For patients who are transferred to another facility at discharge (including Crisis Residential Facility, IMD or other facility), the AVS and the psychiatrist's discharge summary accompany the patient to that facility.

RELATED LINKS:

Attachment A: Placements, Referrals and Community Resources Guidelines

REFERENCES:

A. California Code of Regulations, Title 22, Section: 70717.
B. California Welfare & Institutions Code, Section 5622.
C. The Joint Commission (TJC) 2023 Standards: PC.04.01.01, PC.04.01.03, PC.04.01.05, PC.04.02.01

APPROVALS:

Psychiatry Department: 7/22
Clinical Practice Committee: 8/2022
Patient Care Policy & Evaluation Committee: 9/2022
Medical Executive Committee: 9/2022
Joint Conference Committee: 9/2022

Attachments

Discharge Planning/ After-Care Plan for Inpatient Psychiatry: Attachment A: Placements and Referral Guidelines

Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [GS]	02/2026
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [AL]	02/2026

Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	01/2026
	Kristina Serrano: Mental Health Prog Manager	12/2025

Standards

No standards are associated with this document

Status **Pending** PolicyStat ID **19996054**

Origination	N/A
Last Approved	N/A
Effective	Upon Approval
Last Revised	N/A
Next Review	2 years after approval

Owner	Michael De Peralta: Respiratory Care Services Mgr
Area	Respiratory

Policy for Respiratory Care Patient Transport

POLICY STATEMENT:

All patients requiring High-Flow Nasal Oxygen Therapy, Invasive Mechanical Ventilation, or Non-Invasive Ventilation must be transported either within a facility (intrahospital) or between facilities (inter-hospital) under the direct supervision of a licensed Respiratory Care Practitioner (RCP) or other qualified personnel when high-level respiratory support is required, with transport conducted in collaboration with medical and nursing staff and in strict adherence to established clinical protocols, safety standards, and equipment requirements to ensure continuity of care and minimize risk; prior to transport, a comprehensive clinical assessment, patient and equipment preparation, and clear communication between referring and receiving teams must be completed, and during transport RCPs are responsible for maintaining prescribed respiratory modalities, monitoring patient status, and initiating emergency interventions when necessary.

RELATED LINKS:

REFERENCES:

A. **American Association for Respiratory Care (AARC)**. *Clinical Practice Guidelines: In-Hospital Transport of the Mechanically Ventilated Patient*. AARC, 2002. Available from AARC Clinical Practice Guidelines

B. **Denver Health Medical Center**. *Guideline for Transport to OR with Mechanical Ventilation*. DHMC, 2020. Download PDF Guideline

Approval Signatures

Step Description	Approver	Date
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari	Pending
Medical Director	Initha Elangovan: Exempt Med Stf Physician	03/2026
	Michael De Peralta: Respiratory Care Services Mgr	02/2026

Standards

No standards are associated with this document