

## Patient Care Policy Agenda 9-22-25

\* Indicates policy is pending Medical Executive Committee's approval on 9-29-25.

Title	Area	Revised?	Summary of Changes
Policy for HIV Test Result Follow-Up	Ambulatory Care	Revised	No Comment Provided
Policy for Standing Orders: Nursing	Ambulatory Care	Revised	Removed an attachment for depo Provera as it does not match order set and is a old form. No longer needed.
Ambulatory Physician Privileges *	Hospital & Health Centers	New	No Comment Provided
Hospital Medicine Privileges *	Hospital & Health Centers	New	No Comment Provided
Discipline Dismissal and Due Process Policy for Family Medicine Residency Program	Hospital & Health Centers	New	No Comment Provided
Eligibility Selection Agreements Appointment Promotion and Reappointment	Hospital & Health Centers	New	No Comment Provided
Family Medicine Residency Program Policy for Compensation	Hospital & Health Centers	New	No Comment Provided
Family Medicine Residency Program Policy for Leaves of Absence	Hospital & Health Centers	New	No Comment Provided
Family Medicine Residency Program Policy for Moonlighting	Hospital & Health Centers	New	No Comment Provided
Family Medicine Residency Program Policy for Problem Solving - Grievances	Hospital & Health Centers	New	No Comment Provided
Family Medicine Residency Program Policy for Work Environment and Other Benefits	Hospital & Health Centers	New	No Comment Provided
Policy on Clinical and Educational Work Hours for Family Medicine Residency Program	Hospital & Health Centers	New	No Comment Provided
Policy On Sponsoring Institution and Program Reductions or Closures	Hospital & Health Centers	New	No Comment Provided
Policy on Substantial Disruptions in Patient Care or Education	Hospital & Health Centers	New	No Comment Provided
Program Evaluation Committee	Hospital & Health Centers	New	No Comment Provided
Residency Program Policy on Anti-Discrimination	Hospital & Health Centers	New	No Comment Provided
Resident Supervision Policy	Hospital & Health Centers	New	No Comment Provided
Resident Well-Being and Impairment Policy	Hospital & Health Centers	New	No Comment Provided
Contra Costa Regional Medical Center Joint Conference Committee Expedited Privileges Subcommittee Charter	Hospital & Health Centers	Revised	Routing for approvals per Heather Cedermaz
Policy for Consent to Medical Treatment *	Hospital & Health Centers	Revised	Minor change: replaced moderate sedation with deep sedation in reference to required written consent for procedures needing anesthesia or deep sedation.  Updated CHA Consent Manual reference to current version. Updated policy owner.

Title	Area	Revised?	Summary of Changes
Policy for Suspected Patient Abuse or Neglect While in the Care of the Hospital *	Hospital & Health Centers	Revised	<p>Minor formatting changes, including indents and capitalization for ease of reading.</p> <p>Verified Sherriff's Department phone number, and added dispatch phone number as backup.</p> <p>Quick reference guide attached from CHA is still current version, no changes.</p>
Policy for Family Medicine Residency Program	Hospital & Health Centers	Revised	No Comment Provided
Policy for Requirements for Medical Record Entries by Attending Physician	Hospital & Health Centers	Unchanged	No Comment Provided
Policy for Graduate Medical Education Administration	Hospital & Health Centers	Unchanged	No Comment Provided
Policy for Requirements of Cosignatures of Medical Record Entries	Hospital & Health Centers	Unchanged	No Comment Provided
Negative Pressure Alarm Sign	Infection Control	New	No Comment Provided
Policy for Wound Dressing Changes/Packing	Nursing	Revised	Reviewed and updated by wound educator.
Employee Orientation and Training *	Nutrition	New	No Comment Provided
Food Safety (HACCP) *	Nutrition	New	No Comment Provided
Menu Planning and Purchasing *	Nutrition	Revised	Minor grammar updates - sending through updated approval process
Food Storage	Nutrition	Unchanged	No Comment Provided
Contact List for Disaster Fan-Out Procedures	Pharmacy	Revised	Contact names and phone numbers were updated- Approvals section deleted.
Policy for Bioterrorism Preparedness	Pharmacy	Revised	'Chempack' Activation Flowchart for medications provided through "PushPack and ChemPack supplies"
Policy for Compounding Competency Assessment	Pharmacy	Revised	Removed section regarding nursing competency assessment. it was moved to procedure for immediate-use compounding
Policy for Compounding of Medications	Pharmacy	Revised	<p>Defined Designated Person as Pharmacist II as per 7/8/25 Board of Pharmacy Inspection discussion.</p> <p>Aligned sections regarding components required of Master Formulas and Compounding Records with USP sections 11.1 and 11.2.</p> <p>Added link to new Procedure for Immediate-Use Compounding.</p>

Title	Area	Revised?	Summary of Changes
Policy for Maintenance of Sterile Compounding Facilities and Equipments	Pharmacy	Revised	Updated information regarding acceptable room temperature. Temperature should include <68F as listed in USP 797 to provide comfortable conditions for compounding personnel attired in the required garb but also must be maintained within a temperature range acceptable for room temperature storage of pharmaceuticals as per Policy for Room Temperature Monitoring for Drug Storage Areas.
Policy for Non-Sterile Compounding	Pharmacy	Revised	Defined Designated Person as Pharmacist II as per 7/8/25 Board of Pharmacy Inspection discussion.
Policy for Antineoplastic and Hazardous Drug Handling *	Pharmacy	Revised	1) added designation of Pharmacist II as Designated Person 2) moved facility specific details out of policy into a new procedure 3) updated attachment - list of hazardous drugs 4) updated attachment - assessment of risk template
Policy for Pharmacy Security	Pharmacy	Unchanged	No Comment Provided
Policy For Neonatal High Flow Nasal Cannula	Respiratory	New	No Comment Provided
Policy for Artificial Airway Management *	Respiratory	New	No Comment Provided
Policy for Neonatal Mechanical Ventilation Management *	Respiratory	New	No Comment Provided
Policy for Continuous Nebulizer Therapy	Respiratory	Revised	No Comment Provided
Policy for Airway Clearance Therapy *	Respiratory	Revised	Update information and references



Origination	02/2013
Last Approved	N/A
Effective	Upon Approval
Last Revised	07/2025
Next Review	3 years after approval

Owner	Andrea Sandler: Associate Medical Director- Ex
Area	Ambulatory Care

## Policy for HIV Test Result Follow-Up

### POLICY STATEMENT:

This policy outlines the procedure established to ensure that all HIV+ test results are identified and followed up in a timely, appropriate manner.

### GUIDELINES:

A. Policy:

1. Ordering providers and CCH Public Health are notified of positive results and will follow-up on positive HIV test results as outlined in the following procedure.

B. Procedure:

1. The lab will notify ordering providers and the CCH Public Health HIV Surveillance Coordinator of all positive HIV tests.
  - a. The laboratory will notify the ordering provider by EPIC chat the same day that the test is resulted.
  - b. HIV positive labs ordered during admission will be resulted to the inpatient result pool and addressed by the department.
  - c. The laboratory will notify CDPH and the CCH Public Health HIV Program via CalREDIE as required by California Health and Safety Code. The lab will also notify the PH HIV Program Surveillance Coordinator via ccLink in-basket of test result details..
    - i. Public Health will notify the lab when there is a change in Surveillance Coordinators to contact via in-basket.

2. If the ordering provider of a patient with a positive result cannot be contacted by the laboratory the same day, then the following applies:
  - a. If the ordering provider is an Emergency Department (ED) Provider, the ED provider who has been designated by the department head to receive positive test results shall be notified by ccLink in-basket message.
  - b. If the ordering provider is not an Emergency Department (ED) Provider, then the lab will contact the lead Positive Health (HIV Clinic) provider by ccLink chat message to provide the test results.
    - ~~a. The CCH Positive Health clinical team will notify the lab when there is a change in lead clinicians.~~
    - i. The CCH Positive Health clinical team will notify the lab when there is a change in lead clinicians.
3. Providers are responsible for arranging notification to the patient of their positive HIV test result.
  - a. If unable to reach a patient within 24 hours of receipt of a positive laboratory test result, providers will contact the Public Health HIV program warm line at 925-608-5384 for additional resources and support.
4. Providers will submit a Confidential Morbidity Report for all patients newly diagnosed with HIV. Information on CMRs may be found on the CCH HIV/STI Program website or by calling the HIV Program warm line.
  - a. Providers are encouraged to follow up with a phone call to the HIV Program warm line to notify Public Health of patients newly diagnosed with HIV, and particularly of uninsured patients who do not have a medical home.
5. Following HIV status notification, the PH HIV Program will contact the patient to offer psychosocial support, linkages with case management, and partner notification as appropriate.
6. Negative Test:
  - a. Contra Costa Health Plan Advice Nurses are authorized to give negative test results to patients.
7. All relevant information should be recorded in the patient's ccLink record. Laboratory staff should record in the electronic medical record when and to which provider the positive test results were communicated.

## REFERENCES:

- A. Ambulatory Policy Committee minutes of 11/18/10 and 2/21/2013.
- B. Infection Control Policy ~~No. #209, "HIV Test Results Handling."~~
- C. Ambulatory Care's Policy for Resource Nurse for Critical and Urgent Test Value Notifications

# APPROVALS:

~~Ambulatory Clinical Practice Committee: 6/2017~~

~~Ambulatory Policy Committee: 2/21/2013, 6/2017~~

~~Medical Executive Committee: 7/2017~~

## Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	09/2025
Ambulatory Policy Committee	Laura R. Colebourn [LC]	07/2025
Ambulatory Clinical Practice Committee	Helena Martey	04/2025
	Andrea Sandler	04/2025

## Standards

No standards are associated with this document



Origination 11/2009  
Last Approved N/A  
Effective Upon Approval  
Last Revised 08/2025  
Next Review 3 years after approval

Owner Kelley Taylor:  
Ambulatory Care  
Clin Supv  
Area Ambulatory Care

## 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. 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.
- 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.

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.

Pregnancy Test. Refer to [ProcedurePolicy #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, then 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:

If any point of care testing due to Gaps of Care, all ~~licensed staff~~[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](#). ~~If result is abnormal and it was part of a provider~~ visit, document in MyCCLink.

## ~~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
- 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. 2015 AAP Guidelines/ Bright Future guidelines
- J. 2015/2016 AAFP Primary Care Health Care Guidelines
- K. myCAvax

- L. COVID-19 CDPH
- M. COVID-19 Vaccine Product Guide |IMM 1399
- N. VAERS Reporting Requirement/Instruction-Safe Print Resources | CDC
- O. [COVID-19 Vaccine Management Plan \(eziz.org\)](https://www.eziz.org/)
- P. [Child and Adolescent Recommended Immunization Schedule, 2024](#)

## 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]	09/2025
Ambulatory Policy Committee	Laura R. Colebourn [LC]	07/2025
Ambulatory Clinical Practice Committee	Helena Martey: Chief Nursing Officer-Exempt	06/2025
	Kelley Taylor: Ambulatory Care Clin Supv	06/2025

## Standards

No standards are associated with this document



## Ambulatory Physician 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, CCRM simulation lab, or documented outside trainings.** Medical Staff Office can help you pull relevant reports from EPIC.

### Required Qualifications

<b>Education/Training</b>	Successful completion of an Accreditation Council for Graduate Medical Education (ACGME)—or American Osteopathic Association (AOA)—accredited residency in Family Medicine or Internal Medicine. Family Medicine training is required for Pediatric Privileges.
<b>Certification</b>	Documentation of current certification or board eligibility (with achievement of certification within 3 years) leading to certification in Family Medicine by the American Board of Family Medicine or Family Practice and Osteopathic Manipulative Treatment by the American Osteopathic Board of Family Physicians.  <u>OR</u>  Internal Medicine by the American Board of Internal Medicine or the American Osteopathic Board of Internal Medicine.
<b>Continuing Education</b>	As per California license and section-specific requirements below.

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

<b>Adult Medicine (Initial or Reappointment)</b>	Provision of care, reflective of the scope of privileges requested, for at least 200 adult medicine patient visits during the past 24 months. If requesting pediatric privileges, at least 100 pediatric patients. Please provide clinical activity/procedure log. Experience must correlate to requested privileges  <u>OR</u>  Successful completion of an ACGME—or AOA—accredited residency or clinical fellowship within the past 24 months.
<b>Pediatric Medicine (Initial or Reappointment)</b>	Provision of care, reflective of the scope of privileges requested, for at least 100 pediatric patient visits during the past 24 months. Please provide clinical activity/procedure log. Experience must correlate to requested privileges.  <u>OR</u>  Successful completion of an ACGME—or AOA—accredited residency or clinical fellowship within the past 24 months.

### Ambulatory Physician Core Privileges

Applicant: initial to request	<b>For Core Privileges:</b> you do not have to do all these procedures, but having the privilege allows you to.	Division/ Dept Chair: initial to recommend
(initials)	<p><b>Adult Medicine Core Privileges</b></p> <p>Evaluate, diagnose, treat, and provide consultation to all patients 18 years old and above, with a wide variety of illnesses, diseases, injuries, and functional disorders of the circulatory, respiratory, endocrine, metabolic, musculoskeletal, hematopoietic, gastroenteric, integumentary, nervous, female reproductive and family planning, genitourinary systems, and including mild to moderate -psychiatric disorders, dependence or addition to alcohol or other drugs, and medical management of chronic pain. Assess, stabilize, consult, and determine disposition of patients with emergent conditions.</p> <p>Procedures include, but are not limited to: performance of history and physical; arthrocentesis and joint injections; cryotherapy (e.g. for removal of warts); excision of cutaneous and subcutaneous lesions, tumors, and nodules and superficial foreign body; facilitate medical groups; fluorescein exam; incision and drainage of abscesses; local anesthesia; management of uncomplicated, minor, closed fractures and uncomplicated dislocations; nasal packing for hemostasis; pap smears; POCT (point of care testing); peripheral nerve blocks; provider performed microscopy (PPM); removal of IUD; removal of a nonpenetrating foreign body from the eye, nose, ear, or vagina; simple skin excision and biopsy; simple wound care and management of superficial burns; subcutaneous, intradermal and intramuscular injections; suture of uncomplicated laceration; toenail trephination and removal; venipuncture.</p>	(initials)
(initials)	<p><b>Pediatric Core Privileges</b></p> <p>Evaluate, diagnose, and treat pediatric patients who have common illnesses, injuries, or disorders from birth through 21 years old. This includes routine uncomplicated newborn care in the hospital (i.e. L&amp;D, nursery, postpartum, etc.), assessment of physical, emotional, and social health, treating acute and chronic disease, and determining the disposition of patients with emergent conditions.</p> <p>Procedures include but are not limited to: performance of history and physical; bladder catheterization, cryotherapy (e.g. for removal of warts); excision of cutaneous and subcutaneous lesions, nodules, and superficial foreign body; facilitate medical groups; incision and drainage of abscesses; local anesthesia; management of uncomplicated, minor, closed fractures and uncomplicated dislocations; nasal packing for hemostasis; POCT (point of care testing); peripheral nerve blocks; provider performed microscopy (PPM); removal of IUD; removal of a nonpenetrating foreign body from the eye, nose, ear, or vagina; simple skin excision and biopsy; simple wound care and management of superficial burns; subcutaneous, intradermal and intramuscular injections; suture of uncomplicated laceration; toenail trephination and removal; venipuncture.</p>	(initials)

## Ambulatory Physician Special/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 request	Non-core privileges are requested individually, in addition to requesting core privileges.	Division/ Dept Chair: initial to recommend
(initials)	<p><b>Nexplanon Insertion &amp; Removal</b></p> <p><i>Initial Request:</i> Completion of the Nexplanon training program. Please submit Training Certification.</p>	(initials)

	<i>Reappointment/Renewal:</i> none - MSO has on file.	
(initials)	<b>EMB and/or Insertion of IUD</b> <i>Initial Request:</i> Residency training in EMB and IUD Insertion OR completion of a hands-on training under the supervision of a qualified preceptor. <u>AND</u> 4 successful EMB/IUD insertions within the past 24 months. <i>Renewal/Reappointment:</i> 2 successful EMB/IUD insertions in the past 24 months.	(initials)
(initials)	<b>Paracentesis</b> <i>Initial Request:</i> Residency training in paracentesis OR completion of a hands-on training in paracentesis under the supervision of a qualified preceptor. <u>AND</u> 2 paracentesis procedures in the past 24 months. <i>Renewal/Reappointment:</i> 1 paracentesis procedure in the past 24 months	(initials)
(initials)	<b>Early pregnancy management: manual uterine aspiration (MUA) and treatment with methotrexate</b> <i>Initial Request:</i> Training during or following residency with 50 MUAs. <u>AND</u> 6 MUAs in the past 24 months. <i>Renewal/Reappointment:</i> 6 MUAs in the past 24 months.	(initials)
(initials)	<b>Acupuncture</b> <i>Initial Request:</i> 200 Hours CME or 10 years of experience. <u>AND</u> 10 cases in the last 24 months <i>Renewal/Reappointment:</i> 10 cases in the past 24 months.	(initials)
(initials)	<b>HIV/AIDS care</b> <i>Initial Request and Renewal/Reappointment:</i> Requirements of AB 2168 (see attached) must be met.	(initials)
(initials)	<b>Care of Newborn with Complications in the Level 2 Nursery</b> <i>Routine care of well newborns does not require this privilege.</i> Including but not limited to the admission and care of the late preterm infant 34 – 36 weeks gestation without significant complications, low birth weight, transient hypoglycemia, sepsis risk factors, mild respiratory issues with need for no or minimal respiratory support, in utero drug exposure not requiring medical management, mild to moderate hyperbilirubinemia, and congenital issues without significant clinical impact. This includes attendance at deliveries with mild to moderate risk factors if NRP certification is current. <i>Initial Request:</i> Completion of residency training in the past 24 months that included at least 1 month in the Nursery. <u>OR</u> 10 encounters with this level of care in the past 24 months. <i>Renewal/Reappointment:</i> 10 inpatient encounters in the past 24 months. <b>Specialty Department Chair/Head reviewed (name):</b> _____	(initials)
(initials)	<b>Inpatient obstetrics with consultation</b> Admit, evaluate, and manage patients with uncomplicated term pregnancy, with an expectation of uncomplicated vaginal delivery. <u>Procedures include but are not limited to:</u> amniotomy, assisting with delivery of twins, assisting with fetal versions, augmentation of labor, episiotomy, fetal heart rate monitoring (external and internal), induction of labor, initial management of postpartum hemorrhage, normal spontaneous vaginal delivery; POCUS (please see request below); postpartum care, post-delivery removal of placenta with consultation; repair of 1st and 2nd-degree lacerations; repair of cervical, 3rd, and 4th-degree lacerations with consultation; surgical	(initials)

	<p>assisting; vacuum-assisted delivery with consultation.</p> <p><i>Initial Request:</i> Completion of residency in the last 24 months with documentation of at least 4 months of obstetrical rotation during family medicine residency, 80 patients delivered, and ultrasound training</p> <p><u>OR</u></p> <p>8 deliveries in the past 24 months.</p> <p><i>Renewal/Reappointment:</i> 8 deliveries in the last 24 months.</p> <p><b>Specialty Department Chair/Head reviewed (name):</b> _____</p>	
(initials)	<p><b>Low-risk obstetrics (prenatal and postpartum)</b></p> <p>Evaluate, diagnose, and treat low-risk patients who are pregnant, intend to become pregnant, or are recently post-pregnancy. Management of patients with obesity with BMI <math>\leq 60</math>; chronic Hypertension with BP <math>&lt; 150/100</math> <b>WITHOUT</b> medication; GDM on diet or orals with A1c <math>&lt; 6.5</math>; AMA; history of pre-eclampsia in one previous pregnancy at <math>\geq 37</math> weeks; history of cesarean section; substance abuse with or without buprenorphine therapy; cholestasis of pregnancy; size vs. date discrepancies with EFW <math>&gt; 10\%</math>; UTI; anemia with hemoglobin <math>&gt; 8</math>; vaginitis.</p> <p><u>Procedures include but are not limited to:</u> third-trimester POCUS (please request below)</p> <p><i>Initial Request:</i> training during family medicine residency of at least 2 months of obstetrics, including prenatal/postpartum care and POCUS.</p> <p><u>OR</u></p> <p>50 prenatal/postpartum visits in the past 24 months.</p> <p><i>Renewal/Reappointment:</i> 8 Units AAFP/ACOG CME in prenatal care in the past 24 months.</p>	(initials)
(initials)	<p><b>All focused and limited POCUS (Point of Care Ultrasound)</b></p> <p><i>Initial Request:</i> Successful completion of an accredited POCUS training <u>OR</u> 15 hours of Point of Care Ultrasound CME.</p> <p><u>AND</u></p> <p>6 hours of hands-on POCUS relevant to privileges being requested.</p> <p><i>Renewal/Reappointment:</i> 20 ultrasounds in the past 24 months.</p>	
(initials)	<p>Basic First and Second Trimester POCUS for dating, location, and viability of pregnancy.</p> <p><i>Initial Request:</i> 30 ultrasounds in the past 24 months.</p> <p><i>Renewal/Reappointment:</i> 20 ultrasounds in the past 24 months.</p>	(initials)
(initials)	<p>Third trimester OB POCUS for placental location, viability, presentation, amniotic fluid assessment</p> <p><i>Initial Request:</i> 20 ultrasounds in the past 24 months.</p> <p><i>Renewal/Reappointment:</i> 8 ultrasounds in the past 24 months.</p>	(initials)

## Other Privileges

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

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:
- ☐ Do Not Recommend the Following Requested Privileges:

Privilege	Condition/Modification/Explanation

Notes:

**Department Chair Name (Print):** \_\_\_\_\_

**Department Chair Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_



## Hospital Medicine Privileges

Name:  
(Please Print)

### Instructions to applicants

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

### Required Qualifications

<b>Education/Training</b>	Successful completion of an ACGME or AOA-accredited residency in Family Medicine or Internal Medicine.
<b>Certification</b>	Current certification or Board eligibility in the examination process leading to certification in Family Medicine by the American Board of Family Medicine (ABFM) or American Osteopathic Board of Family Physicians (AOBFP). <u>OR</u> Current certification or Board eligibility in the examination process leading to certification in Internal Medicine by the American Board of Internal Medicine (ABIM) or American Osteopathic Board of Internal Medicine (AOBIM).
<b>Continuing Education</b>	As per California licensing requirements. (Waived for applicants who completed training during the past 24 months.)

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

<b>Clinical Experience (Initial)</b>	Applicants must have provided care for at least 100 patients (as the Attending physician), reflective of the scope and complexity of the privileges requested during the past 24 months. (Waived for applicants who completed training during the past 24 months.)
<b>Clinical Experience (Reappointment)</b>	Applicants must have provided care for an adequate volume of experience (100 inpatients), reflective of the scope and complexity of the privileges requested during the previous 24 months based on results of ongoing professional practice evaluation and outcomes. Each clinical shift is representative of 10 patient encounters.
<b>Other Requirements</b>	Current ACLS required. This document is focused on defining qualifications related to competency to exercise clinical privileges. The applicant must also adhere to any additional organizational, regulatory, or accreditation requirements that the organization is obligated to meet. Note that privileges granted may only be exercised at the site(s) designated by CCRMC and/or setting(s) that have sufficient space, equipment, staffing, and other resources required to support the privilege. This is not intended to be an all-encompassing procedures list. It defines the types of activities/procedures/privileges that the majority of 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.

## Hospital Medicine Core Privileges

Applicant: initial to request	<b>For Core Privileges:</b> you do not have to do all these procedures, but having the privilege allows you to.	Division/ Dept Chair: initial to recommend
(initials)	<p><b>Inpatient Core Privileges</b></p> <p>Admit, Evaluate, Diagnose, Treat, and Provide Consultation to Adolescent (<math>\geq 14</math> y/o) and Adult Patients with Common and Complex Illnesses, Diseases and Functional Disorders of the Circulatory, Respiratory, Endocrine, Metabolic, Musculoskeletal, Hematopoietic, Gastroenteric, Integumentary, Nervous, Alcohol or other Substance Use Disorders, Reproductive, and Genitourinary Systems. May provide care to patients in the Intensive Care Setting, including mechanically ventilated patients as well as tracheostomy patients. Assess, Stabilize, And Determine Disposition of Patients with Emergent Conditions Regarding Emergency and Consultative Call Services.</p> <p>Procedures include, but are not limited to: arthrocentesis and joint injection; assistance at surgery; breast cyst aspiration; continuous renal replacement therapy (under guidance by critical care or nephrology); drawing of arterial blood; excision of cutaneous and subcutaneous lesions, tumors, and nodules; incision and drainage of abscesses; interpretation of ECGs (EKGs) at bedside; intraosseous line placement; lumbar puncture; management of burns, superficial and partial thickness; management of uncomplicated, minor, closed fractures, and uncomplicated dislocations; monitoring of patient undergoing chemotherapy under the direction of oncology; paracentesis; performance of history and physical exam; performance of simple skin biopsy; peripheral nerve blocks; placement of anterior nasal hemostatic packing; placement of a peripheral venous line; suprapubic bladder catheter replacement; suturing of uncomplicated lacerations; toenail removal; and wound care and staging.</p>	(initials)
(initials)	<p><b>Ambulatory Core Privileges</b></p> <p>This applies only to outpatient hospital follow-up clinics and short notice/urgent care clinics for <math>\geq 14</math> y/o.</p> <p>Procedures include but are not limited to: arthrocentesis and joint injections; cryotherapy (removal of warts); excision of cutaneous and subcutaneous lesions, tumors, and nodules; incision and drainage of abscesses; lumbar puncture; management of burns, superficial and partial thickness; management of uncomplicated, minor, closed fractures and uncomplicated dislocations; paracentesis; performance of history and physical exam; performance of PAP smear and pelvic exam; performance of simple skin biopsy; peripheral nerve blocks; placement of anterior nasal hemostatic packing; placement of a peripheral venous line; removal of a nonpenetrating foreign body from the eye, nose, or ear; subcutaneous, intradermal and intramuscular injections; suturing of uncomplicated lacerations; and toenail removal.</p>	(initials)

## Hospital Medicine Special/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 request	Non-core privileges are requested individually, in addition to requesting core privileges.	Division / Dept Chair: initial to recommend
(initials)	<p><b>Thoracentesis</b></p> <p><i>Initial Request:</i> Successful completion of an ACGME—or AOA—accredited postgraduate training program in Internal Medicine or Family Medicine which included training in thoracentesis, or completion of a hands-on training in thoracentesis under the supervision of a qualified physician preceptor.</p>	(initials)

	<p><u>AND</u></p> <p>Demonstrated current competence and evidence of the performance of at least 5 thoracentesis procedures (no more than 2 using SIM models), or completion of training or department-approved in-service in the past 24 months. Please provide clinical activity/procedure log.</p> <p><i>Renewal/Reappointment:</i> Demonstrated current competence and evidence of the performance of at least 2 thoracentesis procedures (SIM lab or patient) and department-approved in-service in the past 24 months based on results of ongoing professional practice evaluation and outcomes.</p>	
(initials)	<p><b>Insertion and Management of Central Venous Catheters, Placement of Temporary Hemodialysis Line, and Arterial Lines</b></p> <p><i>Initial Request:</i> Successful completion of an ACGME—or AOA—accredited postgraduate training program in Internal Medicine or Family Medicine which included training in insertion and management of central venous catheters, placement of temporary hemodialysis lines, and arterial lines, or completion of a hands-on training in insertion and management of central venous catheters and arterial lines under the supervision of a qualified physician preceptor.</p> <p><u>AND</u></p> <p>Documented current competence and evidence of the insertion and management of at least 5 central venous catheters or temporary hemodialysis lines, and at least 5 arterial lines in the past 24 months (no more than 2 in SIM lab), or completion of training, or department-approved in-service in the past 24 months. Please provide clinical activity/procedure log.</p> <p><i>Renewal/Reappointment:</i> Documented current competence and evidence of the insertion and management of at least 2 central venous catheters or temporary hemodialysis lines, and 2 arterial lines (patients or SIM lab) or completion of training, or department-approved in-service in the past 24 months based on results of ongoing professional practice evaluation and outcomes</p>	(initials)
(initials)	<p><b>ECG (EKG) Interpretation</b></p> <p><i>Initial Request:</i> Successful completion of an ACGME—or AOA—accredited postgraduate training program in Internal Medicine or Family Medicine, or documentation of ECG (EKG) interpretation skills by successful completion of ECG (EKG) exams, such as the American Board of Internal Medicine ECG (EKG) exam or equivalent.</p> <p><u>AND</u></p> <p>Documented current competence and evidence of accurate interpretation of at least 200 ECGs (EKGs) during the past 24 months, or completion of training in the past 24 months. Please provide clinical activity/procedure log.</p> <p><i>Renewal/Reappointment:</i> Documented current competence and evidence of accurate interpretation of at least 100 ECGs (EKGs) in the past 24 months based on results of ongoing professional practice evaluation and outcomes.</p>	(initials)
(initials)	<p><b>Exercise Testing – Treadmill</b></p> <p><i>Initial Request:</i> Successful completion of an ACGME—or AOA—accredited postgraduate training program in Internal Medicine or Family Medicine that included a minimum of four weeks, or the department-approved equivalent of training in the supervision and interpretation of exercise testing, and evidence that the training included participation in at least 50 exercise procedures.</p> <p><u>AND</u></p> <p>Documented current competence and evidence of the performance of at least 25 exercise tests in the past 24 months, or completion of training in the past 24 months. Please provide clinical activity/procedure log.</p> <p><i>Renewal/Reappointment:</i> Documented current competence and evidence of the performance of at least 12 exercise tests in the past 24 months based on results of ongoing professional practice evaluation.</p>	(initials)
(initials)	<p><b>Endotracheal Intubation</b></p> <p><i>Initial Request:</i> Documentation of successful completion of an ACGME—or AOA—accredited postgraduate training program in Internal Medicine or Family Medicine that provided the necessary cognitive and technical skills for Endotracheal intubation.</p> <p><u>AND</u></p>	(initials)

	<p>Documented current competence and evidence of the endotracheal intubation of at least 4 patients in the past 24 months, or completion of training in the past 24 months. Please provide clinical activity/procedure log.</p> <p><i>Renewal/Reappointment:</i> Documented current competence and evidence of the endotracheal intubation of at least 4 patients (2 in SIM lab okay) in the past 24 months based on results of ongoing professional practice evaluation and outcomes.</p>	
(initials)	<p><b>Thoracostomy and Thoracic Vent/ Chest Tube Placement</b></p> <p><i>Initial Request:</i> Documentation of successful completion of an ACGME—or AOA—accredited postgraduate training program in Internal Medicine or Family Medicine that provided the necessary cognitive and technical skills for thoracostomy and thoracic vent/ chest tube placement, or department-approved extra training and experience.</p> <p><u>AND</u></p> <p>Documented current competence and evidence of the management of at least 5 cases of thoracostomy and thoracic vent/chest tube placement, in the past 24 months, or completion of training in the past 24 months. Please provide clinical activity/procedure log</p> <p><i>Renewal/Reappointment:</i> Documented current competence and evidence of the management of at least 3 cases of thoracostomy and thoracic vent/chest tube placement (patients, not available in SIM lab), in the past 24 months based on results of ongoing professional practice evaluation and outcomes.</p>	(initials)
(initials)	<p><b>HIV/AIDS Specialist Designation</b></p> <p><i>Initial Request and Renewal/Reappointment:</i> Requirements of AB 2168 must be met.</p>	(initials)
(initials)	<p><b>EMB and/or Insertion of IUD</b></p> <p><i>Initial Request:</i> Residency training in EMB and IUD Insertion OR completion of a hands-on training under the supervision of a qualified preceptor.</p> <p><u>AND</u></p> <p>4 successful EMB/IUD insertions within the past 24 months.</p> <p><i>Renewal/Reappointment:</i> 2 successful EMB/IUD insertions in the past 24 months.</p>	(initials)
(initials)	<p><b>Implantable Contraception Insertion and Removal (Nexplanon)</b></p> <p><i>Initial Request and Renewal/Reappointment:</i> Completion of the Nexplanon training program. Please submit Training Certification.</p>	(initials)

## Point of Care Ultrasound (POCUS) Special/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.

(initials)	<p><i>Initial Request:</i> Successful completion of an ACGME—or AOA—accredited postgraduate training program in Internal Medicine or Family Medicine which included formal hands-on ultrasound instruction and experience.</p> <p><u>OR</u></p> <p>Completion of a Point of Care Ultrasound (POCUS) Course, that has at least six (6) hours of hands-on ultrasound scanning <u>OR</u></p> <p>15 hours of Point of Care Ultrasound CME and at least six (6) hours of hands-on ultrasound scanning</p> <p><u>AND</u></p> <p>20 ultrasounds in the past 24 months.</p> <p><i>Renewal/Reappointment</i> (including <u>non-dating OB</u>, cardiac, abdominal, vascular, ocular, thoracic, procedure related, etc.):</p> <p>10 ultrasounds or 2 proctored ultrasounds in the last 24 months.</p>	(initials)
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## Administration of Sedation and Analgesia Special/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.

**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 4 cases (can be any combination) in the past 24 months, or completion of training in the past 24 months. Please provide clinical activity/procedure log.

**Renewal/Reappointment:** Documented current competence and evidence of the performance of at least 4 cases (can be any combination) in the past 24 months.

Applicant: initial to request	Non-core privileges are requested individually, in addition to requesting core privileges.	Dept Chair: initial to recommend
(initials)	<b>Conscious Sedation</b>	(initials)
(initials)	<b>Ketamine</b> Test is required every 2 years.	(initials)
(initials)	<b>Propofol</b> Test is required every 2 years.	(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:

- 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 situations 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:**  
☐ **Do Not Recommend the Following Requested Privileges:**

Privilege	Condition/Modification/Explanation

*Notes:*

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**Department Chair Name (Print):** \_\_\_\_\_

**Department Chair Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_



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

Owner	Leah Romito: Primary Care Prov Lmted Ex
Area	Hospital & Health Centers

## Discipline Dismissal and Due Process Policy for Family Medicine Residency Program

### PURPOSE STATEMENT:

The purpose of this policy is to establish the Contra Costa Regional Medical Center's oversight of resident and fellow discipline, dismissal, and due process, while ensuring that each ACGME-accredited program defines its specific criteria for promotion, appointment renewal, and termination.

The Contra Costa Regional Medical Center is responsible for ensuring that all programs maintain fair, transparent, and consistent processes that protect the rights of residents and fellows, support professional development, and uphold patient safety and educational standards.

This policy provides the framework for institutional oversight, including monitoring program compliance, addressing areas of non-compliance, and ensuring timely review of disciplinary actions. The policy also references the specific procedures and criteria that each ACGME-accredited program will include below for the determination of promotion, renewal, and termination of residents' and fellows' appointments.

### Contra Costa Family Medicine Residency Program Policy

#### Discussion

A number of administrative actions may affect the continued participation of a Resident in the Residency Program. These include but are not limited to: special requirements for curriculum supervision and evaluation; supervision or restriction of moonlighting privileges; letters of reprimand, warning, or probation; reduction or modification of privileges; suspension from normal assignments of the training program; and dismissal.

A. Special Requirements

In the normal course of administering the training program, the Program Director, with input from relevant faculty, may require special supervision/evaluation procedures or additional curriculum for a Resident beyond those provided by the generic structure of the Program. The Program Director may impose such special requirements at any time when they feel that an individualized approach is indicated to meet program standards for the educational and professional development of the Resident or to safeguard the quality of patient care. In such cases, the Director will inform the Resident of the reasons for and the specifics of the special requirements. This action shall not give rise to a right of review hearing or appeal.

B. Moonlighting Privileges

As delineated in Section 900 of these policies, the Program Director may withdraw or suspend approval for "moonlighting" at any time. In such cases, the Director will inform the Resident of the reasons for the action. This action shall not give rise to the right of review hearing or appeal.

C. Automatic Suspensions

Suspension of clinical privileges which arise from medical record delinquencies/deficiencies or from State action affecting licensure status shall follow the procedures set forth in the Bylaws, Rules, and Regulations of the Medical Staff and shall automatically result in the like suspension from the Residency Program, without right of review hearing or appeal. Participation in the Residency Program shall be reinstated upon reinstatement of clinical privileges pursuant to the Bylaws, Rules, and Regulations of the Medical Staff. Continued or recurrent medical record deficiencies may be cause for additional disciplinary action.

D. Other Suspensions

1. The Program Director may temporarily suspend a Resident from the normal assignments of the training program including suspension of clinical privileges related to the program for a period not to exceed ten (10) days, without right to appeal, at any time that the Director has reasonable cause to suspect that:
  - a. The Resident has been involved in illegal or unethical conduct.
  - b. The Resident's continued participation seriously compromises the acceptable standards of patient care, jeopardizes patient welfare, or severely threatens the effective functioning of the Hospital/Clinics.
  - c. The Resident has failed to rectify deficiencies of which they have been previously notified in a notification of warning, reprimand, probation, or suspension.
  - d. The Resident has failed to meet the standards of the Program for satisfactory progress/performance as assessed through the regular evaluation process and as required by Hospital and Residency Policies and Procedures.
2. The Program Director shall notify the Resident in writing of the reason(s) for the suspension and state whether the Resident is being reassigned. A reasonable effort shall be made to reassign the Resident to non-patient care activities consistent with the educational objectives for the period involved. In the event of such reassignment, the Resident will be notified as to whether the reassignment will meet American Board of Family Medicine requirements and whether the time of suspension will

have to be made up.

3. During the period of suspension, the Program Director may review the Resident's performance and determine whether additional disciplinary action should be taken against the Resident.
4. Where suspension was indicated for reasons that the Director considers to be transient or correctable by a reasonable level of remedial assistance not yet provided, they shall recommend a course of correction and conduct a continuing review of the situation. In such situations, the Resident will be reinstated to regular activities as soon as they demonstrate sufficient improvement.
5. The Program Director may determine that suspension should remain in effect for a period in excess of ten (10) days or that the Resident should be dismissed from the Program. In that event, the Resident shall be notified in writing of the action and of their right to request a review hearing and appellate review as prescribed under the terms of this document.
6. Suspension for reasons which impact upon professionalism and quality of care will be reported to the Chief Medical Officer and the President of the Medical Staff and reported by them as required to the California Medical Board.

E. Letters of Counseling/Reprimand/Warning/Probation

The Program Director may issue a letter of counseling, reprimand, warning, or probation when, in the judgement of the Director, a Resident's performance fails to meet the standards of the Program. In such a case, the Program Director shall meet with the Resident and present the letter. The letter should state the deficiencies and the expectations for improvements. If a period of probation is imposed, the letter should state the dates and terms of the probation period and the likely consequences of failure to meet expectations. Failure to correct the deficiencies, or recurrence of the problem behavior, within the specified period of time may lead to suspension or dismissal. The issuance of a letter of counseling, reprimand, warning, or probation shall not give rise to a right of review hearing or appeal.

F. Dismissal

1. A Resident may be subject to dismissal from the Residency Program by the Program Director during the term of appointment for any of the following reasons:
  - a. The Resident has been involved in illegal or unethical conduct.
  - b. The Resident's continued participation seriously compromises the acceptable standards of patient care, jeopardizes patient welfare, or severely threatens the effective functioning of the Hospital/Clinics.
  - c. The Resident has failed to rectify deficiencies of which he/she has been previously notified in one or more letters of warning, reprimand, probation, or suspension.
  - d. The Resident has failed to meet the standards of the Program for satisfactory progress/performance as assessed through the regular evaluation process and as required by Hospital and Residency Policies and Procedures.
2. Notice of dismissal may be immediate or may follow a period of suspension,

warning, or probation as appropriate to the specifics of the situation in the judgement of the Director. The Resident must be notified of the decision to dismiss in writing. The letter of dismissal must include the reasons for the action and inform the Resident of the right of review hearing and appeal.

3. Except in cases where patient welfare or effective functioning of the hospital/clinics may be in jeopardy, the Resident should be permitted to retain his/her position in the training program, though with restricted or suspended assignments/privileges, pending the final decision of the review or appellate body or the Resident's waiver of the right to review or appeal.

#### G. Review Hearing

1. Upon written notification by the Program Director to a Resident of dismissal or suspension in excess of ten (10) days, the Resident, within a period of ten (10) calendar days, may request a review hearing by written request delivered directly to the Program Director. In the event that the Resident waives the right to a hearing, in writing, or fails to deliver a written request for hearing within the ten (10) day period, the action of the Program Director shall be final and conclusive.
2. Upon request by the Resident for a review hearing, a Review Panel shall be convened within twenty (20) calendar days. The Resident shall be notified of the hearing date not less than ten (10) days prior to the review hearing. The notice shall detail and limit the issues that can be discussed at the hearing.
3. The Review Panel will consist of five individuals, four of whom shall be faculty members of the Residency Program, and one a Resident in good standing in the Program. At least two of the faculty members must be Board-Certified family physicians. The panel members shall be selected by the Chief Medical Officer or, his or her designee.
4. At the hearing, the Program Director and the Resident will each have the opportunity to call witnesses and present relevant evidence. Evidence need not conform to common law or statutory rules that might make it inadmissible in a court of law. Each party will be permitted to ask questions of witnesses as long as this is done in an expeditious manner. The Resident will be given the opportunity to present a personal statement, either orally or in writing, in their own defense. The Resident may be accompanied by or represented by another Resident or faculty member within the Residency Program, but they may not be accompanied or represented by an attorney at law.
5. The proceedings of the review hearing will be closed and will be recorded. The recording will be retained and a transcript made available, if requested and at the Resident's expense, to the Resident or to other parties who have the written consent of the Resident.
6. The Review Panel shall render a decision, in writing, within ten (10) calendar days following the concluding date of the hearing. This shall include a summary of the reasons supporting the decision. A copy of the decision shall be promptly delivered to the Resident and to the Program Director.

#### H. Appeal

1. Following receipt of the Review Panel's decision, the Resident may appeal the decision to the Director of the Health Services Department or their designee. To exercise this right, they shall give written notice of their intent to appeal to the Residency Program Director within ten (10) calendar days following delivery of the decision to them. Failure to give notice in the manner and within the time provided shall constitute a waiver of the right to appeal. Notice of the time and place of the appeal before the Director, which shall be scheduled not less than twenty (20) days following the request for the appeal, shall be given to the Resident not less than (10) days before the time scheduled. The proceedings on appeal shall be in the nature of an appellate review, based upon the record of the hearing before the Review Panel. The Resident and the Program Director shall each have the right to present oral or written statements in support of his or her position on appeal. The Director, or their designee, may affirm, modify, or reverse the recommended action of the Review Panel or may, in their sole judgment and discretion, refer the matter for further review and consideration. The decision of the Director shall be final and conclusive.

I. Medical Staff Proceedings

Nothing in this due process procedure shall be construed to prohibit the Medical Staff of Contra Costa Regional Medical Center and Health Centers from taking disciplinary action against a Resident in accordance with the provisions of the Medical Staff Bylaws. Suspension of the privileges of a Resident or termination of their membership on the Medical Staff by reason of proceedings taken by the Medical Staff in accordance with the Medical Staff Bylaws shall result in like suspension or termination from the Residency Program without any right to appeal or without any right to review or appeal.

J. Procedural Error

The Director of the Health Services Department, in their sole judgment and discretion, shall determine whether or not any failure to follow the procedure outlined in this document has deprived a Resident of due process and should constitute grounds for a new review hearing and appeal or for other remedial action. Their determination with regard to that matter is final and conclusive.

## APPROVALS:

Graduate Medical Education Committee: 4/2021, 9/2025

Reviewed/Revised:

1/2018, 4/2021, 9/2025

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending

Graduate Medical Education  
Committee

Leah Romito: Primary Care  
Prov Lmted Ex [TT]

09/2025

Leah Romito: Primary Care  
Prov Lmted Ex [TT]

09/2025

## Standards

No standards are associated with this document



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

Owner	Leah Romito: Primary Care Prov Lmted Ex
Area	Hospital & Health Centers

## Eligibility Selection Agreements Appointment Promotion and Reappointment

### PURPOSE STATEMENT:

The purpose of this policy is to establish the Contra Costa Regional Medical Center's oversight of the processes for eligibility, selection, appointment, promotion, and reappointment of residents and fellows. Additionally, each ACGME-accredited program shall define its specific criteria for the above categories.

The Contra Costa Regional Medical Center ensures that each program implements fair, transparent, and consistent procedures that comply with ACGME Common and specialty-/subspecialty-specific Program Requirements. This includes verifying eligibility criteria, monitoring selection processes, defining criteria for appointment and reappointment, and establishing standards for promotion within the program.

### Scope

This policy applies to:

- A. The Contra Costa Regional Medical Center;
- B. All ACGME-accredited residency and fellowship programs;
- C. All candidates applying for residency or fellowship positions within the Contra Costa Regional Medical Center.

### POLICY:

- A. Compliance with ACGME Standards
  - 1. All recruitment, selection, eligibility, and appointment processes must comply with

## ACGME Institutional, Common Program, and Recognition Requirements.

### B. Eligibility

1. Programs must verify that applicants meet eligibility requirements for appointment as defined in ACGME Common Program Requirements and applicable specialty-specific requirements.
2. Eligibility includes appropriate medical education, licensure (as required), and visa status (if applicable).
3. An applicant must meet one of the following qualifications to be eligible for appointment to an ACGME-accredited program:
  - a. graduation from a medical school in the United States, accredited by the Liaison Committee on Medical Education (LCME); or,
  - b. graduation from a college of osteopathic medicine in the United States, accredited by the American Osteopathic Association (AOA); or,
  - c. graduation from a medical school outside of the United States, and meeting one of the following additional qualifications:
    - i. holds a currently-valid certificate from the Educational Commission for Foreign Medical Graduates prior to appointment; or,
    - ii. holds a full and unrestricted license to practice medicine in a United States licensing jurisdiction in his or her current ACGME specialty-/subspecialty program.

### C. Selection

1. Residents and fellows must be selected through a process that is fair, equitable, and consistent with institutional policies, federal and state regulations, and the Institution's commitment to diversity and inclusion.
2. When applicable, programs must participate in the **National Resident Matching Program (NRMP)** or other matching services in accordance with institutional policy.
3. An applicant invited to interview for a resident/fellow position will be informed, in writing or by electronic means, of the terms, conditions, and benefits of appointment to the ACGME-accredited program, either in effect at the time of the interview or that will be in effect at the time of the applicant's eventual appointments. Information that is provided will also include information pertaining to:
  - a. stipends, benefits, professional liability coverage, and disability insurance accessible to residents/fellows.
  - b. institutional policy(ies) for vacation and leaves of absence, including medical, parental, and caregiver leaves of absence.
  - c. health insurance accessible to residents/fellows and their eligible dependents.

### D. Issuance of Agreement

1. The CCRMC Graduate Medical Education (GME) Office will prepare a written resident agreement, outlining the terms and conditions of the resident's appointment to a program. The Resident Agreement will directly contain or provide a reference to the following items:
  - a. resident responsibilities;
  - b. duration of appointment;
  - c. financial support for residents;
  - d. conditions for reappointment and promotion to a subsequent PGY level;
  - e. grievance and due process;
  - f. professional liability insurance, including a summary of pertinent information regarding coverage;
  - g. hospital and health insurance benefits for residents and their eligible dependents;
  - h. disability insurance for residents;
  - i. vacation, parental, sick, and other leave(s) for residents, compliant with applicable laws;
  - j. timely notice of the effect of leave(s) on the ability of residents to satisfy requirements for program completion;
  - k. information related to eligibility for specialty board examinations; and,
  - l. institutional policies and procedures regarding resident clinical and educational work hours and moonlighting

#### E. Execution of Agreement

1. The CCRMC GME Office will issue all Resident Agreements and monitor the implementation of terms and conditions of appointment.
2. The Resident Agreement is executed once all of the following signatures are obtained:
  - a. The Designated Institutional Official or their designee
  - b. The Resident candidate
  - c. The Program Director

#### F. Appointment

1. Appointments are formalized through an institutional **contract/letter of agreement**, which outlines terms and conditions of appointment, responsibilities, salary and benefits, duration of appointment, and relevant policies.
2. All initial and continuing appointments are contingent upon satisfactory performance, professionalism, and adherence to institutional and program policies.

#### G. Institutional Oversight

1. The **Designated Institutional Official (DIO)** and **Graduate Medical Education Committee (GMEC)** will monitor all ACGME-accredited programs for compliance

with recruitment, eligibility, selection, and appointment standards.

2. The GMEC will review recruitment and appointment practices periodically and address areas of non-compliance in a timely manner.

#### H. Non-competition

1. Neither the Contra Costa Regional Medical Center nor any of its ACGME-accredited programs will require a resident to sign a non-competition guarantee or restrictive covenant.

## **Policy-Program-Specific: Contra Costa Family Medicine Residency Program**

- A. Resident Selection is through the ERAS system. We do not accept first-year applications outside of the ERAS Match system. Applications are accepted from the following sources:
  1. Graduates of medical schools in United States and Canada accredited by Liaison Committee on Medical Education (LCME)
  2. Graduates of colleges of osteopathic medicine in the United States accredited by American Osteopathic Association (AOA)
  3. Graduates of Fifth Pathway program provided by an LCME-accredited medical school.
  4. Graduates of medical schools outside the United States and Canada who meet one of the following:
    - a. Current valid certificate from Educational Commission for Foreign Medical Graduates PRIOR to appointment
    - b. Permitted to train in California by Medical Board of California.
    - c. Holds a full and unrestricted license to practice medicine in a United States licensing jurisdiction in his or her current ACGME specialty-/subspecialty program.
- B. The Program selects from among eligible applicants based on residency program-related criteria. The Program does not discriminate with regard to sex, race, age, religion, color, national origin, disability, or any other applicable legally protected status. The Program abides by the rules associated with the National Resident Matching Program (NRMP)
- C. Appointments and reappointment for training of Residents are made by the Program Director. While it is the intent and hope of the Program that each resident will successfully complete the full three-year curriculum, appointments and reappointment are for one year only. Decisions on continuation during any academic year and yearly reappointment will be based upon quality of performance and conduct of the Resident.
  1. If, in the opinion of the Program Director, there has not been an adequate period of time for evaluation, the reappointment date may be extended, and the Resident will be so notified in writing. The Program Director will notify in writing any Resident who will require additional training time to meet the standards for promotion and/or graduation within the Program. A Resident who will not be reappointed shall be

informed in writing promptly after the decision is made.

- D. Anticipated Non-Renewal or Non-Promotions. If a resident will not be promoted or re-appointed, that resident will be informed in writing by the Program Director with as much notice of the intent not to renew or promote as circumstances will reasonably allow, prior to the end of the agreement.
- E. Notification regarding reappointment will be provided to each resident physician by the Program Director or the PD's designee, which may include the resident's advisor. Reappointment offers to continuing Residents will be made during the months of February through May of the current training year, or nine months after the current appointment for those Residents appointed after the usual July 1 appointment date. Continuing Residents are required to accept a reappointment offer in writing no later than one month after completion of the applicable reappointment period. If acceptance of the offer is not received by the Program Director by that date, disciplinary actions including but not limited to dismissal may occur.
- F. The Program does not routinely offer part-time or shared residency positions. Individual Residents may petition the Program Director for alterations in the usual full-time position schedule. Such requests will be evaluated and granted or denied on an individual basis taking into account such factors as Accreditation Council for Graduate Medical Education (ACGME) requirements, resource availability, service requirements, and curriculum integrity, as well as the personal and educational needs of the Resident.
- G. Promotion
  - 1. Residents are promoted and graduated based on explicit criteria in accordance with the ACGME and the Review Committee-Family Medicine (RC-FM) Program Requirements. The residency program requires its residents by graduation to obtain competencies in the six areas in alignment with the Family Medicine Milestones.
    - a. Patient Care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health;
    - b. Medical Knowledge about established and evolving biomedical, clinical, and cognate (e.g. epidemiological and social-behavioral) sciences and the application of this knowledge to patient care;
    - c. Practice-Based Learning and Improvement that involves investigation and evaluation of their own patient care, appraisal and assimilation of scientific evidence, and improvements in patient care;
    - d. Interpersonal and Communication Skills that result in effective information exchange and teaming with patients, their families, and other health professionals;
    - e. Professionalism, as manifested through a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to a diverse patient population;
    - f. Systems-Based Practice, as manifested by actions that demonstrate an awareness of and responsiveness to the larger context and system of health care and the ability to effectively call on system resources to provide care that is of optimal value.

- H. The Residency Program Director with the advice of the Clinical Competency Committee decides whether to promote a resident to the next postgraduate year or to graduate a resident from the program, based upon the resident's ability to adequately meet the Family Medicine Milestones. Major performance deficits will be grounds for required educational interventions, probation or dismissal
- I. In addition to adequately meeting the Family Medicine milestones, all residents must meet these standards.
  - 1. Patient Care
    - a. Participation in patient care and management on each rotation as documented by the faculty evaluation forms. Major performance deficits will be grounds for probation. Attendance and behavior are also considered in evaluating performance.
  - 2. Medical Knowledge
    - a. Annual testing by the American Board of Family Medicine: Failure to obtain a composite score above the 10th-percentile for national peer group on the In-Training Exam may be grounds for probation. Scoring below the national average for peer group will identify a resident as at-risk. An at-risk resident is required to meet with his/her faculty advisor to develop and implement a plan to remediate deficits.
    - b. Contribution to the academic and scholarly mission of the residency, including student and resident teaching, conference presentations and participation, as well as overall faculty assessment of resident performance. Major performance deficits will be grounds for required educational interventions.
  - 3. Interpersonal and Communication Skills
    - a. Participation in direct observation of patient encounters with a behavioralist.
    - b. Professionalism
    - c. Personal integrity, which includes strict avoidance of substance abuse, theft, lying, cheating, and unexplained absences. Unauthorized use of equipment and personnel for other than educational, professional, and patient care use is prohibited. Failure to follow this standard will be grounds for required educational intervention and/or probation depending on level of concern.
  - 4. Systems-Based Practice
    - a. Compliance with all hospital and residency record keeping and documentation requirements. A pattern of lateness and noncompliance will be grounds for removal from clinical training until full compliance is obtained.
- J. Graduation: Additional criteria apply:
  - 1. Successful completion of 36 months of ABFM-approved family medicine residency

training. The resident must receive a passing evaluation in all rotations and in the Family Medicine Center.

2. Procedural Care: All residents must be able to perform the following procedures independently by graduation:

- a. Chest X-Ray Interpretation
- b. EKG Interpretation
- c. Large joint injection
- d. Suturing
- e. Paracentesis
- f. Insertion and removal of an intrauterine device (IUD)
- g. Endometrial biopsy
- h. Incision and drainage of abscess
- i. Vaginal delivery
- j. Nexplanon insertion and removal

#### K. Global Health Fellows

1. Global Health Fellows will be selected through an application and interview process through the Residency office and with oversight of the Residency Program Director and the Global Health Fellowship Directors.
2. The Program selects from among eligible applicants based on fellowship program-related criteria. The Program does not discriminate based on sex, race, age, religion, color, national origin, disability, or any other applicable legally protected status.
3. Global Health Fellows are expected to train under the guidelines of the six competency domains as outlined above (Patient Care, Medical Knowledge, Practice-based learning and Improvement, Interpersonal and Communication Skills, Professionalism and Systems-based Practice).
4. While under the educational supervision of the Fellowship and Residency Program, all applicants will be hired as attending physicians and as such hiring, employment and privileging to be completed through the usual Medical Staff workflow.
5. While it is the goal of the fellowship program to support each fellow to complete the program, it is possible a fellow may not complete the program due to circumstances including, but not limited to, the following:
  - a. Incapacitating illness of the global health FELLOW,
  - b. Unsatisfactory performance of the FELLOW as determined by the Global Health Fellowship Directors in collaboration with the Program Director,
  - c. The result of legal, educational, employment, licensing and/or medical staff disciplinary action.

## REFERENCES:

ACGME Institutional Requirements, Section IV.C: *Resident/Fellow Appointments*

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## Family Medicine Residency Program Policy for Compensation

### Family Medicine Residency Program Policy for Compensation

- A. Compensation scales for Residents are per the Memorandum of Understanding (MOU) between the County and the Physicians' and Dentists' Organization of Contra Costa (PDOCC) (i.e. the Union). Each Resident's yearly salary is determined by their postgraduate year level of standing in the Residency Program. If residents are permitted to moonlight, additional compensation earned through "moonlighting" is calculated based on an hourly rate as specified in the MOU.
- B. In recognition of administrative and supervisory responsibilities, the Lead (Chief) Resident(s) may receive a predetermined stipend for their Lead Resident year as determined by the Chief Medical Officer
- C. Residents who successfully complete service for a postgraduate year and are reappointed for a succeeding year shall be advanced to the next higher postgraduate year level of compensation.
- D. Compensation for post-residency fellows will be determined by the unique funding and compensation agreements communicated to the fellow by the Program Director in coordination with the Chief Medical Officer
- E. Resident compensation is determined by the individual's level of standing within the training program, not by their length of employment. A Resident who requires more than the usual twelve months to successfully complete a given postgraduate year will be compensated at the level appropriate for the incomplete level of training until such time as they have been

promoted to the next higher postgraduate year level of standing within the Program.

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## Family Medicine Residency Program Policy for Leaves of Absence

### Leaves of Absence

- A. The residency program abides by the standards on leaves of absence established by the [American Board of Family Medicine](#) (ABFM).
- B. The residency program also abides by the requirements for family medicine residency training specified by the Accreditation Council of Graduate Medical Education (ACGME).
- C. While Federal and California laws as well as the terms of the PDOCC Memorandum of Understanding (MOU) may provide residents, in their role as employees, with certain rights or benefits, ABFM and ACGME requirements still apply in terms of the possible impact of leave on the successful completion of residency.
- D. In cases where a Resident's absence from the Residency Program exceeds 3 months, the Program Director will utilize various criteria to judge the point at which, and conditions under which, the Resident may re-enter the Program. The ABFM will make final determination about the amount of additional training required of the resident.
- E. Vacation Leave:
  - a. A Resident accrues vacation leave credit at a rate specified by the MOU. Vacation may be taken only on specified rotations. Therefore, Residents may be permitted to use vacation accruals in advance of the date they are earned, but never to exceed the anticipated accrual for the current training year.
  - b. Resident vacation requests will be approved when they comply with ACGME and ABFM requirements and rotation-specific vacation leave policies, when Resident service and on-call duties can be properly covered, and when the requests are made

in compliance with standard schedules and procedures.

- c. Vacation leave requests will be approved by mutual agreement among the Lead Resident, applicable Department Chair or Rotation Supervisor, and Program Director. Procedures for requesting vacation leave shall adhere to standard workflows published in the [Submitting Time Away](#) and the [Vacation Request Workflow](#) documents on the Residency Sharepoint Site.
  - 1. In unusual cases, when a request falls outside customary procedures and deadlines, or when there is disagreement regarding approval of a request, the matter will be resolved by the Program Director. Such decisions shall not give rise to a right of review or appeal.

F. Personal Holidays:

- a. A Resident accrues personal holiday credit at a rate specified by the PDOCC MOU. Unlike vacation time, floating holiday time may not be taken in advance of the actual accrual.
- b. The requirements and procedure for requesting floating holiday leave are the same as outlined above for vacation leave.

G. Educational Leave:

- a. Residents qualify for annual educational leave accrual as per the MOU. The requirements and procedure for requesting education leave are the same as outline above for vacation leave.
- b. Time away from the residency program for educational purposes is counted in the general limitation on absences (per the [American Board of Family Medicine](#)) but should not exceed 5 days annually.

H. Sick Leave and Unplanned Absences:

- a. Residents accrue sick leave at a rate specified by the MOU. Upon exhaustion of accrued sick leave, additional leave without pay may be granted at the discretion of the Program Director.
- b. Residents may take unplanned absences when they or a member of their immediate family is unexpectedly ill. Medical appointments, dental appointments or other foreseeable needs do not qualify as unplanned absences. Such planned absences are not dealt with by this section of policies.
- c. In all cases, as soon as a Resident becomes aware of an unplanned absence, the Resident must contact the Lead Resident, applicable Department Chair or Rotation Supervisor, and Program Director. Procedures for submitting sick leave and unplanned absences shall adhere to standard workflows published in the [Submitting Time Away](#) document on the Residency Sharepoint Site.
- d. For illnesses leading to more than 3 days of absence, the Program Director may require a note from the Resident's personal physician.
- e. As per ABFM and ACGME requirements for Family Medicine Residency Training, extended absences that interfere significantly with the Resident's educational experience may jeopardize the Resident's ability to graduate within the usual three

years, continue in the program, and/or board eligibility.

- f. The Resident/Residency Office shall ensure that sick leave is properly recorded on their timesheet.

I. Family Care Leave:

- a. Parental Leave must be requested as early as possible but at least 90 days prior to the scheduled leave commencement date unless an exigency exists using the published template ["FMLA Curriculum."](#)
- b. After formal notification of the Program Director, each resident is entitled to Family Medical Leave as outlined in the PDOCC MOU.
- c. As per ABFM requirements for Family Medicine Residency Training, extended Family Medical Leave absences that exceed ABFM policy ([American Board of Family Medicine](#)) may jeopardize the Resident's ability to graduate within the usual three years, continue in the program, and/or board eligibility.

J. "Off-Campus" Leave

- a. In special circumstances, a Resident may need to leave his/her site of clinical responsibility for a brief period of time. Such occasions should be kept to an absolute minimum and are subject to review for appropriateness.
- b. Before going "off-campus", the Resident shall obtain the approval of their supervising attending physician for the time involved and arrange appropriate coverage of all clinical responsibilities.

K. Jury and Witness Duty:

- a. When necessary, leave of absence for jury duty will be granted.
- b. The Resident shall notify the Program Director promptly upon learning of scheduled jury duty.
- c. If necessary, the Program Director will assist the Resident in communications with appropriate court officials to adjust scheduling of jury duty to a time period during which patient care will not be compromised and the Resident's educational progress will not be inordinately delayed.
- d. The MOU specifies employee procedures required for jury duty. In particular, the MOU specifies the steps the Resident must follow to remain in regular pay status.

L. Global Health Fellows:

- a. Global Health Fellows are temporary employees and therefore do not receive paid time off.
- b. All unpaid time off for Global Health Fellows during the duration of their Fellowship Agreement will be negotiated with a Fellowship Co-Director or the Program Director prior to the leave.

M. Information Access

- a. This information is accessible to the residents at all times on the [Residency Sharepoint Homepage](#).

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## Family Medicine Residency Program Policy for Moonlighting

### PURPOSE STATEMENT:

The purpose of this policy is to define the conditions under which residents and fellows may participate in moonlighting activities. This policy ensures compliance with Accreditation Council for Graduate Medical Education (ACGME) requirements, prioritizes patient safety, and safeguards the educational mission, well-being, and performance of residents/fellows. The Contra Costa Regional Medical Center, in conjunction with the AGME Sponsored residency program, will allow trainees to participate in moonlighting activities if appropriate conditions are met as outlined.

### POLICY:

- A. Residents/fellows must not be required to moonlight. Residency training is a full-time responsibility. Each Resident may choose how to use off-duty hours, except that a Resident should not engage in activities or other employment that interfere with their obligations to the Program or adversely affect the Resident's participation in the Program.
- B. Moonlighting is a privilege, not a right, and may be restricted or revoked at the discretion of the Program Director or Contra Costa Regional Medical Center.
  1. R1 and R2 residents are not permitted to moonlight.
  2. Moonlighting is not required: it is a privilege and fully voluntary.
  3. The Program Director may deny, withdraw, suspend, or condition any approval for such work at any time that he/she feels that such work is contrary to the best interests of the Resident or the Program. Moonlighting is expressly prohibited when the Resident is involved in a Voluntary or Required Educational Intervention.

4. Moonlighting activities may not be performed during any time when the Resident is on duty for the Residency Program, including on-site and off-site "call-back" assignments. Elective rotations are part of the Residency Program and count as being on duty during the Elective experience.
- C. All moonlighting activities must:
1. Be pre-approved in writing by the Program Director;
    - a. Third-Year Residents must obtain the written approval of the Program Director prior to performing any medical work that is not part of the Residency Program
  2. All moonlighting activities count toward the work-hour limits of no more than 80 hours per week, averaged over a four-week period.
  3. Not interfere with the ability of residents/fellows to achieve educational goals or compromise patient safety.
  4. Residents may not moonlight as an Elective (i.e. they may moonlight during off-duty while on Elective but not during their elective curriculum time).
- D. PGY-1 residents are **not permitted** to moonlight in accordance with ACGME requirements.
- E. Resident moonlighting within the Health Services Department is subject to all requirements of the Medical Staff. A resident moonlighting within the Health Services Department does so as a regular member of the Medical Staff, not as a Resident Member. Therefore, the resident must have previously been granted the necessary clinical privileges for performing that work. The resident must apply for such privileges through the Medical Staff Office via its usual procedures.
- F. Approval to moonlight by the Program Director does not imply that such employment is recognized to be within the scope of the Resident's duties within the training program.
- G. Participation in moonlighting is contingent upon the resident/fellow maintaining satisfactory progress, professionalism, and performance in the training program. Approval of permission to moonlight may be withdrawn at any time.

## REFERENCES:

ACGME Institutional Requirements, Section IV.H: *Moonlighting*

ACGME Common Program Requirements, Section VI.F: *Clinical and Educational Work Hours*

## APPROVALS:

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## Family Medicine Residency Program Policy for Problem Solving - Grievances

### POLICY:

- A. The Residency Program wishes to encourage constructive Resident input into the Residency, Hospital, and Medical Staff operations and policy formulation.
- B. A Resident with a problem or grievance is encouraged to contact a Chief Resident, Faculty Advisor, Course Supervisor, Core Faculty, Attending Physician, Department Chair, or the Residency Program Director, depending on the nature of the problem or grievance.
- C. In the care of a patient, the attending medical staff member(s) for that patient and the Department Chairperson are responsible. On educational and administrative matters, the Residency Program Director is responsible.
- D. On educational and administrative matters (including but not limited to Resident duty hours issues) not resolvable at the level of the Program Director, a Resident shall have reasonable access to the Chief Medical Officer and to the Chief Executive Officer of the Hospital and Clinics. On quality of care issues, a Resident shall have reasonable access to the Department Chairs and to the President of the Medical Staff.
- E. Contra Costa Regional Medical Center as outlined in the MOU has a policy regarding submitting and processing resident/fellow grievances at the program and the institutional level, which are available to the resident/fellow.
- F. Residents are part of the physician's union and therefore can ask for representation to limit and conflict of interest that may arise.
- G. Global Health Fellows have the same avenues to pursue problem solving or grievances as listed above with the additional support of the Global Health Fellowship Co-directors.

# REFERENCES:

Memorandum of Understanding

# APPROVALS:

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## Family Medicine Residency Program Policy for Work Environment and Other Benefits

### PURPOSE STATEMENT:

The purpose of this policy is to ensure that the Sponsoring Institution complies with ACGME Institutional Requirements related to residents and fellow well-being and safety. The Institution is committed to fostering a clinical and educational environment that supports physical, mental, and emotional health, while ensuring safe, high-quality patient care.

### Scope

This policy applies to:

- A. The Sponsoring Institution;
- B. All ACGME-accredited residency and fellowship programs within the Institution;
- C. All residents and fellows enrolled in ACGME-accredited programs.

### Definitions

- A. **Residents/Fellows:** All individuals enrolled in an ACGME-accredited training program at the Sponsoring Institution.
- B. **Well-Being Resources:** Institutional services that include confidential counseling, mental health support, and facilities that promote resident/fellow health and safety.
- C. **Clinical and Educational Environment:** The physical and organizational settings in which residents/fellows provide patient care and receive training.

# POLICY:

The Sponsoring Institution, in partnership with its ACGME-accredited programs, will:

- A. Provide a choice of comprehensive health insurance plans for Residents and their families as delineated in the Memorandum of Understanding (MOU) between the County and the Physicians' and Dentists' Organization of Contra Costa (PDOCC).
- B. Provide confidential, affordable mental health services, including access to urgent and emergent care 24 hours a day, seven days a week.
  - 1. As with all other salaried employees, residents/fellows will have access to the Employee Assistance Program (see separate Contra Costa Health Policy)
- C. Maintain a safe and healthy clinical and educational environment, including:
  - 1. Ready access to food during clinical and educational assignments (Meals shall be provided for Residents at no charge during scheduled duty periods, during the times the cafeteria is open serving meals);
  - 2. On call room sleep/rest quarters that are to be maintained and accessible at all times, located near their duties for patient care
  - 3. Safe transportation options for residents/fellows too fatigued to safely return home on their own (discussed during orientation and outlined in Resident Scoop)
  - 4. White coats shall be provided and maintained for Residents.
  - 5. Clean, private lactation facilities in proximity to patient care areas, with clean and safe refrigeration for breast milk storage;
- D. Ensure proper safety and security measures appropriate to the clinical learning environment, including but not limited to:
  - a. Restricted badge access to clinical environments for staff
  - b. Detention Safety Training
  - c. Locked Inpatient psychiatry wards
  - d. Sheriff and Deputy Presence when required
  - e. SERS reporting system if safety events
  - f. Annual Safety Trainings for all employees
- E. Reasonable accommodations for residents/fellows with disabilities, consistent with the Sponsoring Institution's policies and applicable law.
  - a. Residents with disabling conditions may, at times, require reasonable accommodations to their schedule, regular duties or work conditions. Residents with disabling conditions may have certain employment rights through the American with Disabilities Act ([ADA](#)). Such rights may supersede restrictions within these Policies. ADA-related matters will be resolved on a case-by-case basis by the Program Director in consultation with the county's Health Services ADA coordinator as needed.

- F. Workers' Compensation coverage exists under the laws of the State of California for work-related illness or accident. Additional details are as specified in the MOU.
- G. The County shall provide professional liability coverage for Residents during their performance of Program-approved activities. Contra Costa County is self-indemnified and malpractice coverage for residents is the same as that for Medical Staff. See Appendix A400.
- H. Other benefits shall apply to Residents as provided by the MOU and relevant Contra Costa Health policies.

## REFERENCES:

ACGME Institutional Requirements, Section IV.E: *Well-Being and Clinical Environment*

Sponsoring Institution Human Resources Policy on Disability Accommodations

Sponsoring Institution Wellness and Employee Assistance Program Policies

Memorandum of Understanding (MOU)

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## Policy on Clinical and Educational Work Hours for Family Medicine Residency Program

### PURPOSE STATEMENT:

The purpose of this policy is to ensure compliance with Accreditation Council for Graduate Medical Education (ACGME) requirements regarding clinical and educational work hours and provide program specific policies regarding work hour policies. The Contra Costa Regional Medical Center is committed to protecting patient safety, resident/fellow well-being, and high-quality education by maintaining oversight of clinical and educational work hours.

### Scope

This policy applies to:

- A. The Contra Costa Regional Medical Center;
- B. All ACGME-accredited residency and fellowship programs within the Institution;
- C. All residents and fellows enrolled in ACGME-accredited programs.

### Definitions

- A. **Clinical and Educational Work Hours (CEWH):** All clinical and academic activities related to the residency/fellowship program, including patient care, in-house call, administrative duties related to patient care, scheduled academic activities (e.g., conferences), and moonlighting. Travel to and from the hospital is excluded.
- B. **ACGME CEWH Requirements:** The limits, standards, and expectations outlined in the ACGME

Common Program Requirements, including maximum weekly hours, time off between shifts, call frequency, and maximum shift lengths.

- C. **Moonlighting:** Voluntary, compensated, medically-related work (internal or external) not part of the program's educational requirements; counts toward CEWH limits.

## POLICY:

The Contra Costa Regional Medical Center will maintain a CEWH policy that ensures:

- A. Oversight of institutional and program-level compliance with all ACGME CEWH requirements.
- B. Resident/fellow clinical and educational work hours are scheduled and monitored in a manner that promotes:
  - 1. Patient safety;
  - 2. Resident/fellow well-being;
  - 3. Education that fosters professional development and clinical excellence.
- C. Each ACGME-accredited program develops and enforces a program-specific CEWH policy consistent with institutional policy and ACGME requirements.
- D. Residents/fellows are provided a process to report CEWH concerns without fear of intimidation or retaliation.

## PROCEDURES:

- A. Institutional Oversight
  - 1. The **DIO** and **GMEC** will monitor compliance with CEWH requirements through:
    - a. Review of ACGME survey data,
    - b. Internal program evaluations,
    - c. Periodic audits of program scheduling and duty hour violation reporting.
  - 2. Non-compliance or concerns will be addressed by the Program Director, GMEC and, if necessary, institutional leadership.
- B. Program-Specific Policies
  - 1. Each program must:
    - a. Establish a written CEWH policy consistent with institutional and ACGME requirements (see below),
    - b. Clearly define procedures for tracking, documenting, and reporting work hours;
    - c. Educate residents/fellows and faculty annually about CEWH policies and compliance expectations.
- C. Resident/Fellow Responsibilities
  - 1. Residents/fellows must:

- a. Accurately document CEWH in program-designated systems;
- b. Adhere to institutional and program-specific CEWH policies;
- c. Report concerns about non-compliance or unsafe scheduling to their Program Director, the DIO, or the GME Office.

#### D. Faculty Responsibilities

##### 1. Faculty must:

- a. Monitor and respect resident/fellow CEWH limits;
- b. Schedule assignments to balance patient care, resident/fellow education, and CEWH compliance;
- c. Support a culture of patient safety and resident/fellow well-being.

##### 2. Responsibilities

- a. **Contra Costa Regional Medical Center Leadership:** Ensure resources and systems to monitor CEWH.
- b. **DIO:** Oversee institutional compliance with CEWH requirements.
- c. **GMEC:** Monitor CEWH across all programs and address compliance issues.
- d. **Program Directors:** Develop and enforce program-specific CEWH policies; monitor resident/fellow compliance.
- e. **Faculty:** Support compliance with CEWH requirements in scheduling and supervision.
- f. **Residents/Fellows:** Accurately report CEWH and comply with institutional/program policies.

## Program-Specific Policies- Contra Costa Family Medicine Residency Program

### Scheduling of Duties and Work-Hour Limits

#### A. The Program shall endeavor whenever possible to:

- 1. Schedule duty time fairly for each Resident.
- 2. Distribute on-call and holiday call duties as equitably as possible among Residents of the same postgraduate level, subject to patient care and departmental requirements.
- 3. Abide by the work-hour limits as specified in the ACGME Common Program and Family Medicine requirements.
- 4. Maintain a schedule of home "call-back" assignments to be used when on-site residents request additional help. The frequency and hours that the call-back resident is used will be monitored and count toward all ACGME work-hour limits.
- 5. Monitor duty hours regularly. Work-hour violations identified will be evaluated via the

Duty Hour Violations Protocol, in order to strategize to comply with duty hour restrictions for all residents.

- B. Regular, "non-call" service duties of Residents shall be assigned by the Program Director or their designee, in consultation with department faculty, for each clinical rotation. This shall include assignment of weekday, weekend day, and holiday duties.
- C. The Program Director determines the frequency, structure, and content of Resident on-call schedules and may delegate to the Chief Resident(s) responsibility for the equitable assignment of on-call duties amongst Residents. The Chief Resident(s) shall be responsible for the timely formulation and distribution of the Resident on-call schedule. The clerical support services of the Residency Program Office will be available to assist this effort.
- D. The Director shall determine the structure of the schedule of on-call responsibilities for holidays. The Director may delegate to the Chief Resident(s) responsibility for assignment of Resident on-call schedules for holidays. Holiday call shall be distributed as equally as possible among Residents of the same postgraduate level. The officially recognized holidays are specified in the Memorandum of Understanding (MOU). The exact dates of the holidays are specified annually by the federal government.
- E. It is the responsibility of the Chief Resident(s) to arrange coverage of on-call assignments for all Resident leaves of absence.
- F. The Program Director shall be responsible for reassignment of Resident and staff duties to cover daily, "non-call" service responsibilities during periods of Resident leaves of absence.
- G. Residents shall be permitted to trade on-call assignments, provided that proper coverage is arranged within the requirements of the affected department(s) and of the Program. Such trades are subject to review and may be disallowed by the Chief Resident, applicable Department Chair, or Program Director. Any trade which would cause an individual to violate ACGME work-hour limits is not acceptable. It is the responsibility of the Resident initiating any change in the published call schedule to notify all clinical service areas affected by the change and to amend posted schedules appropriately.
- H. The record of Resident's night, weekend, and holiday call work will be maintained online (at the time of this revision, the residency is using Amion.com).
- I. Resident work schedules will be set by the Program Director, taking into account the possibility of unplanned Resident absences (sick leave, parental leave, etc.) and changes in service requirements. In accepting appointment to the Program, each Resident acknowledges and understands that the Director may make changes in Resident schedules and workloads. Such changes shall not, however, exceed the ACGME work-hour limits, and shall be, to the extent possible, equally distributed amongst the Residents of a given year of training. Resident compensation is based upon fulfillment of the Resident schedule and workload.
- J. Changes to the expected workload pursuant to these Policies and Procedures (and the limits specified herein) do not constitute cause for changes in reimbursement.
- K. Moonlighting- Please see separate policy for specifics regarding moonlighting
- L. Residents – individually, collectively, and through their representatives, the Chief Resident(s) – shall work with the Program Director and Core Faculty to effectively implement a program of education and services within the structure of ACGME work-hour limits. Whenever a Resident has a problem or grievance with respect to duty hours that is not, in her or his judgment,

adequately addressed through this structure, that Resident is encouraged to contact the Chief Resident, Faculty Advisor, Department Chair, Core Faculty member, or the Program Director. For duty hours issues not resolvable at the level of the Program Director, a Resident shall have reasonable access to the Chief Medical Officer and to the Chief Executive Officer of the Hospital and Clinics.

## REFERENCES:

ACGME Institutional Requirements, Section IV.G: *Clinical and Educational Work Hours*

ACGME Common Program Requirements, Section VI.F: *Clinical and Educational Work Hours*

Memorandum of Understanding (MOU)

## APPROVALS:

Graduate Medical Education Committee: 7/2020, 9/2025

Reviewed/Revised:

1/2018, 7/2020, 9/2025

Origination Date 1/2018, 9/2025

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Graduate Medical Education Committee	Leah Romito: Primary Care Prov Lmted Ex [TT]	09/2025
	Leah Romito: Primary Care Prov Lmted Ex [TT]	09/2025

## Standards

No standards are associated with this document



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Owner	Leah Romito: Primary Care Prov Lmted Ex
Area	Hospital & Health Centers

## Policy On Sponsoring Institution and Program Reductions or Closures

### PURPOSE STATEMENT:

To address how the Contra Costa Regional Medical Center will support Accreditation Council for Graduate Medical Education (ACGME) program(s) in the event of reductions in size or closure of ACGME program(s) or closure of the Contra Costa Regional Medical Center. This policy establishes a framework for resident/fellow education and well-being during such transitions.

### Scope

This policy applies to:

- A. The Contra Costa Regional Medical Center;
- B. All ACGME-accredited residency and fellowship programs within the Contra Costa Regional Medical Center;
- C. All residents and fellows enrolled in ACGME-accredited programs sponsored by the Institution;
- D. The GMEC, the Designated Institutional Official (DIO), and program directors.

### Definitions

- A. **Contra Costa Regional Medical Center:** The organization that assumes ultimate financial and academic responsibility for a program of graduate medical education.
- B. **Reduction in Program Size:** A decrease in the resident/fellow complement approved by the ACGME for a given program.

- C. **Program Closure:** The permanent discontinuation of an ACGME-accredited program.
- D. **Institutional Closure:** The permanent discontinuation of the Contra Costa Regional Medical Center's role in graduate medical education.
- E. **GMEC:** Graduate Medical Education Committee, which exercises oversight over all ACGME-accredited programs sponsored by the Institution.
- F. **DIO:** Designated Institutional Official, who has authority and responsibility for oversight of all ACGME-accredited programs sponsored by the Institution.

## ~~POLICY:~~

## POLICY:

The Contra Costa Regional Medical Center will maintain transparency, fairness, and compliance with ACGME requirements when reductions in program size or closures occur. The Institution will notify stakeholders in a timely manner and will ensure that residents/fellows are provided appropriate opportunities to complete their education either within the Institution or in another ACGME-accredited program.

## ~~PROCEDURES:~~

## PROCEDURES:

### A. Notification of GMEC and DIO

1. The Contra Costa Regional Medical Center must inform the GMEC and the DIO as soon as possible when it intends to:
  - a. Reduce the size of an ACGME-accredited program;
  - b. Close an ACGME-accredited program; or
  - c. Close the Contra Costa Regional Medical Center.

### B. Notification of Affected Residents/Fellows

1. The Contra Costa Regional Medical Center must inform affected residents/fellows as soon as possible of the intent to reduce program size, close a program, or close the Contra Costa Regional Medical Center.
2. Notification will include the rationale, anticipated timeline, and available resources.

### C. GMEC Oversight

1. The GMEC will review and oversee all plans related to program reduction or closure, including:
  - a. The process for notification of residents/fellows, faculty, and staff;

- b. The timeline and implementation plan;
- c. Support for affected residents/fellows, including assistance in identifying and securing positions in other ACGME-accredited programs when necessary.

#### D. Resident/Fellow Continuity of Education

1. The Contra Costa Regional Medical Center should allow residents/fellows already in an affected program to complete their education at the Contra Costa Regional Medical Center whenever possible.
2. If completion at the Contra Costa Regional Medical Center is not feasible, the Institution will assist residents/fellows in enrolling in other ACGME-accredited program(s) in which they can continue their education without undue disruption.
3. The DIO will coordinate with program director, GMEC, and external institutions to facilitate transitions.
4. The Program Director is responsible for supporting affected residents/fellows and assisting with placement efforts when necessary.
5. Residents/fellows are responsible for engaging in placement processes if relocation is required and for maintaining communication with program leadership.

#### E. Communication with the ACGME

1. The DIO will notify the ACGME promptly, in accordance with ACGME Institutional Requirements, regarding any reductions in size, program closures, or institutional closure.

## REFERENCES:

ACGME Institutional Requirements, Section IV.C.1–2: *Reductions in Size and Closures of Programs and Contra Costa Regional Medical Centers*

ACGME Common Program Requirements

Memorandum of Understanding (MOU)

## APPROVALS:

Graduate Medical Education Committee: 11/2020, 9/2025

Reviewed/Revised:

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## Policy on Substantial Disruptions in Patient Care or Education

### PURPOSE STATEMENT:

To address how the Contra Costa Regional Medical Center (CCRMC) will support Accreditation Council for Graduate Medical Education (ACGME) program(s) in the event of a disaster or other substantial disruptions in patient care or resident/fellow education. This policy establishes a framework for supporting residents, fellows, and ACGME-accredited program(s) during such events, including continuity of salary, benefits, professional liability coverage, and educational assignments.

### Scope

This policy applies to:

- A. The Contra Costa Regional Medical Center (CCRMC);
- B. All ACGME-accredited residency and fellowship programs sponsored by the Institution;
- C. All residents and fellows enrolled in ACGME-accredited programs within the Institution;
- D. Institutional leadership, program directors, faculty, and the Graduate Medical Education Committee (GMEC).

### Definitions

- A. **Substantial Disruption:** An event or series of events that significantly interferes with either the ability of the Contra Costa Regional Medical Center (CCRMC) and/or its programs to provide adequate patient care or graduate medical education. Examples include natural disasters,

pandemics, loss of clinical training sites, cyberattacks, or other catastrophic events.

- B. **Disaster:** A sudden, unanticipated event declared by the Contra Costa Regional Medical Center (CCRMC) or appropriate authorities that significantly interrupts patient care and/or educational activities.
- C. **GMEC:** Graduate Medical Education Committee, which provides oversight of all ACGME-accredited programs.
- D. **DIO:** Designated Institutional Official, who has authority and responsibility for oversight of all ACGME-accredited programs sponsored by the Institution.

## POLICY STATEMENT:

The Contra Costa Regional Medical Center (CCRMC) will maintain a disaster and substantial disruption response policy that prioritizes resident/fellow safety, well-being, and educational continuity. The Institution will provide support for continuation of salary, benefits, and professional liability coverage as reasonably able, and will coordinate educational assignments to ensure compliance with ACGME standards.

## PROCEDURES:

### Notification of GMEC, DIO, and ACGME

- A. Contra Costa Regional Medical Center (CCRMC) will notify the GMEC and the DIO immediately upon recognition of a substantial disruption or disaster that affects patient care or resident/fellow education.
- B. The DIO will notify the ACGME in accordance with the ACGME *Policies and Procedures* regarding substantial disruptions or declared disasters.

### Resident/Fellow Support

- A. **Salary and Benefits:** Residents/fellows will continue to receive their salary and benefits during the period of temporary disruption, consistent with institutional employment policies. In the event of a prolonged disruption, Contra Costa Regional Medical Center (CCRMC) will make reasonable effort to continue the salary and benefits of residents/fellows similar to all other salaried employees.
- B. **Professional Liability Coverage:** Residents/fellows will maintain professional liability (malpractice) coverage during the disruption, regardless of clinical assignment modifications.
- C. **Well-Being Resources:** The Institution will ensure that residents/fellows have access to physical and mental health support resources during the disruption.

### Educational Continuity

- A. **Assignments:** The Institution will make reasonable efforts to maintain residents/fellows in educationally appropriate assignments as able.
- B. **Alternate Sites:** If patient care or educational functions cannot be maintained at the primary

clinical site(s), the Institution will arrange educational assignments at alternate ACGME-accredited sites or other appropriate institutions as able.

- C. **Transfer or Relocation:** If Contra Costa Regional Medical Center (CCRMC) cannot ensure adequate educational experiences or maintain adequate salary and benefits, it will work with the ACGME and other institutions to facilitate temporary or permanent transfer of residents/fellows to programs where training can continue.

## GMEC Oversight

- A. The GMEC will oversee the implementation of plans during and after a substantial disruption, including:
  - 1. Ensuring communication with affected residents/fellows, faculty, and staff;
  - 2. Monitoring adequacy of educational experiences;
  - 3. Reviewing institutional support for salary, benefits, and liability coverage;
  - 4. Evaluating long-term recovery and restoration of program functions.

## Communication with Residents/Fellows

- A. Residents/fellows will be informed promptly regarding:
  - 1. The nature of the disruption;
  - 2. Expected changes to clinical and educational assignments;
  - 3. Available resources and institutional support;
  - 4. Processes for transfer or reassignment if necessary.

## Recovery and Transition

- A. Once the disruption resolves, as reasonably able Contra Costa Regional Medical Center (CCRMC) will:
  - 1. Restore programs and educational functions to normal operations;
  - 2. Evaluate the impact of the disruption on resident/fellow education;
  - 3. Report recovery actions to the GMEC and ACGME as required.

## Responsibilities

- A. **Sponsoring Institution Leadership:** Ensures adequate resources for salary, benefits, and liability coverage during disruptions as able.
- B. **DIO:** Coordinates notification to ACGME, oversees continuity of education, and ensures compliance with this policy.
- C. **GMEC:** Provides oversight, monitors educational adequacy, and documents deliberations and actions.
- D. **Program Directors:** Support residents/fellows, ensure appropriate supervision at alternate sites, and communicate program-specific changes.

- E. **Residents/Fellows:** Engage in assigned clinical and educational activities, maintain communication with program leadership, and access institutional support resources as needed.

## REFERENCES:

ACGME Institutional Requirements, Section IV.D: *Substantial Disruptions in Patient Care or Education*

ACGME *Policies and Procedures* (current edition)

Sponsoring Institution Human Resources Policies on salary and benefits

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Graduate Medical Education Committee	Leah Romito: Primary Care Prov Lmted Ex [TT]	09/2025
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## Standards

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## Program Evaluation Committee

### POLICY STATEMENT:

The functions of the Program Evaluation Committee (PEC) are carried out by the Core Faculty Group, chaired by the Program Director, along with the Chief Residents.

The PEC oversees program evaluation. It uses those elements specified in the Common Program Requirements and Family Medicine requirements and any additional tools developed by the Program. These tools are outlined in each year's Annual Program Evaluation.

### APPROVALS:

Graduate Medical Education Committee: 4/2021

Reviewed/Revised:

1/2018, 4/2021

### Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending

Graduate Medical Education  
Committee

Leah Romito: Primary Care  
Prov Lmted Ex [TT]

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## Residency Program Policy on Anti-Discrimination

### **POLICY:**

- A. All policies and procedures of the Residency Program shall be applied to all Residents and faculty without discrimination based upon age, sex, race, color, national origin, sexual orientation, gender identity, religion and disability
- B. The residency prohibits discrimination in employment on the basis of age, sex, race, color, national origin, sexual orientation, gender identity, religion and disability.
- C. The residency abides by Title IX of the Education Amendments of 1972, which prohibits discrimination in education on the basis of sex.
- D. The Residency Program should follow all harassment and discrimination policies as outlined by the Contra Costa Regional Medical Center MOU and Policies.

### Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
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## Resident Supervision Policy

### PURPOSE STATEMENT:

The purpose of this policy is to ensure compliance with Accreditation Council for Graduate Medical Education (ACGME) Institutional Requirements regarding the supervision of residents and fellows. Additionally, it provides program- specific supervision policies for the Contra Costa Family Medicine Residency. The Contra Costa Regional Medical Center and the Contra Costa Family Medicine Residency Program are committed to providing a clinical and educational environment that ensures safe, high-quality patient care while fostering progressive autonomy and professional development for residents/ fellows.

### Scope

This policy applies to:

- A. The Contra Costa Regional Medical Center;
- B. All ACGME-accredited residency and fellowship programs within the Institution;
- C. All residents, fellows, faculty, and supervising practitioners involved in graduate medical education.

### Definitions

- A. **Supervision:** The provision of guidance and oversight by faculty and other qualified supervisors that ensures patient safety and supports resident/fellow development.
- B. **Direct Supervision:** The supervising physician is physically present with the resident/fellow and the patient.

- C. **Indirect Supervision with Direct Supervision Immediately Available:** The supervising physician is not physically present but is immediately available in the clinical setting.
- D. **Indirect Supervision with Direct Supervision Available:** The supervising physician is not physically present but is available by phone or electronic communication, and able to provide direct supervision if required.
- E. **Oversight:** Supervising physician reviews procedures/encounters after they are completed, with feedback provided to the resident/fellow.
- F. **Program-Specific Supervision Policy:** Written supervision guidelines developed by each program, consistent with this institutional policy and applicable ACGME requirements. This can also apply to location specific supervision, where supervision for a specific clinical area may have different levels of supervision required.

## POLICY:

The Contra Costa Regional Medical Center requires that:

- A. All residents/fellows must be supervised by faculty and other appropriately credentialed supervisors in a manner that ensures both patient safety and the development of progressive independence.
- B. Each ACGME-accredited program must establish and maintain a **written program-specific supervision policy** consistent with:
  - 1. This institutional supervision policy;
  - 2. The ACGME Common Program Requirements; and
  - 3. The applicable specialty-/subspecialty-specific Program Requirements.
- C. Residents/fellows must be informed of and have ready access to their program's written supervision policy.
- D. Faculty and supervising practitioners must be informed of their responsibilities regarding supervision, oversight, and documentation of resident/fellow clinical activities.

## PROCEDURES:

- A. Institutional Oversight
  - 1. The GMEC will review and approve this institutional supervision policy.
  - 2. The DIO and GMEC will monitor compliance across programs through:
    - a. Annual program evaluations,
    - b. ACGME resident/fellow and faculty surveys,
    - c. Periodic internal reviews.
- B. Program-Specific Supervision Policies
  - 1. Each ACGME-accredited program must:

- a. Develop a program-specific supervision policy consistent with institutional, Common Program, and specialty requirements;
- b. Define supervision levels appropriate to the specialty and stage of training;
- c. Clearly describe when faculty must be physically present, when indirect supervision is acceptable, and when oversight applies;
- d. Communicate supervision expectations to all residents/fellows and supervising faculty.

#### C. Resident/Fellow Responsibilities

##### 1. Residents/fellows must:

- a. Know their level of authority and responsibility in all patient care settings;
- b. Seek assistance from supervising faculty whenever patient care is beyond their level of knowledge, skill, or responsibility;
- c. Adhere to supervision policies at all times to ensure patient safety.

#### D. Faculty Responsibilities

##### 1. Faculty and supervising practitioners must:

- a. Provide appropriate supervision to ensure safe patient care;
- b. Adjust levels of supervision based on resident/fellow ability, patient complexity, and clinical circumstances;
- c. Be available to residents/fellows at all times for consultation and escalation;
- d. Provide timely feedback to residents/fellows to support development of independence.

#### E. Escalation of Concerns

##### 1. Residents/fellows may report supervision concerns (including inadequate supervision or excessive independence) to:

- a. Their Program Director,
- b. The DIO, or
- c. The GME Office.

##### 2. Concerns will be reviewed promptly by program leadership and, if necessary, by the GMEC.

## Responsibilities

- A. **Contra Costa Regional Medical Center Leadership:** Ensure a safe and supportive learning environment with appropriate supervision structures.
- B. **DIO:** Oversee compliance with institutional and program-specific supervision policies.
- C. **GMEC:** Approve and monitor program-specific supervision policies and institutional oversight.
- D. **Program Directors:** Develop, implement, and enforce program-specific supervision policies; communicate policies to residents/fellows and faculty.
- E. **Faculty:** Provide appropriate supervision and feedback; ensure safe, high-quality patient care.
- F. **Residents/Fellows:** Adhere to supervision policies; seek guidance and supervision whenever patient care exceeds their level of competence.

## Contra Costa Family Medicine Residency Program - Resident Supervision Policies and Guidelines

The following is an overview of protocols for resident and attending physicians ("attendings") delineating appropriate supervision policies for specific clinical situations:

- A. The Program Director, with input from residents, faculty, and administration, shall design and implement a system for qualified supervision of residents.
- B. The Program Director and Department Chairs will be responsible for maintaining attending staff on-call schedules to ensure that supervision is readily available to residents on duty.
  - 1. Supervising attendings for all Contra Costa inpatient medicine and surgery services are listed in the appropriate section in Amion, login name: ccrmc
  - 2. Supervising attendings for all Contra Costa obstetrics and gynecology services are listed in the appropriate section in Amion, login name: ccob
  - 3. Supervising attendings for Contra Costa outpatient family medicine clinics are listed in the appropriate section in Amion, login name: ccfp
- C. The Attending of Record (AR) is the attending responsible for resident supervision and thereby patient care at a moment in time. The Attending of Record will be clearly communicated through the medical record and through Amion.
- D. Explanation of Definitions of Supervision:
  - 1. Direct Supervision (DS): Attending present with resident and patient
  - 2. Indirect Supervision with Direct Supervision Immediately Available (IS-DSIA) : Attending immediately available (in same building or campus)
  - 3. Indirect Supervision with Direct Supervision Available (IS-DSA): Attending is not physically present on site, but is immediately available by phone and able to return to the hospital for Direct Supervision
  - 4. Oversight (O): Attending will review and provide feedback after care is performed
- E. Service-specific supervision requirements are as follows:

1. See Appendix E for Supervision and Documentation Protocols for each service
2. Hospital Medicine and General Surgery Services
  - a. The Attending of Record (AR) is the attending responsible for resident supervision and thereby patient care at a moment in time. The Attending of Record may be the attending for the team under which the patient is cared or the on-call attending. The Attending of Record will be clearly communicated through the medical record and through Amion for off-hours consultations or admissions.
  - b. Residents have direct patient care responsibility on all inpatient rotations. CCFMR does not use a typical "resident team" approach, so each inpatient resident is assigned direct care responsibilities with direct supervision by an attending.
  - c. Progressive Responsibility for patient management: Attending rounds take place 7 days per week for all three years, yet level of supervision shifts toward resident independence toward R3 level.
    - i. First year residents are assigned attendings skilled at working with R1s—providing directly supervised care with expectation that the resident needs assistance from assessment to management.
    - ii. R2s are provided attendings who focus on development of independent assessment and initial management, except in cases of critical care and acutely deteriorating patients.
    - iii. R3s are provided attending supervision that remains direct, yet more independent assessment and management is expected, including in the care of critically ill and acutely deteriorating patients.
  - d. During regular weekday hours (Monday-Friday 8am-5pm) clinical questions and admissions can be discussed directly with the Attending of Record. Alternatively, the Wards MD or MOD (Medical Officer of the Day) as listed on Amion is available to help with admissions during the day if the regular Attending of Record is not available. The Wards MD as listed on Amion is available for questions on admitted patients.
  - e. During weekend daytime hours, clinical questions and admissions can be discussed with the designated Attending of Record on the Weekend Rounder Amion schedule.
  - f. Supervision after hours (between 5pm and 8am) is provided by the Swing Shift and Nocturnist physicians, as found on Amion. This attending will be immediately available to provide consultation for all admissions and clinical needs.
  - g. Admissions:
    - i. All hospital admissions performed by residents are to be presented to either a senior resident or medicine attending at time of admission according to the following schedule:

- a. 8AM-12PM – Primary Rounding Attending
  - b. 12PM-5PM – Primary Rounding Attending or Wards MD or the MOD listed on Amion
  - c. 5PM-8AM - Swing Shift / Nocturnist attending or R2 / R3 ICU/Night Float Resident with immediately available attending
- ii. If admissions are done by a 1st year resident, they should be presented to the R2 / R3 ICU Night Float Resident first. The senior or the 1st year resident can then discuss with the attending.
- iii. Admission H&P should be co-signed with any appropriate addendums and the orders reviewed by the Attending of Record.
- h. Transfer of Care Settings:  
All admitted patients transitioning to a higher level of care must be discussed with an immediately available attending at the time of admission or transition regardless of year of training.
- i. Discharges and Transfers to Outside Facilities:  
All discharges and transfers to outside facilities must be done with the direct approval of the supervising attending.
- j. Consultation:  
Consultation with specialists regularly occurs in the inpatient setting. R1s will be expected to speak with the primary Attending of Record prior to contacting specialists. R2 and R3s may independently seek consultation from specialists.
- k. Do Not Resuscitate/Do Not Intubate:  
DNR/DNI orders may be written by a first year resident but must be confirmed by an attending physician at the time the order is written. DNR/ DNI orders may be written by second and third year residents under the immediately available supervision of an attending and must be discussed with the primary Attending on rounds the following day.
- l. Operating room supervision:  
A fully privileged attending physician in the Department of Surgery must be present in the O.R. for the duration of any operative procedure in which a resident is scrubbed in.
- 3. Critical Care (ICU)
  - a. CCFMR functions on a "closed" ICU model (with some degree of "semi-open") whereby ICU patients are managed on teams that include hospitalists and a critical care-trained physician. Residents actively participate in the management of all critically ill patients.
  - b. The primary supervising attending of all ICU patients is the Hospital Medicine attending for the team. At this attending's discretion, Emergency Medicine or Anesthesia attendings may supervise resident-performed

procedures. While the Critical Care Attending functions primarily in a consultative role, residents may seek supervision from this Attending as well.

c. Respiratory Distress

i. **Pre-intubation Decision**

- a. Resident discusses case with in house attending (Primary Hospital Medicine, Swing Shift, or Nocturnist Attending)
- b. Critical Care attending to be called at the discretion of the team
- c. If needed, in house ED or anesthesia attendings can be called
- d. If options a-c are not immediately available, any resident who has been certified for supervision privileges for intubations can be called

ii. **Intubation:** Direct Supervision can be provided by:

- a. Hospitalist or critical care physician
- b. ED staff physician
- c. Anesthesia physician
- d. Resident with supervision privileges for intubation

iii. **Post Intubation Management:** Direct Supervision or Indirect Supervision with Direct Supervision Immediately Available by:

- a. Primary Attending, Swing Shift, or Nocturnist Attending
- b. Critical Care attending

d. Other Procedural Care in the ICU is addressed under **Procedural Supervision**.

4. OB/Gyn (Labor & Delivery and Gynecology inpatient service)

- a. The Attending of Record (AR) is the attending responsible for resident supervision and thereby patient care at a moment in time. This is generally the OB Registrar or the Ob/Gyn Attending. The Attending of Record will be clearly communicated through the medical record and through Amion.
- b. Residents have direct patient care responsibility on labor and delivery and the inpatient gynecology service. There are in house Family Physician Registrars and Ob/Gyns available for resident supervision at all times.
- c. Progressive responsibility for patient management:
  - i. With 24 hour in house physician staffing, all supervision is either direct supervision or indirect supervision with direct supervision immediately available.

- ii. R1s provide directly supervised care with the expectation that the resident needs assistance from assessment to management.
  - iii. R2s focus on development of independent assessment and initial management, in addition to continued focus on procedural skills.
  - iv. R3s have direct supervision available at all times, but more independent assessment and management is expected. R2s and especially R3s also provide supervision for junior residents and medical students.
- d. OB Triage
  - i. Interns are expected to conduct OB Triage procedures initially under direct and subsequently under indirect supervision (with direct supervision immediately available) via an available attending or certified resident at the attending's discretion (see next section).
  - ii. As part of progressive responsibility, upper level residents (R2 & R3s) who have been assessed as capable of doing so are expected to manage triage independently for the initial workup (IS-DSIA). All cases are reviewed with the attending prior to discharge.
- e. Management of Labor
  - i. Interns provide management of labor by under the direct supervision of an attending.
  - ii. Residents (R2 & R3) are allowed to manage patients on L&D with indirect, immediately available supervision.
- f. All vaginal and operative deliveries are directly supervised by an attending physician. All residents must contact the Attending of Record at the time of delivery.
- g. Fetal Distress and Emergent C-Sections: A supervising attending must be contacted immediately for all cases of fetal distress and emergent c-sections to provide direct supervision, regardless of year of training.
- h. Operating room supervision: a fully privileged attending physician in the Ob/Gyn department must be present in the O.R. for the duration of any operative procedure in which a resident is scrubbed in.
- i. Postpartum Management
  - i. R1s must staff all patients (including low risk) with an attending prior to major management decisions.
  - ii. R2 & R3:
    - a. Low risk patients (NSVD with no medical complications): R2 & R3s may round, write orders and

discharge prior to discussion with an attending. Attending physicians are always available if questions arise.

- b. High risk (anything not low risk) patients: R2 & R3s must staff all high risk patients with an attending prior to major management decisions.

## 5. Emergency Medicine

- a. The Attending of Record (AR) is the attending responsible for resident supervision and thereby patient care at a moment in time. This will generally be the assigned teaching physician for the shift in the Department of Emergency Medicine. The Attending of Record will be clearly communicated through the medical record and through Amion.
- b. Residents have direct patient care responsibility on all Emergency Medicine rotations. Residents are assigned one primary EM physician to work with throughout the shift.
- c. Progressive Responsibility for patient management:
  - i. With 24 hour in house physician staffing, all supervision is either direct supervision or indirect supervision with direct supervision immediately available. Given all cases are staffed with an attending, it is left to the attending's discretion if they provide direct or indirect supervision.
  - ii. First year residents are generally directly supervised with the expectation that all cases are presented to the attending prior to placing orders or making management decisions.
  - iii. R2s focus on development of independent assessment and initial management, except in cases of acutely deteriorating patients. There is a continued focus on procedural skills.
  - iv. R3s have direct supervision available at all times, but more independent assessment and management is expected. R2s and especially R3s also provide supervision for junior residents and medical students.
- d. Specific Clinical Situations
  - i. Critically Ill Patient: Regardless of year, the resident will make the supervising EM attending aware of the presence of any critically ill patient. This can be communicated through a nurse when necessary due to the need to provide direct attention to the patient.
    - a. Interns must have initial diagnostic and therapeutic plans supervised by the EM Attending
    - b. Residents (R2 & R3) are expected to develop their initial diagnostic and therapeutic plans independently, but may receive consultation from the attending as

needed.

ii. Complex Medical & Surgical Patients

- a. Interns are expected to staff complex medical and surgical patients with the Attending immediately following the initial evaluation. The Attending will supervise the diagnostic and therapeutic plans for these patients
- b. Residents (R2 & R3s) are expected to begin a diagnostic and therapeutic plan independently and may seek Attending Supervision when diagnostic studies return.

6. Pediatrics

- a. The Attending of Record (AR) is the attending responsible for resident supervision and thereby patient care at a moment in time. The Pediatrics Department provides 24 hour a day in house supervision for inpatient nursery and neonatal resuscitation on labor and delivery. The Attending of Record will be clearly communicated through the medical record and through Amion.
- b. Progressive responsibility for patient management:
  - i. The inpatient newborn nursery rotation is a specific R1 and R2 rotation, although at times R3s participate in resuscitations or in care of their continuity patients.
  - ii. With 24 hour in house physician staffing, all supervision is either direct supervision or indirect supervision with direct supervision immediately available.
  - iii. Throughout the rotation residents are expected to have a progressive shift toward more independent decision making.
- c. Specific Clinical Situation
  - i. Birth/Delivery: All levels of resident must seek immediate supervision from an Attending at the time of birth for any newborns that are not low risk or do not transition well.
  - ii. Neonatal Rounds
    - a. Residents are expected to initially have Direct Supervision by an Attending MD for Level 1 and 2 patients
    - b. According to experience, the Intern may see Level 1 neonates with indirect supervision at the attending's discretion
  - iii. Infant in Respiratory Distress: All levels of resident must seek immediate supervision from an Attending

- iv. Hypoglycemia: All levels of resident must seek immediate consultation from an Attending after initiation of hypoglycemia protocol
- v. Hyperbilirubinemia: Residents are expected to seek consultation from an Attending for all neonates with hyperbilirubinemia, with a trend toward independent initial diagnostics and management recommendations.
- vi. Feeding Difficulties: Residents are expected to seek consultation from an Attending for all neonates with feeding difficulties, with a trend toward independent initial diagnostics and management recommendations.
- vii. Infection (to include rule out sepsis): Residents are expected to seek consultation from an Attending for all neonates with evidence of infection including rule out sepsis.

## 7. Family Medicine Clinic

- a. The Attending of Record (AR) is the attending responsible for resident supervision and thereby patient care at a moment in time. This will generally be the assigned preceptor. The Attending of Record will be clearly communicated through the medical record and through Amion.
- b. A family medicine board-certified preceptor provides the supervision, with always at least 1 preceptor for every 4 residents and ideally 1 preceptor for every 3 residents.
- c. Progressive Responsibility for patient management:
  - i. For R1, R2, and R3s, supervision is indirect with direct supervision immediately available from a preceptor in the immediate clinic area.
  - ii. Residents present all patients prior to the end of clinic with a one line summary. More detailed presentation, including discussion of management decisions, is required depending on the resident's level of training and the patient's acuity.
  - iii. R1s in the first six months of training must present every patient to the preceptor prior to discharge. In the second half of the year, they must present at least 60% of patients and all patients who are complicated, unusual, or acutely ill prior to discharge.
  - iv. R2s and R3s must present all complicated, unusual, or acutely moderately to severely ill patients (e.g. mild URIs do not have to be presented) prior to discharge.
- d. Specific clinical situations
  - i. Prenatal patients must be presented by all residents prior to discharge.
  - ii. Children under 12 months of age must be presented by all residents prior to discharge.

- iii. Patients who require transfer to a higher level of care (e.g. to an emergency room or direct admission) should be presented by all residents at the time of decision to transfer.
- e. The number of unread messages in each resident's "In Basket" is periodically globally assessed to identify residents who need additional teaching or support on "In Basket" management.
- f. Preceptors perform periodic detailed chart reviews, using a standardized template, of all residents.
- g. Preceptors perform periodic "fly-on-the-wall" direct observation of patient visits of all residents.

#### F. Procedural Supervision

All residents have privileges for procedures based on supervision by attending faculty.

##### 1. Higher Risk and Problem-Prone Procedure List (HRPP)

- a. The Residency Leadership Group and Medical Staff will work together to provide an updated Higher Risk and Problem-Prone Procedure (HRPP) List.
- b. **Group 1: Current Bedside Procedures considered Highest Risk and Problem-Prone that will be performed with Direct Supervision throughout training**
  - i. Large Bore Chest Tube insertion, management, removal
  - ii. Amniocentesis
  - iii. Endotracheal Intubation
  - iv. Surgical Airway (cricothyrotomy)
  - v. DC Cardioversion
  - vi. Pericardiocentesis, insertion, management, removal
  - vii. Epidural Anesthesia, insertion, management, removal
  - viii. Vacuum-Assisted Delivery
  - ix. NSVD Labor management and delivery
- c. **Group 2: Current Bedside Procedures considered Higher Risk or Problem-Prone which residents may apply for Unsupervised Status** once specific targets are reached and Department Chair or designee with oversight of that procedure has signed them off.
  - i. Central Line insertion, management, removal
  - ii. Thoracentesis
  - iii. Thoracic Vent placement
  - iv. Paracentesis
  - v. Complex laceration repair
  - vi. Complex Bedside I&D

- vii. Bone Marrow Biopsy
- viii. Pericardial line management
- ix. Moderate Sedation
- x. Arterial Line
- xi. Intraosseus line
- xii. Joint aspiration and injection

**"Ur" status** = Independent privilege. **SEE APPENDIX B** All residents have some level of supervision throughout their training. Direct supervision is NOT required for residents achieving the "Ur" status for that particular procedure. Residents achieving "Ur" status may also supervise other residents for that particular procedure under consultation with their attending.

#### **G. Supervision and Documentation Requirements for HRRP Procedures performed by Residents**

1. **Initial supervision must be Direct, or immediately available** by a physician with privileges and/or unsupervised certification for the procedure.
2. **Specific Privileging-level Targets for each HRPP procedure will be set by the CCC in consultation with the Core Faculty.**
3. Supervising physician will be required to confirm the procedure within 30 days or the confirmation request will be forwarded to their department chair. The program director or his/her designee may also confirm procedures at his/her discretion.
  - a. **Group 3: Lower Risk, High Volume or Simple procedures**
    - i. **High volume, Simple and/or Low Risk Procedures that may be performed under consultation(Cr) or readily available physician supervision**
      - a. Lumbar Puncture
      - b. Simple Bedside I&D
      - c. Simple laceration repair
      - d. Punch Biopsies
      - e. Simple wound debridement
      - f. Other simple/low risk procedures as defined by attending physician and NOT present on the HRPP lists above.
4. Any procedure not listed in the above sections (HRPP list or Low Risk Procedure) shall be assumed to be a High Risk Problem-Prone procedure and direct attending supervision shall be sought in order to perform the procedure. The resident may proceed with the procedure if the supervising attending deems the procedure to be low risk.
5. **Do Not Resuscitate/Do Not Intubate** DNR/DNI orders may be written by a first year resident must be confirmed by an attending physician at the time the order is

written. DNR/DNI orders may be written by second and third year residents, under the readily available supervision of an attending, either in person or by telephone.

6. **Residents Supervising Fellow Residents.** Certified / Credentialed Residents may provide supervision for fellow residents in procedural training under supervision of their assigned attending.
7. **Emergency Medicine and Obstetrical Triage Supervision:** Residents are required to present all cases in Emergency Department and Obstetrical Triage to their supervising attending. Residents will document the name of the supervising attending through the electronic medical record. Documentation will include name of supervising attending with date and time of consultation.
8. **OB-Triage Certification:** Licensed residents in good standing may be provided OB-Triage Certification for purposes of moonlighting or requiring diminished supervision standards based on OB Departmental Privileging and Residency approval.
9. **Universal Procedure Protocols at Bedside**  
The Peri-operative Care Committee (PCC) has developed a Universal Procedure Protocol that must be followed by resident and supervising attending.

#### H. Global Health Fellow Supervision

1. Global Health Fellows will be supervised and proctored in accordance with CCRMC Medical Staff Bylaws and policies. Global Health Fellows will not be expected to perform activities or procedures for which they are not privileged without appropriate faculty oversight as deemed by the clinical department in which the fellow is based. Appropriate oversight will be determined with input from the clinical department head, Global Health Fellowship Co-directors and Program Director.

#### I. Inadequate supervision

1. **Inadequate Supervision**, as deemed by the Program Director, is grounds for loss of Teaching Faculty Position at the discretion of the Program Director. Faculty members Teaching Role may be suspended for 10 days by the Program Director without appeal. Extensions of Teaching Role suspensions beyond 10 days require written notification of the Faculty Member with specific concerns and expected plan of action.
2. The Program Director may recommend Educational Interventions for any Teaching Faculty at any time. Required Educational Interventions for Teaching Faculty requires written notification, timeline to completion similar to that of Required Educational Interventions for Residents (See Section XV, item 14 for Resident Required Educational Interventions).
3. Inadequate supervision tenets apply for Global Health Fellows as well and can result in faculty discipline as stated above (I.1).

## REFERENCES:

ACGME Institutional Requirements, Section IV.F: *Supervision of Residents/Fellows*

ACGME Common Program Requirements, Section VI.A: *Supervision and Accountability*

## Specialty-/Subspecialty-Specific ACGME Program Requirements

*HF Revision approved GMEC September 2017, 9/2025*

*Reviewed 2015, 1/2018, 9/2025*

Origination Date: 1/2015

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Graduate Medical Education Committee	Leah Romito: Primary Care Prov Lmted Ex [TT]	09/2025
	Leah Romito: Primary Care Prov Lmted Ex [TT]	09/2025

## Standards

No standards are associated with this document



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Owner	Leah Romito: Primary Care Prov Lmted Ex
Area	Hospital & Health Centers

## Resident Well-Being and Impairment Policy

### PURPOSE STATEMENT:

The purpose of this policy is to ensure that the Contra Costa Regional Medical Center provides effective oversight of all ACGME-accredited programs in fulfilling their responsibility to support the well-being of residents, fellows, and faculty. The Contra Costa Regional Medical Center is committed to fostering a safe, supportive, and professional clinical learning environment that promotes personal wellness, reduces burnout, and safeguards patient safety. This policy outlines the steps that the ACGME-accredited program(s) take in order to fulfill these responsibilities.

### POLICY:

- A. The foundation of the Residency Program approach to physician impairment is an awareness of the problem. The stresses of Residency training place Resident physicians at high risk for impaired function as a result of fatigue and/or mental or emotional illness.
- B. The Program intends to provide a structured experience that avoids excessive stress and offers support for the individual who may be experiencing difficulty.
- C. If a resident is believed to be suffering from impairment, the Program will assist the involved resident while safeguarding the quality of patient care and upholding the educational standards of the Residency.
  1. The Program Director will act in the best interests of the individual resident, the larger residency community, and patient safety. In addition to upholding residency policy, the program director will adhere to Contra Costa Medical Staff policies and Bylaws as well as employment rights and protections.
  2. The Program Director will act in consultation with the Program's Director of

- Behavioral Medicine or their designee.
3. Reasonable effort to maintain confidentiality of an involved resident will be made.
- D. A number of Program activities and structures within the organization contribute to the effort to achieve these goals through prevention, early recognition, and intervention.
1. The program attempts to maintain high ratios of faculty to residents, especially on the most stressful and demanding rotations.
  2. Each Resident is assigned a Faculty Advisor for the duration of his/her Training. This Advisor may be instrumental in detecting, intervening or monitoring cases of impairment.
  3. Resident Duty Hours – The Program endorses the substance and spirit of accreditation standards limiting resident duty hours. Limits are placed on the frequency and duration of resident work assignments. A call schedule for back-up in times of overload is maintained.
  4. Evaluation system - Any of the sources of information for evaluation of Resident performance may contribute to prevention and recognition of Resident impairment.
  5. Annual Retreat - Social activities are important to reduce stress. The annual All Residency Educational Conference is intended, in part, to serve this function by providing an informal weekend retreat for all Residents and their families in an attractive setting remote from the hospital.
  6. Behavioral Sciences Conferences - Behavioral Sciences faculty conduct regular small-group conferences for Residents, including class-specific personal and professional development (PPD) sessions. Issues contributing to Resident stress are frequently discussed.
  7. Support Group Meetings – In many of the most stressful rotations, a facilitated Support Group meets on a regular basis.
  8. Medical Staff Assistance Committee - This Medical Staff committee aims to promote the well-being of the medical staff, including residents. It may provide advice, counseling and referrals as needed. A Resident representative sits on the Committee. Education - The Medical Staff Assistance Committee and Residency Program share responsibility for education of Residents and faculty about provider health, well-being, and impairment.
- E. Whenever a Resident, faculty member, or other member of the Residency community has concern that a Resident's performance may be impaired, that concern should be communicated, either verbally or in writing, to the Program Director or to the Medical Staff Assistance Committee. Self-referrals for assistance are also encouraged.
- F. Upon receiving such information, the Program Director, a core faculty member or the Medical Staff Assistance Committee will investigate and assess the individual's situation. Based on the gathered information and discussion with the involved Resident, recommendations may then be made in the form of advice, counseling, or referrals to relevant treatment professionals and programs. Coverage for these services exists under County-offered health plan options available to all Residents.
- G. At times, continuation of a resident in the training program may be contingent upon that

resident's participation in assessment or treatment. This requirement will be made clear to the involved resident in a meeting with the Program Director or core faculty member.

- H. The Program Director may recommend adjustments in the usual schedule of assignments, duties, and supervision for a Resident (e.g. leave of absence, adjusted curriculum plan, increased supervision requirements).
- I. The involved resident may be required to be temporarily relieved of their clinical duties for assessment and planning. The Program Director can place the resident on administrative leave for this purpose for up to ten (10) days without advanced notice. The resident will be notified of this in a meeting with the program director or core faculty member.
- J. The intent of this plan is to assist the involved physician. Disciplinary measures will be taken by the Program Director when necessary to safeguard patient care or to uphold standards of the Program, after reasonable efforts to provide assistance have been unsuccessful.
- K. If the actions or potential actions of a Resident pose an unreasonable risk to patients, the Program Director may communicate with appropriate supervising bodies (e.g. the Medical Staff Executive Committee, the Medical Board of California).
- L. If a Resident is identified as having a problem, is referred for treatment, and subsequently returns to his/her usual assignments, the Program Director or Medical Staff Assistance Committee, advisor and core faculty are responsible for monitoring their performance and recovery program.

## APPROVALS:

Graduate Medical Education Committee: 4/2021, 9/2025

Reviewed/Revised:

1/2018, 4/201, 9/2025

Origination Date: 1/2018

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Graduate Medical Education Committee	Leah Romito: Primary Care Prov Lmt'd Ex [TT]	09/2025
	Leah Romito: Primary Care Prov Lmt'd Ex [TT]	09/2025

## Standards

No standards are associated with this document



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Owner Heather Cedermaz:  
Family Nurse Practitioner  
Area Hospital & Health Centers

## Contra Costa Regional Medical Center Joint Conference Committee Expedited Privileges Subcommittee Charter

### Purpose

The Contra Costa Regional Medical Center (CCRMC) Joint Conference Committee (JCC) establishes this charter for the review and approval of expedited credentialing of medical staff members for Category 1 applications by a JCC Expedited Credentialing Subcommittee. It outlines the roles, responsibilities, and processes for the Subcommittee to ensure compliance with regulatory standards and to maintain high-quality patient care.

### Scope

This charter applies to all CCRMC and Clinics medical staff members and applicants with a Category I initial and reappointment application who are seeking credentials in an expedited procedure via the use of the Subcommittee.

### Definitions

- A. **Category I applications must be complete and have no issues on record that would cause them to have a category II application as outlined in the Medical Staff Bylaws.**
- B. **On-Cycle Credentialing:** The regular monthly process of credentialing files via Medical Staff Office (MSO), the Credentials Committee (CC), and the Medical Executive Committee (MEC) meetings.
- C. **Off-Cycle Credentialing:** The process of granting privileges outside the standard schedule due to various circumstances such as recruitment needs, changes in service demand, or urgent staffing requirements.

## Membership

- A. The Expedited Credentialing Subcommittee will consist of three members, two of whom must be voting members of the CCRMC JCC.
- B. Members of the Subcommittee will be appointed by the CCRMC JCC for two-year terms every 2 years. Vacancies on the Subcommittee will be filled by appointment of the Chair of the CCRMC JCC to complete the remaining term of the vacant seat.
- C. **Composition:** The Subcommittee shall consist of three members:
  - 1. CCRMC Chief Medical Officer (CMO) or Chief Executive Officer (CEO); and
  - 2. 2 members who are voting members of the CCRMC JCC.

## Procedure

- A. Medical Staff Office (MSO) staff will determine if expedited credentialing is warranted based on the following criteria:
  - 1. There is a staffing need, and
  - 2. Completed application for initial appointment, reappointment or request for additional privileges is turned into the MSO timely and before JCC convenes, and it is identified as a category 1 application. Application processing includes the following guidelines:
    - a. On-cycle: staff is not needed until after MEC
    - b. Off-cycle: Completed application is turned into MSO at a time when it cannot be processed through the regular committee cycle;
  - 3. If application is off cycle:
    - a. Department Chair and Credentials Committee Chair meet on behalf of the Credentials Committee for approval;
    - b. Special MEC meeting called for approval of application(s); and
    - c. JCC Expedited Credentialing Subcommittee reviews application for approval on behalf of JCC and Board Of Supervisors.
- B. **Review Applications:**
  - 1. To qualify for expedited credentialing, all applications for both on-cycle and off-cycle must be considered Category 1 as defined above.
  - 2. Applications will not be considered for expedited credentialing if the applicant has submitted an incomplete application or if the Medical Executive Committee makes a final recommendation that is adverse or has limitations.
  - 3. The following situations will be evaluated on a case-by-case basis and usually result in ineligibility for the expedited process:
    - a. There is a current challenge or a previously successful challenge to licensure or registration,
    - b. The applicant has received an involuntary termination of medical staff membership at another hospital,

- c. The applicant has received involuntary limitation, reduction, denial, or loss of clinical privileges.
- d. There has been either an unusual pattern of, or an excessive number of, professional liability actions resulting in a final judgment against the applicant.

**C. Decision Making:**

- 1. If any group (Credentials Committee, MEC, JCC Subcommittee) believes that an application is not category I, they will **not** proceed with expedited credentialing and the file will go through the non-expedited credentialing approval process.
- 2. If expedited credentialing occurs, the governing body (JCC) must still review the expedited files at the next regularly scheduled meeting.
- 3. A unanimous decision by the Subcommittee is required for approval of all applications considered under the Expedited Credentialing process.

**D. Monitoring and Quality Assurance:**

- 1. The JCC Expedited Credentialing Subcommittee will produce meeting minutes for review in regular JCC meetings.
- 2. All approved files will be included in subsequent BoS credential procedures.
- 3. MSO will report out to MEC every year about the number of expedited credentials completed, both on- and off-cycle.

## **Meeting Frequency**

- A. The subcommittee shall meet twice monthly as needed: once following each MEC meeting to address on-cycle requests and once during the first half of month to address any off-cycle requests.

## **Review and Amendments**

- A. This Charter shall be reviewed annually and amended as necessary to reflect changes in regulations, best practices, and institutional policies.
- B. Any proposed amendments to this Charter must be approved by the CCRMC Joint Conference Committee.

## **Confidentiality**

- A. All personnel documents pertaining to credentialing decisions are confidential and shall be treated as such in accordance with applicable laws and institutional policies during the committee.

## **Compliance**

- A. This Charter will comply with all relevant federal, state, and local laws, as well as accreditation standards set forth by regulatory bodies.

## References

- A. CMS section 482.12
- B. The Joint Commission Standard MSO 06.01.11 EP01

## Approval Signatures

Step Description	Approver	Date
	Tom Ta: Health Svcs Admin- Level C	07/2025

## Standards

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Owner	Leah Carlon: Health Care Risk Manager
Area	Hospital & Health Centers

## Policy for Consent to Medical Treatment

### POLICY STATEMENT:

This policy outlines the importance of obtaining the consent of patients receiving medical treatment at Contra Costa Regional Medical Center and Health Centers (CCRMC & HC). It is the physician's or provider's duty to inform the patient about the recommended care and of the risks of refusing to undergo the recommended procedure. Staff is responsible to obtain the signature of the patient after the physician has completely informed and consented the patient except for the minor procedures.

### GUIDELINES:

During hospitalization or clinic treatment, important rights of a patient are affected. The consent of the patient to those activities of the treating physician(s) and health services personnel which might affect those rights, establishes a defense to any subsequent charge that such rights were transgressed without permission.

Both personal and property rights of the patient are affected during the treatment process. Of paramount concern is the potential for committing a battery against the patient. A charge of battery can arise out of the slightest physical contact and would include treatment without patient consent.

Due to the nature of hospitalization and medical treatment, the courts have held that the patient's consent, depending on the complexity of treatment, must be informed. The principle of informed consent is met when the signer:

- A. knows what they/he/she is signing
- B. knows what procedures are being recommended or contemplated

- C. knows what alternative methods of treatment are available
- D. knows the risks and benefits involved and the expected outcome of the treatment and its alternative(s).

Informed consent should be used for treatments and procedures that are complicated in that the average layperson would not understand the nature of the treatment or procedure and associated risks and benefits. For example: a medical procedure performed in the operating room.

The activities related to hospitalization also raise the potential for allegations of false imprisonment and invasion of privacy. Evidence of the patient's informed consent establishes a defense for the attending physician(s) and CCRMC & HC.

CCRMC & HC will not permit any medical treatment (except for emergency treatment) unless the patient or a person legally authorized to act on the patient's behalf has consented thereto.

Consent to medical treatment must be freely given by the patient or legally authorized representative and will not be obtained through the exercise of either duress or coercion. A patient's informed consent for surgery/diagnostic/therapeutic procedures will be evidenced in writing. Consent for these procedures is valid for maximum of three (3) months from date of signing consent unless the specific consent form states otherwise.

Simple consent is required for treatments or procedures where risks and benefits are commonly understood by the average layperson and activities where consent is included in Consent to Treat. Simple consent is needed for hospital and clinic lab personnel to draw blood for anonymous HIV testing on behalf of the Public Health Department. Other examples include chest x-ray and nursing services.

As per the Centers for Medicare and Medicaid Services, procedures which require anesthesia (deep sedation or anesthesia) require a written consent with information about the risks, benefits, and alternatives of the procedure. The information discussed during informed consent should be documented in the medical record. Patients undergoing a procedure with anesthesia or deep sedation require a written consent. This consent can be documented either on a procedure consent form or as an electronic consent in the electronic medical record. Patients undergoing a procedure without anesthesia nor deep sedation may consent verbally but the discussion of the risks, benefits and alternatives should be documented in the medical record. In all cases, the patient should be informed of the type of procedure, its risks, benefits and alternatives as part of the consent process.

For procedures which do not require anesthesia, a verbal consent is sufficient. The verbal consent should include the risks, benefits or alternatives to the procedure and estimated recovery times when appropriate. The consent discussion should be documented in a procedure note. Topical or local analgesia such as a lidocaine injection is **not** considered anesthesia (ie. does not cause sedation or change in consciousness.)

Notwithstanding the consent described in this paragraph, if the undersigned is a foster parent (as defined by Health and Safety Code section 1527), the consent only applies to ordinary medical treatment in accordance with Health and Safety Code section 1530.6 and as otherwise prescribed by the juvenile court.

# RELATED LINKS:

[Procedure for Consent to Medical Treatment](#)

Attachment A: [Contra Costa Regional Medical Center and Health Centers Procedure or Treatment Consent](#)

Attachment B: CHA Decision Makers for Medical Treatment of Adults

<https://calhospital.org/wp-content/uploads/2021/04/quickreferenceguides.pdf>

Attachment C:

1. CHA Consent Requirements for Medical Treatment of Minors (<https://calhospital.org/wp-content/uploads/2021/04/quickreferenceguides.pdf>)
2. Authorization for Third Party to Consent to Treatment of Minor Lacking Capacity to Consent ([MR44-7](#) and [MR 44-A-1](#))
3. [MR 497-6 Authorization for Minor to Receive Follow-Up Outpatient Treatment Without Presence of Parental/Legal Representative](#)
4. Caregiver's Authorization Affidavit, [MR 673 \(English\)](#), [MR 674 \(Spanish\)](#)
5. [MR 99-4 Self-sufficient Minor Information Form](#)
6. Authorization by Juvenile Court for Treatment of a Minor (MR 498)

Attachment D: Procedure Specific Consents and Referenced California Law

Attachment E: [Refusal to Permit Medical Treatment \(MR242\)](#)

Attachment F: [Consent for Blood or Blood Products Transfusion \(MR39C\)](#) and CDPH "A Patient's Guide to Blood Transfusion." 03/2022 [A Patient's Guide to Blood Transfusion | MBC \(ca.gov\)](#)

Attachment G: Limited English Proficiency policy

Attachment H. 4V Minor Consent Medi-Cal Services <https://www.dhcs.ca.gov/services/medi-cal/eligibility/Documents/MEPM/4V-MinorConsent-12-16-21.pdf>

# REFERENCES:

Centers for Medicare and Medicaid Services Memo# QSO-24-10 Hospitals. 4.1.2024

California Hospital Association: [20232024 Consent Manual: Patient consent to treatment and related health care law](#) ([4950<sup>th</sup>](#) edition, [20232024](#))

Health Services Department Policies and Procedures, Policy No. 402 – "Access to Services for Limited English Proficient, Deaf and Hearing Impaired Persons"

The Joint Commission Standard RI.01.01.01, "The hospital respects, protects and promotes patient rights."

The Joint Commission Standard RI.01.03.01, "The hospital honors the patient's right to give or withhold informed consent."

AMA Code of Medical Ethics, 2.1.2 Decisions for Adult Patients Who Lack Capacity

22 California Code of Regulations §§ 51305.1 - 51305.4

California Welfare & Institutions Code §§ 5326.5 and 5326.6

California Penal Code § 242, People v. Longoria, 34 Cal. App. 4th 12, 14

# APPROVALS:

Patient Care Policy and Evaluation Committee: 2/2023, 12/2023, 9/2024

Medical Executive Committee: 2/2023, 12/2023, 09/2024, 9/2024

Joint Conference Committee: 3/2023, 3/2024, 3/2025

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## Attachments

 [Definition of General Anesthesia and Levels of Sedation-Analgesia.docx](#)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	09/2025
Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	08/2025
	Leah Carlon: Health Care Risk Manager	08/2025

## Standards

No standards are associated with this document



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Next Review 3 years after approval

Owner Leah Carlon:  
Health Care Risk  
Manager  
Area Hospital & Health  
Centers  
References TJC 2025

## Policy for Suspected Patient Abuse or Neglect While in the Care of the Hospital

### POLICY STATEMENT:

Instances of known or reasonable suspicion of abuse or neglect of patients while in the hospital shall be promptly addressed and reported to the appropriate agency. Any physician, nurse, practitioner, or employee who within the scope of his/her employment, becomes aware of an incident, told by a patient or has reasonable cause to believe that a patient is being abused, neglected, or exploited, or is in a condition which is the result of abuse, neglect or exploitation is required to report.

### GUIDELINES:

#### A. Definitions:

1. Neglect:  
Neglect occurs when the employee responsible for a patient's welfare fails to provide the level of services, care, or medical treatment that a reasonably prudent person would have provided in order to avoid physical harm or mental anguish to the patient. Negligence may also be the failure to notice a patient's condition and to take appropriate action.
2. Abuse:  
Abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental or emotional anguish. This includes staff neglect or indifference to infliction of injury or intimidation of one patient to another, or hospital visitor to patient, or any willful act executed to cause emotional pain, injury, mental anguish (e.g. verbal aggression or threat, threats of

institutionalization, social isolation, or humiliating statements).

3. Financial Abuse:  
Financial abuse is the taking, retaining, or assisting to take personal property of an elder or dependent adult with the intent of wrongful use and/or to defraud.
4. Threatened Abuse:  
Threatened abuse is an offer of abuse or actions coupled with the apparent ability to execute the threat or attempt.
5. Sexual abuse:  
Sexual abuse includes molestation or relations with a patient or the encouragement of the same with a patient. (Examples include, but are not limited to, intentional touching of a patient for the purpose of sexual arousal and/or actual sexual relations with a patient.)
6. Reasonable suspicion:  
Reasonable suspicion means that it is objectively reasonable for a person to entertain such a suspicion based upon facts that could cause a reasonable person in a like position, drawing when appropriate on his/her training and experience, to suspect abuse.

B. Recognition of suspected Abuse:

1. The following descriptions are not necessarily proof of abuse, but they may be clues that a problem exists. Signs that may indicate someone has been a victim of abuse by staff or another patient may include:
  - a. Fearful of another patient, roommate or staff member
  - b. Appears over medicated
  - c. Unkempt appearance, soiled, body odor
  - d. Unusual scratches, skin tears, appearance of pressure ulcers.
  - e. Bilateral bruising (bruises on opposite sides of the body) or "Wrap around" bruises.
  - f. Burns (may be caused by hot water).
  - g. Unexplained fractures or sprains.
  - h. Injuries which are unexplained or incompatible with explanations.
  - i. Unexplained or uncharacteristic changes in behavior, e.g. a patient who suddenly becomes passive or withdrawn.
  - j. Fearful of being left alone or with another patient.
  - k. Intense fear reaction to certain individuals (e.g. certain patients or caregivers) in particular.
  - l. Refusing care or treatment – may ask to be discharged.
  - m. Not eating, drinking, and neglecting hygiene.

C. Prevention:

1. Screening:

Human Resources performs a background check of employees and physicians prior to hire.

2. Training:

Upon hire, and periodically thereafter, new staff and physicians are educated in this policy.

3. Monitoring:

Patient care is routinely monitored to assess care provided, patient response to care, staff, and/or to other patients. Staff should be aware of patients who may be at risk of abuse or assault of other patients, including patients who wander, suffer from dementia, are unpredictable and who may become aggressive.

D. Immediate Actions:

1. Healthcare practitioners, including physicians, social workers, nurses, pharmacists, and other licensed personnel should maintain awareness of signs of patient abuse or neglect.

When abuse or neglect is suspected, this should be immediately reported to administrative / clinical leadership.

2. A thorough investigation should be promptly initiated and documented.

3. If the allegation / suspicion is abuse or neglect by an employee, the employee should be removed from direct care of patients and may be temporarily relieved from all duty, such as placement on administrative leave. For contracted employees, the agency / vendor should also be notified.

4. If the allegation / suspicion is abuse or neglect by a member of the medical staff, the physician/provider should be restricted from direct care of the patient whenever possible. Reasonable efforts should be made to replace the physician. If no other physician to care for the patient is available, the physician should be accompanied by another healthcare professional, e.g. a registered nurse or other member of the medical staff, whenever contact with the patient is required.

5. If the abuse is suspected from another patient, efforts will be made to separate the patients, including moving the patient to another room or unit.

6. Provide appropriate care for any obvious injury, and appropriate intervention for emotional distress.

7. The physician responsible for the care of the patient should be notified.

8. A trusted individual, such as a social worker, may be helpful to assist with the interview of the patient.

9. If there is a question of credibility of the patient's allegations when symptoms such as delusions or other psychiatric symptoms are present, or in the presence of dementia, staff should involve other professionals in the evaluation, such as a trained professional such as a psychiatric social worker or psychiatrist.

E. Internal Reporting:

1. Report to clinical or administrative leadership.

2. Escalate reporting up the chain of command, if needed.

3. Complete an event report (SERS).
4. No supervisor, administrator or physician shall impede reporting duties.

F. External Reporting:

1. Cases of suspected or known abuse should be given priority, investigated thoroughly, and reported promptly to the appropriate agency. No supervisor, administrator or physician shall impede reporting duties.
2. When a reasonable suspicion exists, the staff member or physician is required to make a report by telephone as soon as practically possible, and to send a written report to the local law enforcement agency within two working days.  
Note: when more than one staff member has knowledge of suspected abuse they may agree on which one will make the report.
3. If physical or sexual abuse is suspected, contact the Contra ~~costa~~Costa County Sheriff Department. ~~Local phone: (925) 305-5315. Be Prepared to provide the following information to the agency:~~  
~~Name of person making the report;~~  
~~Name of the patient;~~  
~~Present location of the patient;~~  
~~Nature and extent of injury;~~  
~~Other information requested by Agency.~~
  - a. Local phone: (925) 305-5315. If no one answers/you cannot reach anyone at this number, call the Sheriff's Department dispatch at (925) 646-2441 to initiate a report. Be Prepared to provide the following information to the agency:
    - i. Name of person making the report;
    - ii. Name of the patient;
    - iii. Present location of the patient;
    - iv. Nature and extent of injury;
    - v. Other information requested by Agency.
4. The patient should be notified that a report has been or will be made.
5. Refer to CCHS Policies for appropriate reporting agency and documents.  
~~Suspected Child Abuse Report (for patients under the age of 18 should be reported to the Children's Protective Services Central Screening Unit. The 24-hour number is 877-881-1116. Refer to CCHS Policy 400-PCS.~~  
~~Suspected Elder (65 years of age or older) and Dependent Adult (18-64 years) Abuse Report to be sent to the Adult Protective Services. The 24-hour toll-free telephone number is 1-877-839-4347. Refer to CCHS Policy 405-PCS.~~
  - a. Suspected Child Abuse Report (for patients under the age of 18 should be reported to the Children's Protective Services Central Screening Unit. The 24-hour number is 877-881-1116. Refer to CCHS Policy 400-PCS.
  - b. Suspected Elder (65 years of age or older) and Dependent Adult (18-64 years) Abuse Report to be sent to the Adult Protective Services. The

24-hour toll-free telephone number is 1-877-839-4347. Refer to CCHS Policy 405-PCS.

## RELATED LINKS:

[California Hospital Association's "A Quick Reference Guide to Assault and Abuse Reporting Requirements"](#)

## APPROVALS:

Patient Care Policy & Evaluation Committee: 5/4/2022

Medical Executive Committee: 6/20/2022

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	09/2025
Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	08/2025
	Leah Carlon: Health Care Risk Manager	08/2025

## Standards

No standards are associated with this document



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Last Approved	N/A
Effective	Upon Approval
Last Revised	09/2025
Next Review	3 years after approval

Owner	Leah Romito: Primary Care Prov Lmted Ex
Area	Hospital & Health Centers

## Policy for Family Medicine Residency Program

### POLICY STATEMENT:

It is the policy of Contra Costa Regional Medical Center and Health Centers to support the Family Practice Residency Program politically, budgetarily, and operationally.

### PROCEDURES:

#### A. Commitment to Medical Education

1. Contra Costa Regional Medical Center and Health Centers sponsors graduate medical education in the specialty of Family Medicine for the following reasons:
  - a. As a public institution, Contra Costa Regional Medical Center and Health Centers recognizes its responsibility to improve public health;
  - b. As a specialty, Family Medicine is the foundation for the delivery of cost-effective, quality health care;
  - c. Training Family Medicine Residents allows CCRMC/HC to attract and retain high quality attending physicians;
  - d. Those attending physicians are stimulated by their teaching responsibilities and thus remain current in their knowledge and skills;
2. Quality attending physicians and Family Medicine Residents facilitate the institution's mission of providing quality, cost-effective health care to its constituents, while simultaneously producing well-trained primary care physicians.
3. Institutional resources will be distributed to the Residency Program through a process of meetings, both formal and informal, between the CEO of the Medical

Center and Health Centers, the Residency Program Director, and the CMO. The Residency Program Director shall sit on the Medical Executive Committee, along with the Medical Staff Department heads, key committee chairpersons, the CEO of the Medical Center and Health Centers, the CMO, and the Chief Resident. The Residency Program does not have its own budget or cost center, but shall be supported in its goals through programmatic commitment and appropriate resource allocation by each individual cost center. The Family Practice Residency Program is the sole residency sponsored by this institution, and no others are planned.

4. The Residency Program Director and the appropriate department head, in consultation with the CEO of the Medical Center and Health Centers and the CMO, shall coordinate activities regarding the appointment of teaching staff. The Residency Program Director must approve all such appointments.
5. Resident selection shall occur by a process set forth by the Residency Program Director, subject to the following requirements:
  - a. The process must comply with Section 3 of the "General Requirements for Residency Training" (as adopted by the ACGME);
  - b. The teaching staff must have input or involvement in the process.
6. The supervision of Residents shall occur as set forth by the Residency Program Director, subject to the following requirements:
  - a. The Residency Program Director, in cooperation with the appropriate department head, is responsible for assuring that schedules be maintained identifying, at all times, attending staff responsible for resident supervision.
  - b. The attending staff and the appropriate department heads are ultimately responsible for the quality of medical care rendered by each resident physician.
  - c. The evaluation and advancement of residents shall occur as set forth in the Residency Program Evaluation Plan and the Residency Program Policy and Procedures. The dismissal of residents whose performance is unsatisfactory and the assurance of due process for residents shall occur as set forth in the Residency Program Evaluation Plan and the Residency Program Policies and Procedures. The assurance of due process for teaching staff shall occur as set forth in the Medical Staff Bylaws.
  - d. Periodic analyses of the Residency Program shall be conducted to assess the effectiveness of the program and the appropriateness of resource utilization. Instructional plans shall be formulated to achieve the identified goals. Specifically, the Residency Program Director is responsible for performing yearly evaluation of the program, utilizing residents and attending feedback. This information shall be reported to the medical staff and to the Executive Director, with input from residents, attending staff, and administration.

## B. Inter-institutional Agreements

1. When Family Medicine Residents of the Contra Costa Regional Medical Center and

Health Centers Family Practice Residency Program utilize other institutions as part of their scheduled training, inter institutional agreements shall be maintained. The Family Practice Residency Program Director of this program shall remain administratively responsible for the residents while they rotate to other institutions.

C. Facilities and Resources

1. Contra Costa Regional Medical Center and Health Centers shall maintain facilities and resources adequate to provide the educational experiences and opportunities set forth. These include, but are not limited to, an adequate library, sufficient space for instruction, adequate facilities for residents to carry out their patient care and individual education and responsibilities, a medical record system which facilitates both quality patient care and education, and clinical support services such as pathology and radiology.

D. Hospital Accreditation

1. Contra Costa Regional Medical Center and Health Centers shall make every effort to maintain TJC accreditation. The CEO of the Medical Center and Health Centers shall communicate with the Residency Program Director in writing regarding any actions or decisions that directly impact on the TJC accreditation status of the institution.

E. Policy Revision

1. The Residency Program policies may be revised at the discretion of the Program Director, subject to approval by the Graduate Medical Education Committee, taking into consideration input from Residents, Faculty and Administration. Revisions that will have a substantial impact on residents or faculty will be communicated prior to implementation.

F. Participation on Committees

1. Residents are encouraged to contribute to quality assurance activities and formulation and interpretation of Residency and Hospital policy through their participation on committees.
2. Residents may have positions on Committees of the Medical Staff as specified in the Medical Staff Bylaws and as appointed by the Medical Staff President.

G. Contra Costa Regional Medical Center Oversight

1. Contra Costa Regional Medical Center will oversee all residency and fellowship program-specific policies to ensure alignment with ACGME Institutional, Common, and specialty-/subspecialty-specific Program Requirements. Each program is responsible for maintaining written policies consistent with institutional standards, which must be reviewed by the Program Director, submitted to the Graduate Medical Education Committee (GMEC) for oversight, and made available to residents and fellows.
2. The GMEC and Designated Institutional Official (DIO) will monitor compliance with these policies and address deficiencies in a timely manner. Residency specific policies included, but not limited to, the related links below.

# REFERENCES:

Residency Program Policy and Procedures

Accreditation Council for Graduate Medical Education (ACGME) Family Practice Residency Program Application

TJC MS 2.5 and 6.9

Instructional Plans

Residency Program Evaluation Plan

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Graduate Medical Education Committee	Leah Romito: Primary Care Prov Lmted Ex [TT]	09/2025
	Leah Romito: Primary Care Prov Lmted Ex [TT]	09/2025

## Standards

No standards are associated with this document



Origination 01/2005

Last Approved N/A

Effective Upon Approval

Last Revised 01/2005

Next Review 3 years after approval

Owner Geena Jester:  
Hospitalist  
Exempt

Area Hospital & Health  
Centers

## Policy for Requirements for Medical Record Entries by Attending Physician

### POLICY STATEMENT:

Patients with Intensive Care status will have daily medical record entries by the Attending Physician of record and/or the Attending Physician caring for the patient that day.

### GUIDELINES:

Patients with Intensive Care status will have daily medical record entries by the Attending Physician of record and/or the Attending Physician caring for the patient that day. Examples of minimal content of daily progress notes are outlined in the CMS, Teaching Physician's Billing Guide.

### REFERENCES:

Centers for Medicare & Medicaid Services, Teaching Physician's Billing Guide

### APPROVALS:

Medical Executive Committee:

Patient Care Policy and Evaluation 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]	09/2025
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [TT]	08/2025
Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	07/2025
	Geena Jester: Hospitalist Exempt	06/2025

## Standards

No standards are associated with this document



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Last Approved	N/A
Effective	Upon Approval
Last Revised	09/2013
Next Review	3 years after approval

Owner	Leah Romito: Primary Care Prov Lmt'd Ex
Area	Hospital & Health Centers

## Policy for Graduate Medical Education Administration

### POLICY STATEMENT:

To formally describe the Graduate Medical Education Administration and define the responsibility of oversight of all aspects for the Family Medicine Residency. Describe the oversight of Contra Costa Regional Medical Center to maintain an organized, educational administration that will oversee all residency programs sponsored by the institution.

### POLICY:

#### A. The Graduate Medical Education Committee

1. The Director of Medical Staff Affairs, upon the recommendation of the Residency Program Director, shall appoint the Graduate Medical Education Committee (GMEC). The committee shall include, at a minimum, two peer-selected residents, two Faculty members, the Residency Program Director, the Director of Quality and Safety or their designee, and an attending familiar with GME but not a Core Faculty member.
2. The GMEC shall meet at least quarterly and minutes shall be kept. The office of the Residency Program Director shall staff the meeting and provide agendas and supportive material to the members.
3. The GMEC responsibilities include: (1) establishment and implementation of policies that affect all residency programs regarding the quality of education and the work environment for the residents; (2) establishment and maintenance of appropriate oversight of the program director and other personnel involved in the program; (3) regular review of all educational programs to assess their compliance with the Institutional and Program Requirements of the Family Medicine Residency Review Committee (RRC) and the ACGME; (4) assurance the program establishes and implements formal written criteria and processes for the selection, evaluation, promotion and dismissal of residents in compliance with the Institution and Program Requirements of the RRC; (5) assurance of an educational environment in which residents may raise and resolve issues without fear of intimidation or retaliation; (6) collecting of intra-

institutional information and making recommendations about appropriate funding levels for the program; (7) monitoring of the program's attention to resident work hours and working environment; and (8) assurance that the resident's curriculum complies with RRC requirements. The Designated Institutional Official may assign other appropriate duties to the GMEC

#### B. The Residency Leadership Group

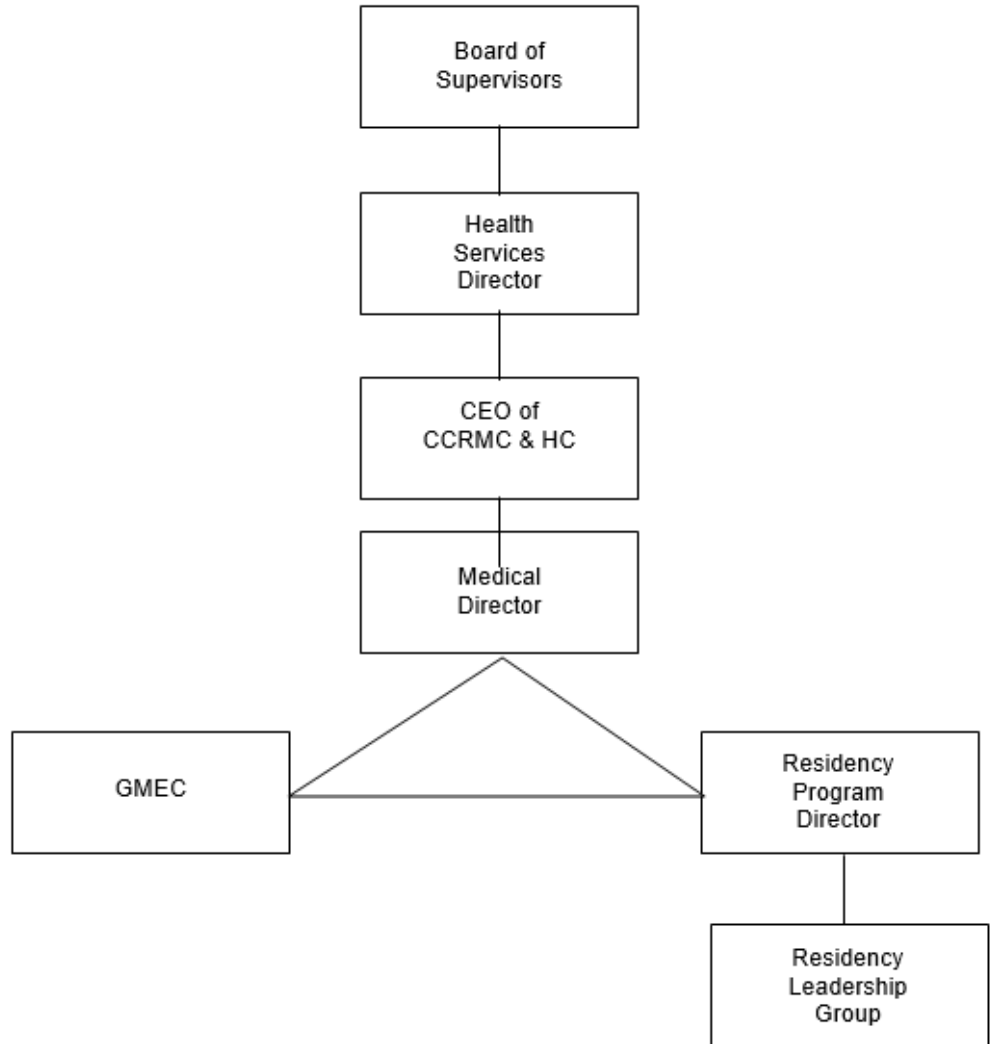
1. The Residency Program Director, CEO, the Designated Institutional Official shall appoint a Residency Leadership Group after consultation and advice from faculty. The members of the Group must meet the RRC requirements for residency faculty and must be willing to provide administrative support to the Residency Program Director.
2. The Residency Leadership Group shall provide advice and support to the Residency Program Director in the implementation of her/his duties.

#### C. Residency Program Director

1. The Designated Institutional Official and CEO, with the consent of the GMEC, shall appoint a qualified Residency Program Director. The Residency Program Director must be licensed to practice medicine in the State of California, certified by the American Board of Family Medicine, and be a member in good standing of the Medical Staff of the Contra Costa Regional Medical Center and Health Centers. Also, the Residency Program Director must have a minimum of two years of full-time professional activity in Family Medicine and have demonstrated ability as a teacher, clinician, and administrator.
2. The Residency Program Director is responsible for the following:
  1. Preparation of written educational goals for the residents, which comply with the RRC requirements.
  2. Development and implementation of policies and procedures for selection of residents in compliance with RRC requirements.
  3. Selection and supervision of the program teaching staff and faculty.
  4. Development and implementation of policies and procedures that assure appropriate and adequate resident supervision and teaching.
  5. Resident evaluation and discipline pursuant to appropriate written policies.
  6. Promotion and assurance of resident well-being.
  7. Provision of accurate and complete information to the RRC as requested.
  8. Notification of the RRC of any significant change in the program.
  9. Overall supervision and monitoring of the residency program in order to assure that it complies with RRC requirements, CCRMC and HC policies, and accepted standards of quality.
  10. Implementation of administrative directives regarding the program.
  11. Assurance that appropriate administrative officials are aware of significant issues regarding the residency program and the residents and faculty.

#### D. Organizational Structure

1. The organizational structure of the Graduate Medical Educational Administration is as follows:



## AUTHORITY/RESPONSIBILITY

The Chief Executive Officer (CEO), the Chief Medical Officer acting as the Designated Institutional Official (DIO), and the Residency Program Director will have joint responsibility to carry out this policy.

## REFERENCES:

ACGME Institutional Requirement

Residency Review Committee (RRC) for Family Medicine

Memorandum of Understanding (current)

## Approval Signatures

Step Description

Approver

Date

Medical Executive Committee	Sarah E. Mcneil	Pending
Graduate Medical Education Committee	Leah Romito: Primary Care Prov Lmted Ex [TT]	09/2025
	Leah Romito: Primary Care Prov Lmted Ex [TT]	09/2025

## Standards

No standards are associated with this document



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Last Revised	07/2014
Next Review	3 years after approval

Owner	Leah Romito: Primary Care Prov Lmted Ex
Area	Hospital & Health Centers

## Policy for Requirements of Cosignatures of Medical Record Entries

### POLICY STATEMENT:

Specific medical record entries require authentication by the responsible medical practitioner when the documentation is done by a resident, podiatrist, dentist, physician assistant, family nurse practitioner, midwife, or student.

### POLICY:

- A. Pre-anesthesia Evaluations by a resident must be cosigned by a staff physician.
- B. Discharge Summaries by a resident, nurse practitioner, midwife, physician assistant, or podiatrist must be cosigned by a staff physician when complete.
- C. Inpatient History and Physicals by a resident, family nurse practitioner, physician's assistant, midwife, dentist (DDS) or podiatrist must be cosigned by a staff physician when complete.
- D. Consultation Reports by a resident must be cosigned by a staff physician.
- E. Medication orders – written by Advance Level Practitioner (NP, CMN, PA, etc.) will utilize standard order sets from the CCRMC. Verbal consultation with the attending will be requested for any significant deviation from the usual orders or if the usual protocol is not clear.
- F. Operative or Delivery Notes by the resident must be cosigned by the staff physician (or his/her designee) who was in attendance.
- G. Physical and Occupational Therapy Notes for treatment documentation by an aide must be cosigned by a licensed physical or occupational therapist.
- H. Nutritional Assessments by a Dietetic Technician must be cosigned by a Registered Dietitian.

- I. Any student notes or orders will need to be cosigned by a licensed practitioner in the same area of study.

## REFERENCES:

TJC Accreditation Manual for Hospitals, RC.01.01.01, RC.01.02.01

Contra Costa Regional Medical Center and Health Centers Medical Staff Rules and Regulations 1.12

Medicare Conditions of Participation (COP) 42 CFR § 491.10 (a)(3)(i-iv), Interpretive Guidelines

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Graduate Medical Education Committee	Leah Romito: Primary Care Prov Lmted Ex [TT]	09/2025
	Leah Romito: Primary Care Prov Lmted Ex [TT]	09/2025

## Standards

No standards are associated with this document



**GREEN LIGHT:** Pressure is negative in the isolation room.



**RED LIGHT:** Pressure is NOT negative in the isolation room.

- ✓ Check to make sure the room and anteroom doors are closed.
- ✓ No open windows in room
- ✓ If no issues found in room and alarm continues to sound Page Engineer #350, MCS #243



Origination 06/2004  
Last Approved N/A  
Effective Upon Approval  
Last Revised 06/2025  
Next Review 3 years after approval

Owner Ira-Beda Sabio:  
Director, Inpatient  
Nursing OP  
Area Nursing

## Policy for Wound Dressing Changes/Packing

### POLICY STATEMENT:

To provide guidelines for dressing or packing wound appropriately and to prevent contamination and cross-infection during dressing changes.

Dressing changes will be performed using standard precautions and as ordered by the practitioner in ccLink.

**Do not remove** surgical dressings without provider's orders.

### GUIDELINES:

- A. Identify patient using at least two patient identifiers.
- B. Determine need for pain medication before beginning procedure.
- C. Perform hand hygiene; prepare supplies; don clean gloves.
- D. Remove soiled dressings and dispose of dressing and packing.
  1. Moisten dressing if adherent to wound.
- E. Examine dressings for wound drainage: amount, color consistency, and presence of odor
- F. Dispose of dressing and packing in biohazard bin.
- G. Remove and discard gloves.
- H. Perform hand hygiene and don clean gloves.
- I. Assess wound site.
  1. Identify location of wound.

2. ~~Observe wound bed appearance.~~ Assess wound bed, margins and periwound skin condition.
  3. Check wound size, shape, depth, ~~margins.~~
  4. Observe exudates or drainage.
  5. Evaluate presence of pain.
- J. Remove soiled gloves, and discard.
  - K. ~~Don~~ Perform hand hygiene and don clean gloves.
  - L. Clean wound with saline solution (use if wound culture ordered), sterile water or wound cleanser, per order. Pat wound with 4x4 gauze.
  - M. Obtain wound culture (if ordered) after cleansing wound with sterile saline. Do not take specimen from exudate or eschar.
  - N. If tunneling present, loosely pack tunneling area of wound if present before filling the base of the wound.
    1. Place packing material in wound: using a sterile gloved hand or a clean gloved hand with either sterile forceps or sterile cotton tipped applicator, gently guide enough packing material into the wound cavity, undermining, sinus or tunnel to fill the dead tissue without causing the wound tissue to stretch or bulge.
  - O. Use only one piece or length of packing wherever possible. Leave "tail" end visible.
  - P. Fill rest of wound with dressing as ordered. Then cover with a dry dressing.
  - Q. Remove and dispose gloves; dispose soiled instruments. Perform hand hygiene.

## RELATED LINKS:

Patient Care Record in ccLink  
Wound documentation tab in ccLink

## REFERENCES:

TJC Standard PC.01.02.05, "Qualified staff or licensed independent practitioners assess and reassess the patient."

~~Iwamoto, P., Post, M., & Oregon Patient Safety Commission (2014, October 2). Aseptic Technique. In Basic Principles of Infection Prevention Practice. Retrieved 9-20-2022, from [http://text.apic.org/toc/basic-principles-of-infection-prevention-practice/aseptictechnique#book\\_section\\_584](http://text.apic.org/toc/basic-principles-of-infection-prevention-practice/aseptictechnique#book_section_584)~~

Perry, A., Potter, P. & Ostendorf, W., and Laplante, N. (2018 ~~2022~~). Clinical nursing skills & techniques pp. ~~1016-1017~~ (10th ed). Elsevier.

Wound Ostomy and Continence Nurses Wound Committee and the Association for Professionals in Infection Control and Epidemiology, Inc. 2000 Guidelines Committee. (2011). *Clean vs. Sterile Dressing Techniques for Management of Chronic Wounds: A Fact Sheet*. Wound, Ostomy and Continence Nurses

Society.

## APPROVALS:

Clinical Practice Committee: 2/2018, 10/2022

Patient Care Policy & Evaluation Committee: 3/2018, 11/2022

Medical Executive Committee: 5/2018, 11/2022

Joint Conference Committee: 3/2023

## Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	09/2025
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [TT]	07/2025
Clinical Practice Committee	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	06/2025
	Ira-Beda Sabio: Director, Inpatient Nursing OP [LS]	06/2025

## Standards

No standards are associated with this document



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

Owner	Stephanie Dockham: Dietitian
Area	Nutrition

## Employee Orientation and Training

### POLICY STATEMENT:

Food & Nutrition Services staff participate in hospital and departmental orientation programs, initial job-specific training and competency assessment during the on-boarding process. In addition, ongoing in-service education and training is provided to reinforce knowledge and skills, and to address changes in health care and/or work assignments to ensure employees have adequate skills and knowledge to perform assigned job duties and to promote safe, high-quality operations.

### GUIDELINES:

All hospital Food and Nutrition Services employees are required to attend hospital orientation. The focus of orientation is the mission and philosophy of the organization, human resources policies & procedures, general safety, emergency management and infection control. Attendance is documented via ccLearn.

All new Food & Nutrition Services employees complete a general departmental orientation conducted by a manager, supervisor and/or lead. The focus of orientation is departmental policies & procedures; performance expectations; customer service; general safety, emergency planning and infection control specific to the functions within Food & Nutrition Services; food safety and HACCP practices; job description and the employee's role in safety and performance improvement (if applicable). The possible methods used are discussion, observation, demonstration, assigned readings, trainings and/or videos.

- A. A departmental orientation checklist is completed by new employees and their manager, supervisor and/or lead. A copy of this checklist is maintained in the employee's file.
- B. Employees complete an orientation to the specific position(s) to which they have been

assigned. The manager, supervisor and/or lead, in partnership with the employee, maintains responsibility for the completion of this orientation. The focus is the clinical, technical and/or support responsibilities detailed in the individual's job description.

- C. A position-specific checklist is completed to document training and competency assessment. Documentation of the training and competency assessment is maintained in the employee's file.

Ongoing education and training is provided to continue to develop and/or reinforce critical skills and knowledge needed for safe and high-quality performance of assigned duties.

- A. Mandatory facility in-service education and competency assessment is completed for all Food & Nutrition Services employees per Contra Costa Health Services policies.
- B. Annual departmental in-services are conducted for all Food & Nutrition Services employees on customer service, food safety and general safety.
- C. Documentation of completed training & education is maintained in personnel files.
- D. Departmental training and in-service plans are adjusted to reflect emerging needs in the health care environment; changes to departmental policies and practices; and challenges identified during ongoing competency assessment processes.

## REFERENCES:

- A. Centers for Medicare & Medicaid Services: State Operations Manual for Hospitals (2018)
- B. The Joint Commission: Comprehensive Accreditation Manual for Hospitals (2019)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [SP]	09/2025
Infection Prevention & Control Committee	Kathy Ferris: Infection Control Coord	09/2025
	Stephanie Dockham: Dietitian	07/2025

## Standards

No standards are associated with this document



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

Owner	Stephanie Dockham: Dietitian
Area	Nutrition

## Food Safety (HACCP)

### POLICY STATEMENT:

To ensure the safety and quality of the food served to patients and customers Food and Nutrition Services has a Food Safety/HACCP Program in place that complies with the US Food & Drug Administration Food Code.

Hazard Analysis Critical Control Points (HACCP) is a comprehensive food safety and self-inspection system that traces the flow of potentially hazardous foods throughout the foodservice operation. It follows the path from recipe development through delivery of products, storage, preparation, holding or displaying, serving, cooling & storing leftovers and reheating of foods. A Critical Control Point is any point or procedure in a specific food system at which control can be applied to prevent, eliminate or reduce food safety hazards.

### GUIDELINES:

- The current Sodexo HACCP Manual is in place as a reference for managers and employees.
- Managers are ServSafe certified.
- All employees hired for a food handling position must complete safety training. Topics covered include personal hygiene, HACCP system, thermometers, cooking, cooling, reheating, hot and cold holding, receiving, storing, cleaning, sanitizing and service
- Mandatory ongoing training is provided and documented annually.
- Food Safety Audits and Comprehensive Food Safety Self-Inspections are conducted and documented with corrective action plans and follow-up for any areas not meeting standards.
- Food Safety Documentation Logs are maintained with corrective actions documented as

applicable.

## REFERENCES:

- A. Centers for Medicare & Medicaid Services: State Operations Manual for Hospitals (2018)
- B. Sodexo: SodexoNet – HACCP Manual (2019)
- C. The Joint Commission: Comprehensive Accreditation Manual for Hospitals (2019)
- D. US Food & Drug Administration: Food Code (2017)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [SP]	09/2025
Infection Prevention & Control Committee	Kathy Ferris: Infection Control Coord	09/2025
	Stephanie Dockham: Dietitian	07/2025

## Standards

No standards are associated with this document



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Last Approved N/A  
Effective Upon Approval  
Last Revised 07/2025  
Next Review 3 years after approval

Owner Stephanie Dockham: Dietitian  
Area Nutrition

## Menu Planning and Purchasing

### POLICY STATEMENT:

Inventory levels for food and departmental supplies reflective of the menu planning process will be consistently maintained at sufficient levels to meet demands of the department. Food and Nutrition Services will ensure the safe and accurate purchase, receipt, and check-in of food and non-food supplies.

### GUIDELINES:

- A. Food and Nutrition Services adheres to the Purchasing Division's policies and procedures when purchasing food and departmental supplies.
- B. The following is ensured when purchasing food supplies:
  - 1. All fresh or processed foods containing meat, fish, poultry, eggs, milk, and other dairy products have been government-inspected and certified as safe and wholesome.
  - 2. Only pasteurized milk and milk products are purchased.
  - 3. Shellfish is purchased from reliable sources, which comply with the regulations of the State Shellfish Authority.
  - 4. Donated food such as home-canned foods, salads, mixtures, custards, and other potentially hazardous foods are not accepted.
  - 5. All food items for the facility meet all state, local and national standards.
- C. An inventory is maintained on the premises, appropriate to meet the requirements of the menu, for 7 days' usage of staple goods and 2 days' usage of perishables.
- D. Upon delivery, all items are inspected to prevent acceptance of contaminated or substandard products. **Any Vendors are notified of any** items that do not meet quality standards **and** are

either returned to the vendor for credit or disposed of per their instruction.

## REFERENCES:

- A. The Joint Commission Standard PC.02.02.03 EP 7, 9 & 11
- B. Center for Medicare and Medicaid Services § 482.28
- C. 22 California Code of Regulations § 70277

## APPROVALS:

Infection Control Committee:

Patient Care Policy and Evaluation Committee: 9/2023

Medical Executive Committee: 9/2023

Joint Conference Committee:

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [SP]	09/2025
Infection Prevention & Control Committee	Kathy Ferris: Infection Control Coord	09/2025
	Stephanie Dockham: Dietitian	07/2025

## Standards

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Owner	Stephanie Dockham: Dietitian
Area	Nutrition

## Food Storage

### POLICY STATEMENT:

Food and Nutrition Services maintains safe and sanitary storage of food in compliance with the US Food & Drug Administration Food Code to prevent contamination of food from chemicals and/or transmission of disease-carrying microorganisms.

### GUIDELINES:

- A. Food must be stored separate from cleaning supplies and/or flammable liquids.
- B. Dry and staple items must be stored at least 12" above the floor in a clean and well-ventilated room.
- C. Food is regularly inspected for signs of damage (e.g., dents, bulges, leaks, rust, etc.) and discarded upon identification of damage.
- D. Food must be stored in food grade containers.
- E. Disposable containers are not to be reused.
- F. Dry bulk foods must be stored in non-reactive metal or plastic container with a tight-fitting lid.
- G. Scoops are not to be stored in the food (including but not limited to ice.)
- H. Food products/storage containers are labeled and dated per regulatory standards.
  - I. Stock is rotated to support the use of the "First-In, First-Out" (FIFO) approach.
- J. Corrugated cardboard is not to be stored in any refrigerators or other dry storage areas.
- K. There shall be a reliable thermometer in each refrigerator and freezer used to store perishable food.

- L. Hazard Analysis and Critical Control Point (HACCP) documentation logs are maintained for all refrigerator and freezer units per regulatory standards. Corrective actions are noted for temperatures outside the acceptable ranges.
- M. Perishable foods are to be stored in the refrigerator or freezer promptly upon receipt and must be kept refrigerated/frozen until prepared or served.
- N. Prepared foods are to be store above raw meats, poultry, or fish to prevent cross contamination.
- O. Prepared foods are to be stored in the refrigerator or freezer promptly after preparation until served.

## REFERENCES:

- A. The Joint Commission Standard PC.02.02.03 EP 11
- B. Center for Medicare and Medicaid Services § 482.28
- C. 22 California Code of Regulations § 70273

## APPROVALS:

Infection Control Committee:

Patient Care Policy and Evaluation Committee: 9/2023

Medical Executive Committee: 9/2023

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]	09/2025
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [TT]	08/2025
Infection Prevention & Control Committee	Kathy Ferris: Infection Prevention & Control Manager	07/2025
	Stephanie Dockham: Dietitian	06/2025

## Standards

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Owner Shideh Atai:  
 Director Of  
 Pharmacy Svcs  
 Area Pharmacy

## Contact List for Disaster Fan-Out Procedures

### PURPOSE STATEMENT:

To provide a mechanism to recall off-duty staff in the event an emergency incident is declared.

### PROCEDURE:

- A. The Director or designee will continue the fan-out in order of proximity and availability.
- B. The number of staff members called in will be at the discretion of the Director of Pharmacy Services and dependent upon the scope of the disaster.
- C. Once contacted, staff is expected to report to CCRMC immediately, unless directed otherwise.

#### **Inpatient Pharmacy Staff:**

NAME	Home Phone	Cell Phone	Location
<u>ABELLA, ROSARIO (RN)</u>		<u>510-410-8231</u>	<u>Vallejo</u>
ALAVI, SHIRIN		760-828-2150	Walnut Creek
AL-RAWI, SHAMS		925-567-4570	Walnut Creek
ASCENCION, LISETTE		925-852-4868	Oakley
ATAI, SHIDEH		925-482-4733	Danville
BRODERICK, ETHEL (MDF)		510-375-5356	Martinez
<del>CARONE, LORI</del>		<del>510-575-8637</del>	<del>Pineole</del>
CHAMBERLIN, HOLLY (MDF)		925-207-0156	Martinez
CHOI, SUN		949-293-8497	Pleasant Hill

ELIA, HALA		707-631-4252	Fairfield
EMINUE, GLORY		404-604-0705	<del>Vallejo</del> Fairfield
<u>EVANS, RONNICA (MDF)</u>		<u>925-577-3418</u>	<u>Pittsburg</u>
FAKURNEJAD, ADEEBEH		925-285-4322	Berkeley
FENG, TRACY		408-368-2027	Martinez
FUNG, SHARON		415-650-8293	Hercules
LAM, ERIC		925-212-4667	Concord
LAI, SHELLY		301-979-1947	Fairfield
LIANG, KENNY		510-520-2699	Concord
LIU, JOE ( <del>MDF</del> )		415-963-2366	Pacifica
LOLHAM, IVET		925-360-3982	Martinez
LOPEZ, ERICA		415-640-5534	Vallejo
LUO, ANDY		925-698-5698	Pittsburg
MA, ALEX (MDF)		415-937-4718	Antioch
<del>MAKEEV, FRANCHESKA</del>		<del>925-766-6560</del>	<del>Walnut Creek</del>
MALANA, VANESSA		925-642-7883	Pittsburg
MANULAT, NECO (MDF)		650-660-6531	Emeryville
MIRADOR, ROMIE (MDF)		707-319-2784	Vallejo
NG, NHU (BONNIE) (MDF)		408-234-0385	<del>Hayward</del> Walnut Creek
NGO, PHONG		408-982-7476	Pleasant Hill
<u>OMER, MARYAM</u>		<u>408-708-8585</u>	<u>San Jose</u>
ORELLANA, MARJAN		510-410-6088	Kensington
OUABO, BRIGITTE		661-609-1409	Antioch
PATINO, CHRISTINE		510-677-4527	San Leandro
PAULE, JERICO		707-656-1069	Fairfield
PEREZ, BERNICE		707-315-9748	Benicia
PHAM, KHAI		714-318-8691	Walnut Creek
<u>REYNOSO, JUAN</u>		<u>925-305-0992</u>	<u>Pittsburg</u>
RHEE, GA (MONICA)		707-342-0968	Benicia
RHEE, JOSEPH	707-751-1570		Benicia
<del>RIVERA, TROY</del>		<del>925-768-5868</del>	<del>Martinez</del>
SAHAGUN, CRYSTAL		707-853-7403	Vallejo
SHAH, SONAM		562-980-6535	Concord
<u>SINGH, AMANDEEP (MDF)</u>		<u>925-329-5633</u>	<u>Baypoint</u>

SOTSKOVA, MARINA		925-285-9799	Concord
<a href="#">SPARKS, ANDREA (RN)</a>		<a href="#">510-860-6426</a>	<a href="#">Crockett</a>
TRAN, KRISTIE		408-464-5805	Pleasant Hill
VORA, USHMA		925-788-4343	Clayton
WANG, AMANDA		510-225-8105	Pleasant Hill
WONG, MEILIN		408-219-9236	San Leandro
WONG, CHI HOU (ANTONIO)		650-963-6388	Walnut Creek
WOOD, DENISE		510-807-5578	Walnut Creek

#### Per Diem Staff:

NAME	Home Phone	Cell Phone	
DO, WILLIAM		714-325-8177	Oakland
KNAUS, ELIZABETH		503-312-2382	San Francisco
<a href="#">MAKEEV, FRANCHESKA</a>		<a href="#">925-766-6560</a>	<a href="#">Walnut Creek</a>
NGUYEN, VICKIE		714-244-2710	<del>Walnut Creek</del> <a href="#">Lafayette</a>
PARVATANENI, RAO <a href="#">(Ret.)</a>	925-372-9737	925-293-6308	Martinez
PAUL, SUDA <a href="#">(Ret.)</a>	925-376-5165	925-788-1149	Orinda
PECK, RAPHAEL <a href="#">(Ret.)</a>		510-684-8023	Albany
<a href="#">SANCHEZ, LESLIE (NICHOLE)</a>		<a href="#">707-393-1847</a>	<a href="#">Antioch</a>
<a href="#">TUNGOL, ANGELO</a>		<a href="#">415-900-6443</a>	<a href="#">Antioch</a>
VU, HEATHER		510-501-3877	Alameda

#### Clerical Staff:

NAME	Home Phone	Cell Phone	
MACHA, TATIANA		925-351-5589	Brentwood
<del>SEOVIA</del> <a href="#">SEGOVIA</a> , IRENE		408-800-8661	Oakley

## RELATED LINKS:

[Policy for Pharmacy Disaster Fan-Out Procedures](#)

## REFERENCES:

- A. TJC Standard EM.02.01.01, EM.02.02.01, EM.02.02.07
- B. CMS CoP § 482.11(a)(c), 482.12(f), 482.23(c), 482.25(a)(b), 482.41(a)(b), 482.42(a), 482.43(a)(c)(d), 482.55
- C. CCRMC Disaster Plan

# APPROVALS:

~~Patient Care Policy and Evaluation Committee: 3/2024~~

## Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	09/2025
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	07/2025
	Shideh Ataii: Director Of Pharmacy Svcs	06/2025

## Standards

No standards are associated with this document



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Last Revised	07/2025
Next Review	3 years after approval

Owner	Shideh Atai: Director Of Pharmacy Svcs
Area	Pharmacy

## Policy for Bioterrorism Preparedness

### POLICY STATEMENT:

In the event of a bioterrorist attack, the HEICS plan would be activated, and those plans and procedures would become operational. CCRMC would work very closely with the Public Health Department in managing and treating the victims. All hospitals in the county play an important part in being prepared. ~~Each facility has been asked to keep a specified amount of medications in stock, and in date, at all times. We have been charged with having enough medication to treat or prophylaxis 50 people for 10 days for any chemical or biological agent that could be used. CCHS has prepared a flip chart as a quick reference guide in the management and treatment for exposure to the most likely agents.~~

### GUIDELINES:

~~Pharmacy will post a CCHS Bioterrorism Quick Guide posted for reference in the event a bioterrorism event is announced.~~

The Pharmacy will cooperate fully with the coordinating agency. In the event of a bioterrorist attack, the Public Health Department would be in charge and would have the authority to commandeer medication or personnel. In addition, Public Health has authority over the federal 'PushPack' and 'ChemPack' supplies. (See the attachment for the 'Chempack' Activation Flowchart for medications provided through 'PushPack and ChemPack' supplies. ~~(See the attachment for the 'Chempack' Activation Flowchart".)~~

~~The Pharmacy will keep a stock supply, as requested, of medications that would be used to treatment or prophylaxis of 50 people for 10 days. This stock can include inpatient stock, stock from the outpatient pharmacy.~~

~~The CCHS Bioterrorism Quick Guide and the attached chart may be used as a resource for treatment~~

~~options in the event of an exposure or outbreak of disease.~~

~~On a routine basis, inventory will be taken, and expiration dates will be checked. All medications necessary to bring stock up to the required level will be ordered. Soon-to-expire medications should be rotated through working stock to minimize wastage.~~

## REFERENCES:

### REFERENCES:

- A. CCRMC Policies and Procedures (Disaster Manual)
- B. TJC Standards EM.02.01.01, EM.02.02.03, EM.02.02.07, MM.03.01.03
- C. CMS CoP § 482.12(f), 482.23(c), 482.25(a)(b), 482.41(c), 482.55
- D. ~~CCHS Bioterrorism Quick Guide~~
- E. The Center for Disease Control: [www.bt.cdc.gov/Agent/Agentlist.asp](http://www.bt.cdc.gov/Agent/Agentlist.asp)

## APPROVALS:

~~Patient Care Policy and Evaluation Committee: 10/2022~~

~~Medical Executive Committee:~~

~~Joint Conference Committee:~~

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## Attachments

 [B: Chempack Activation Flowchart](#)

## Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	09/2025
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [TT]	08/2025
	Shideh Ataii: Director Of Pharmacy Svcs	07/2025

## Standards

No standards are associated with this document



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 Next Review 1 year after approval

Owner Shideh Atai:  
 Director Of  
 Pharmacy Svcs  
 Area Pharmacy

## Policy for Compounding Competency Assessment

### POLICY STATEMENT:

The Designated Person~~(s)~~ (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.

DP assigns 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, or might prepare, or have direct oversight of compounding of **non-sterile** compounded products must be initially trained and qualified by demonstrating knowledge and competency and no less frequently than once every 12 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.

**~~Nursing Staff:~~**

- P. ~~All Nursing Staff who might be expected to admix or compound an immediate-use sterile compounded product (CSP) must pass an annual assessment of their aseptic technique.~~
- Q. ~~Pharmacy Department will train the trainer and these individual(s) will be responsible for assessing the technique of all nurses. Professional Staff Development will maintain records of competency.~~

## RELATED LINKS:

[Attachment A. Sterile Compounding Competency Assessment](#)

[Attachment B. Non-Sterile Compounding Competency Assessment](#)

[Procedure for Gloved Fingertip Test and Surface Sampling](#)

[Procedure for Media Fill Test](#)

[Procedure for 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. Title 16 California Code of Regulations Articles 4.5, 7 and 7.5 § 1735, 1751

## ~~APPROVALS:~~

~~Patient Care Policy and Evaluation Committee: 2/2025~~

~~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]	09/2025
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [TT]	08/2025
	Shideh Ataii: Director Of Pharmacy Svcs	08/2025

## Standards

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Next Review 1 year after approval

Owner Shideh Atai:  
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. ~~The inactive ingredients to be used – identities and amounts~~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 ~~process or procedure used to prepare~~instructions for preparing the compound, including equipment, supplies, a description of compounding steps, and any special precautions.
  - e. ~~The quality review required at each step of the compounding process~~
  - f. ~~Post-compounding process or procedure required, if any~~
  - g. Physical description of the final CSP.
  - h. Maximum allowable beyond-use date (BUD) and the rationale or reference source justifying its determination.
  - i. Instructions for storage and handling of the compounded drug preparation.
  - j. The quality review required at each step of the compounding process.
  - k. Quality Control (QC) procedures (e.g., pH testing, filter integrity testing).

- l. 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).
  - m. 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
  - n. 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. ~~Name, weight or volume, and strength of each component~~
      - iii. Date and time of preparation of the CSP
      - iv. Assigned internal identification number (e.g., prescription, order, or lot number)
      - v. The ~~date and time~~ identity of the staff member who compounded the product ~~was compounded~~ ~~The identity of the staff member who compounded the product~~
      - vi. The identity of the pharmacist reviewing the final product
      - vii. Name, weight or volume, and strength of each component
      - viii. 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.

- ix. The quantity of each component used in compounding (e.g., weight, volume, strength, activity, etc.)
- x. The total quantity compounded
- xi. ~~The manufacturer, expiration date and lot number of each ingredient~~
  - ~~Required for CSPs prepared for more than one patient~~
  - ~~Required for CSPs prepared from non-sterile starting ingredients~~
  - ~~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.~~
- xii. ~~The equipment used in compounding (see definition)~~
- xiii. ~~The pharmacy-assigned unique reference number (order number)~~
- xiv. Final yield (e.g., quantity, containers, number of units)
- xv. The beyond-use date and storage requirements of the final product
- xvi. ~~The final quantity/amount of drug being compounded~~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 1<sup>st</sup> of every odd year or whenever the Pharmacy changes PIC or owner.
5. **Initial and annual or 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](#)

[Procedure D. for Garbing for 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 4.5, 7 and 7.5 § 1735, 1751, 1751.4, 1707.5

## APPROVALS:

~~Patient Care Policy and Evaluation Committee: 8/2024~~  
~~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 [SP]	09/2025
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [TT]	08/2025
	Shideh Ataii: Director Of Pharmacy Svcs	08/2025

### Standards

No standards are associated with this document



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Owner Shideh Atai:  
 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 ([sDP](#)), [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.
- 9. ~~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
- 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

## 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 [SP]	09/2025
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [TT]	08/2025
	Shideh Ataii: Director Of Pharmacy Svcs	07/2025

## Standards

No standards are associated with this document



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Owner Shideh Atai:  
Director Of  
Pharmacy Svcs  
Area Pharmacy

## Policy for Non-Sterile Compounding

### POLICY STATEMENT:

~~Every policy must begin with a policy statement. Policy statements summarize the policy and expectations (you answer the questions who, why, what, when, and where of the policy). Policy statements address what is the standard, not how to implement the standard. They do not include background details. The policy statement specifies the main audience for the policy, conditions, and restrictions for applying the policy, expectations, and exclusions.~~

~~The Designated Person is responsible for all requirements of the USP 797, USP 800, and USP 795.~~

The Designated Person, Pharmacist II, is responsible for performance and operation of the pharmacy and personnel for the preparaiton 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.
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](#)
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<sup>®</sup> 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](#)

# REFERENCES:

- A. Joint Commission Standards
- B. California State Board of Pharmacy Regulations: Section 1735 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

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## Attachments

 [A. Inpatient Pharmacy Non-Sterile USP 795 Compounding Cleaning Log \(Rm 1306\)](#)

## Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	09/2025
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [TT]	08/2025
	Shideh Ataii: Director Of Pharmacy Svcs	08/2025

## Standards

No standards are associated with this document



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Owner Shideh Atai:  
 Director Of  
 Pharmacy Svcs  
 Area Pharmacy

## Policy for Antineoplastic and Hazardous Drug Handling

### POLICY STATEMENT:

All ~~healthcare~~health care personnel who handle Hazardous Drug (HD) preparations and entities that store, prepare, transport, or administer ~~HDs~~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 is responsible for all requirements of the USP 797, USP 800, and USP 795.~~

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~~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. ~~Entity maintains a list of HDs~~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. ~~List~~CCRMC maintains a list of HDs that includes all items on the current NIOSH list ~~that the entity handles, and is reviewed at least every 12 months~~
- 4. ~~Entity reviews list at least every 12 months~~
- 5. ~~Assessment of risk for specific dosage forms reviewed every 12 months~~
- 6. ~~Documentation of alternative containment strategies for specific dosage forms reviewed in the assessment of risk~~
- 7. 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.
- 8. ~~Assessment of Risk considers: type~~CCRMC's AoR developed 2 Categories of HD ~~(e.g., antineoplastic, non-antineoplastic, reproductive risk only), dosage form, risk of exposure, packaging, manipulation. CCRMC developed 2 Categories of HD handling:~~
  - a. **Category C:**
    - i. NIOSH Table 1 ~~injectable HDs~~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 Oral and Topical HDs that do not require additional manipulation~~
    - ii. NIOSH Table ~~2 HDs~~1 non-antineoplastic drugs – all dosage forms
    - iii. NIOSH Table ~~32 non-antineoplastic~~ HDs – all dosage forms
    - iv. NIOSH Table 2 antineoplastic HDs – oral and topical dosage forms

## B. Responsibilities of Personnel Handling HDs

- 1. ~~Entity designates a person to oversee compliance~~
- 2. ~~Designated person is qualified and trained~~
- 3. ~~Designated person monitors compliance, maintains reports of testing/ sampling~~
- 4. All personnel who handle HDs are responsible for practices and precautions to prevent patient harm, minimize worker exposure, and minimize environmental contamination.
- 5. Only Pharmacy Department personnel specially trained and ~~certified (by passing Procedure for Chemotherapy Aseptic Technique Test Using CSTDs)~~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~~
- ~~iii. Unpacking from shipping containers does not occur in sterile compounding area~~

### ~~2. HD Storage area(s):~~

- ~~i. Signs designating the hazard are displayed at entrance~~
- ~~ii. HD drugs are not stored on the floor~~
- ~~iii. Manner of storage prevents spills and breakage~~
- ~~iv. Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms are stored separately from non-HDs~~
- ~~v. Refrigerated HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH~~
- ~~vi. HDs are stored in externally vented, negative pressure room with at least 12 ACPH~~
- ~~vii. Non-antineoplastic (NIOSH Table 2), reproductive risk only (NIOSH Table 3), and final dosage forms of antineoplastic HDs (NIOSH Table 1) may be stored with other inventory~~

### ~~3. Compounding – Sterile Products~~

- ~~i. Containment primary engineering control (C-PEC) (type: Nuair® compounding aseptic containment isolator (CACI))~~
- ~~ii. C-PEC is externally vented, and C-PEC operates continuously~~
- ~~iii. Containment secondary engineering control (C-SEC) (room where C-PEC placed – ISO 7 buffer room with ISO 7 ante-room)~~

#### ~~1. Buffer room~~

- ~~a. C-SEC externally vented through HEPA filtration~~
- ~~b. Physically separate from other preparation areas~~
- ~~c. Negative pressure relative to surrounding areas (0.01–0.03 in. water)~~
- ~~d. Minimum 30 air changes per hour (ACPH) of HEPA-filtered supply air~~

#### ~~2. Ante-Room~~

- ~~a. Minimum 30 air changes per hour (ACPH) of HEPA-filtered supply air~~
- ~~b. Positive pressure > 0.02 in. water relative to adjacent unclassified areas~~
- ~~c. ISO Class 7 air quality or better~~

3. Sink for handwashing is available at least 1 meter from entrance to the HD buffer room
  4. Eyewash station is available
  5. Water sources and drains must be at least 1 meter away from the C-PEG
4. Compounding – Nonsterile products – Not performed at CCRM
  5. Splitting, Unit-Dosing Nonsterile HDs
    - i. For occasional nonsterile HD manipulation, a C-PEG used for sterile compounding may be used, but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEG
    - ii. The purge time of 10 minutes must be observed for the C-PEG before beginning sterile compounding immediately following nonsterile manipulations.
    - iii. NIOSH Table 1 nonsterile HD manipulations are performed in the negative pressure CACI dedicated for nonsterile HD manipulations
    - iv. NIOSH Table 2 and 3 nonsterile HD manipulations are performed in the positive pressure CACI dedicated for nonsterile HD manipulations
  6. Supplemental Engineering Controls
    - i. Closed system transfer device (CSTD) **should** be used during **compounding**, when dosage form allows
    - ii. CSTD **must** be used when **administering** when the dosage form allows
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. ~~Assesses and documents facility~~Facility & personnel compliance with USP <797> (sterile compounding) with regards to nonviable and viable air sampling, surface sampling, and employee competency gloved fingertip sampling (~~See are assessed and documented (See~~ [Policy for Maintenance of Sterile Compounding Facilities and Equipments](#), [Policy for Compounding Competency Assessment](#)).

## ~~G. Personal Protective Equipment (See~~ [Procedure D. Garbing for Sterile Compounding](#))

1. ~~Chemotherapy gloves~~
  - i. ~~Chemotherapy gloves are powder-free and meet ASTM standard D6978~~
  - ii. ~~Sterile gloves required for sterile compounding~~
  - iii. ~~Double gloves required to be worn for sterile and nonsterile HD compounding and antineoplastic HD administration~~
  - iv. ~~Must be changed when torn, punctured, or contaminated.~~
  - v. ~~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 timeframe at the discretion of the department.~~
1. ~~Contec<sup>®</sup> Critigear<sup>™</sup> Gloves:~~ can be worn up to 240 minutes (4 hours) with no documentation of breakthrough with the following drugs: cisplatin, cyclophosphamide, doxorubicin, etoposide, fluoruracil, methotrexate, paclitaxel:
  - a. ~~Carbimustine (BCNU) permeates in 40 minutes~~
  - b. ~~Thiotepa permeates in 120 minutes.~~
2. ~~Covidien<sup>®</sup> ChemoPlus<sup>™</sup> Sterile 8 mil Gloves:~~ can be worn for up to 240 minutes (4 hours) with no documentation of breakthrough with the

following drugs: cyclophosphamide, cytarabine, doxorubicin, etoposide, fluorouracil, methotrexate, paclitaxel.

a. Carmustine (BCNU) permeates in 1 minute. Use not recommended.

b. Thiotepa permeates in 60 minutes.

## 2. Chemotherapy gowns

i. Gowns shown to resist HD permeation

ii. Disposable gowns:

1. Are made of polyethylene-coated polypropylene or other laminate materials

2. Close in back, are long-sleeved and have closed cuffs that are elastic or knit

3. Does not have seams

iii. Gowns required to be worn when administering injectable antineoplastic HDs.

iv. For all other activities, gowning is determined by entity's assessment of risk, based on risk of exposure and activities performed.

v. Must be changed immediately after a spill or splash.

vi. Gown manufacturer documented breakthrough time determines the frequency of gown change. If unknown, change gowns every 2-3 hours.

1. Contec<sup>®</sup> CritiGear<sup>™</sup> Chemo Gown with BloxTech<sup>™</sup> Fabric: can be worn up to 240 minutes (4 hours) with no documentation of breakthrough with the following drugs cisplatin, cyclophosphamide, doxorubicin, etoposide, fluorouracil, methotrexate, paclitaxel.

a. Carmustine (BCNU) permeates in 16 minutes

b. Thiotepa permeates in 16 minutes

## 3. Head, hair, and shoe covers for HD preparation

i. Second pair of shoe covers must be donned before entering the C-SEG and doffed when exiting the C-SEG

## 4. Eye and face protection

i. Must be worn when risk for spills or splashes (e.g. working at or above eye level, cleaning a spill, etc.)

## 5. Respiratory protection

i. Elastomeric half-mask with multi-gas cartridge and P100 filter should be worn when unpacking HDs not contained in plastic until packaging integrity can be ensured that no breakage or spillage occurred during transport.

ii. Surgical N95 respirator provides adequate respiratory protection and provides barrier to splashes, droplets, and sprays around nose and mouth.

- iii. ~~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:~~
      - 1. ~~Attending to HD spills larger than what can be contained with a spill kit~~
      - 2. ~~Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEG~~
      - 3. ~~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~~
- 7. ~~Required PPE for **Compounding/Manipulation**~~
  - i. ~~**Category C** (NIOSH Table 1 injectable HDs)~~
    - 1. ~~Double glove, chemo gown, double shoe cover, hair/face mask~~
    - 2. ~~Use closed-system transfer device, if compatible~~
  - ii. ~~**Category H**~~
    - 1. ~~NIOSH Table 1 oral/topical HDs that require compounding, splitting, unit-dosing, or further manipulation~~
      - a. ~~Double glove, chemo gown, double shoe cover, hair/face mask~~
    - 2. ~~NIOSH Table 2 and 3 HDs that require compounding, splitting, unit-dosing, or further manipulation~~
      - a. ~~Glove, gown, shoe cover, hair/face mask~~
- 8. ~~Required PPE for **Dispensing/Handling Final Dosage Forms**~~
  - i. ~~Category C: double ASTM D6978 gloves~~
  - ii. ~~Category H: single pair of ASTM D6978 gloves~~

## H. Hazard Communication Program

- 1. Workers who handle HDs are informed of the risks and ~~method~~methods of reducing exposure.
- 2. Written hazard communication program in place (~~see~~ (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 onsite for each hazardous chemical~~
- 5. ~~SDSs~~SDS are available for each hazardous chemical and accessible to personnel in all locations and at all times (<http://hq.msdsonline.com/contracostareghealthsl>)
- 6. ~~Personnel receive initial and updated information and training~~
- 7. Personnel of reproductive capability confirm understanding of risks in writing (~~see Attachment D. Cytotoxic Drug Handling Informed Consent~~) (see [Attachment D. Cytotoxic Drug Handling Informed Consent](#))

## **~~I. Personnel Training~~**

- ~~1. Initial training for HD handling is provided and documented (see [Policy for Compounding Competency Assessment](#), [Procedure for Chemotherapy Aseptic Technique Test Using CSTDs](#), Attachment D: Cytotoxic Drug Handling Informed Consent)~~
- ~~2. Initial HD handling competency is evaluated~~
- ~~3. HD handling competency is validated at least every 12 months~~
- ~~4. Training is provided prior to introduction of new HD, new equipment, or new/significant change in process or SOP.~~
- ~~5. Other competencies may include:~~
  - ~~i. Environmental sampling~~
  - ~~ii. Material handling~~
  - ~~iii. Use of SEG~~

## **~~J. Receiving~~**

- ~~1. SOPs are in place for receiving HDs~~
- ~~2. HDs are segregated from other drugs~~
  - ~~i. Supplier clearly marks outer container~~
  - ~~ii. Single container should contain only HDs~~
  - ~~iii. HDs in marked container should be enclosed in impervious plastic~~
- ~~3. PPE is provided and worn by workers unpacking HDs~~
  - ~~i. Elastomeric half-mask with multi-gas cartridge and P100 filter should be worn when unpacking HDs not contained in plastic until packaging integrity can be ensured that no breakage or spillage occurred during transport.~~
- ~~4. HDs are delivered to HD storage area immediately after unpacking~~
  - ~~i. These packages are decontaminated and disinfected prior to storage in the negative pressure buffer room~~
  - ~~ii. When removed from packaging, vials will be wiped down to remove any exterior contamination that may have occurred during the manufacturing process~~
- ~~5. SOPs address handling damaged or broken HD containers~~
- ~~6. Spill kit available in receiving~~

## **~~K. Labeling, Packaging, Transport, and Disposal~~**

- ~~1. HDs are always clearly labeled during transport~~
- ~~2. HDs are packaged to maintain integrity, stability, and sterility (if needed) during transport~~
- ~~3. HDs are transported in a manner to minimize breakage or leakage~~

- i. All doses of antineoplastic agents will be sealed in a zip lock bag for transport
  - ii. If being transported by anyone other than a pharmacist or nurse and other than directly to the infusion clinic, all antineoplastic doses are to be placed in a red impervious plastic transport box
  - iii. If the box is transported by anyone other than a pharmacy staff member, the box will be secured with a pull-tight seal
  - iv. The outside of the container is labeled with "Chemotherapy—Dispose of Properly"
- 4. Policies address HD waste handling based on local, state, and federal regulations
  - i. All antineoplastic waste shall be labeled with the words "Chemotherapy—Dispose of Properly"
  - ii. All material ancillary to compounding shall be disposed of as trace chemotherapy waste or bulk chemotherapy waste in the appropriate container(s).

## **~~L. Dispensing Final Dosage Forms~~**

- 1. Dosage forms not requiring manipulation may not need all containment requirements (see [CCRMC Assessment of Risk for Hazardous Drugs](#))
- 2. Dedicated equipment is used for counting and repackaging HDs and should be decontaminated after each use
- 3. Automated counting or packaging machines are not used for solid HD forms
- 4. IV tubing attached and primed prior to adding HD's to infusion container (Using a CSTD)
- 5. Designated decontamination agent used to wipe final CSP surface prior to transfer out of C-PEG
- 6. Final containers have luer lock or CSTD systems in place
- 7. Final CSP placed in zip-locked bag clearly marked

## **~~M. Compounding~~**

- 1. Compounding is performed in proper engineering controls
- 2. Plastic-backed preparation mats are used on work surface of C-PEG
- 3. Equipment used for compounding HDs is dedicated for use with HDs
- 4. All chemotherapy orders, doses, and calculations are independently double-checked by two pharmacists.
- 5. Recordkeeping follows [Policy for Compounding of Medications](#)

## **~~N. Deactivating, Decontamination, Cleaning and Disinfecting~~**

- 1. Written procedures exist for decontamination, deactivation, cleaning and for sterile compounding areas, disinfection (see [Policy for Maintenance of Sterile Compounding](#))

### Facilities and Equipments)

2. Policies specify agents, dilutions, frequency, and documentation requirements
  - i. Decontamination agent is EPA registered oxidizing agent (Peridox RTU® and HD Clean®)
  - ii. Cleaning agent contains a surfactant (Peridox RTU®)
  - iii. Sporicidal agent is used weekly (Peridox RTU®)
  - iv. Sterile IPA 70% used as disinfectant
  - v. Contact time documented for all agents used
  - vi. Manufacturer instructions followed for use of all agents
  - vii. MSDS available for all cleaning agents
  - viii. Documentation of non-RTU solutions available
3. Cleaning performed from cleanest to dirtiest
4. Monitoring program exists for compliance with P&P
5. Appropriate cleaning supplies used (mops, buckets, etc.)
6. Cleaning equipment stored appropriately
7. Personnel performing activities are trained and wear appropriate PPE
  - i. Eye/face protection worn when cleaning and disinfection performed
  - ii. Respiratory protection utilized as appropriate
8. Only authorized pharmacy personnel clean C-PEG

## **O. Medical Surveillance**

1. Entity has process to identify workers who are potentially exposed to HDs
2. Medical surveillance services are available onsite or by contract
3. Entity provides periodic surveillance (health history, exposure history, physical assessment, and laboratory testing if appropriate)
4. Entity monitors surveillance data
5. Entity has plan for post-exposure follow up

## **P. Spill Control**

1. In the event of direct contact with anti-neoplastics, personnel must know emergency procedures. This includes the location of spill kits and the eyewash station.
2. Spill training provided annually
3. Spill kits available in all areas where HDs are handled (available through Medline carts and additional kit made by pharmacy for internal use)
  - i. Spill kits available on Medline carts for patients released on CADD Pump from the

infusion-center

4. ~~Spill reporting process in place via SERS~~

5. ~~Handling Exposure~~

- ~~i. Immediately wash/flush the affected skin area with soap and water.~~
- ~~ii. A physician should examine the affected area as soon as possible.~~
- ~~iii. For eye exposure, immediately flood the affected eye at the eyewash station. Medical attention must be obtained immediately.~~
- ~~iv. Refer to the MSDS for treatment guidelines.~~
- ~~v. Notify the supervisor immediately.~~
- ~~vi. File an AK-30 Employee Injury Report and submit to Pharmacy Administration~~

6. ~~Hazardous Chemical Spill~~

- ~~i. In the event a hazardous chemical is spilled within the Pharmacy, inform other staff members in the immediate area and evacuate all persons not involved with clean up and signs should be posted denying entry~~
- ~~ii. Inform Pharmacy Administration~~
- ~~iii. Spills **less than 5 mL** are to be managed pharmacy staff~~
- ~~iv. **In the event of a disaster or extreme spill that represents an immediate life-threatening danger, rescue persons in immediate danger, evacuate the area and follow Policy for Hazardous Materials Chemical Spill/Leak (Code Orange).**~~
  - ~~1. Follow Code Orange procedures~~
  - ~~2. Dial "222" and specify that the emergency is a chemotherapy spill, identifying the chemical if possible.~~
  - ~~3. The supervisor will determine if evacuation of the immediate area is necessary to prevent over-exposure or injury.~~
  - ~~4. If necessary, contact the hospital engineer to prevent the spread of fumes/gases through the air supply of the hospital.~~
- ~~v. For spills **larger than 5 ml**, **immediately contact the County Hazardous Materials office for clean-up** by calling the 24-hour phone number **925-655-3232**. Notify Medical Center Supervisor via pager at 925-346-4243. Refer to Policy for Hazardous Materials Chemical Spill/Leak (Code Orange).~~
- ~~vi. For spills **less than 5 ml**, an appropriately garbed and trained individual will utilize a Chemotherapy Spill Kit to contain and clean up the spill. Staff involved must wear appropriate protective garments, as indicated in the MSDS. Notify the supervisor immediately.~~
- ~~vii. Follow procedures outlined in the MSDS and use the Chemotherapy Spill Kit to contain and clean up the spill.~~
  - ~~1. Obtain the Spill Kit and notify others that a spill has occurred and place the spill sign near the area.~~

- ~~2. Don dual chamber respirator.~~
- ~~3. Don protective equipment: double gloves, gown, mask, eye protection and shoe covers during clean up. They are available in the spill kit.~~
- ~~4. Follow instructions in the spill kit to clean and decontaminate the spill area. Collect and seal contaminated clean-up materials in chemo bag provided in the spill kit.~~
- ~~5. Refer to the MSDS for special precautions or considerations in clean up.~~
- ~~6. Remove personal protective equipment and place in second chemo bag.~~
- ~~7. Seal the second chemo bag and dispose of both bags as bulk chemo waste along with second pair of inner gloves in the appropriate waste receptacle. Take the receptacle directly to the hazardous waste storage area.~~
- ~~8. The contaminated area must be decontaminated and cleaned at least three (3) times with new rinse water and deactivating/decontaminating/cleaning agent each time.~~
- ~~9. Once initial cleaning has been done, Environmental Services may take over.~~

~~viii. File an online Safety & Event Report (SERS) and/or Employee Injury Form AK-30.~~

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 Hazardous Materials Chemical Spill/Leak \(Code Orange\)](#)

[Policy for Compounding of Medications](#)

[Procedure D. Garbing for Sterile Compounding](#)

[Policy for Maintenance of Sterile Compounding Facilities and Equipments](#)

[Policy for Compounding Competency Assessment](#)

[Procedure for Chemotherapy Aseptic Technique Test Using CSTDs](#)

[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/NIOSH PUB2023130>](#)
- D. ~~NIOSH "Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Healthcare Settings", September 2004~~[NIOSH "List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings," December 2024](#)
- E. ~~NIOSH "List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings," September 2016~~
- F. OSHA Standards: Hazard Communication Standard (29 CFR 1910.1200) Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450)
- G. OSHA ~~technical manual guidelines~~[Technical Manual Guidelines](#) "Controlling Occupational Exposure to Hazardous Drugs"
- H. USP General Chapter <797>. Pharmaceutical Compounding – Sterile Preparations
- I. USP General Chapter <800>. Hazardous Drugs – Handling in Healthcare Settings
- J. Title 16 California Code of Regulations Articles 4.5, 7 and 7.5 § 1735, 1751

# APPROVALS:

~~Patient Care Policy and Evaluation Committee: 9/2024~~

~~Medical Executive Committee:~~

~~Joint Conference Committee:~~

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## Attachments

- [!\[\]\(f94dcbc2427c712b5608a6686d260d1d\_img.jpg\) A: Hazardous Drugs List](#)
- [!\[\]\(306ee6c42c0047d0cf2802c516a3cd96\_img.jpg\) B: <USP 800> Assessment of Risk Template](#)
- [!\[\]\(a698656048d0cf962f87db85c60fea12\_img.jpg\) D: Cytotoxic Drug Handling Informed Consent](#)
- [!\[\]\(2f90fc4d7e905ed540e74e5fd59a0f1f\_img.jpg\) E: Chemo/HD Spill Cleanup Procedure](#)
- [!\[\]\(00f863b3bfcc719e416821696e5bafa4\_img.jpg\) F. Equashield® Procedure Manual for Using Equashield Closed System Drug Transfer Device](#)

# Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	09/2025
	Shideh Ataii: Director Of Pharmacy Svcs [TF]	09/2025

## Standards

No standards are associated with this document



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Next Review	3 years after approval

Owner	Shideh Atai: Director Of Pharmacy Svcs
Area	Pharmacy

## Policy for Pharmacy Security

### POLICY STATEMENT:

Security of the Pharmacy shall be maintained in accordance with federal, State and local laws. All personnel on duty shall protect Pharmacy assets and records and guard against the theft or diversion of drugs it contains. In addition to ensure that all medications are stored in a secure manner, consistent with all applicable federal and state laws.

### GUIDELINES:

Pharmacist is responsible for maintaining the security of the pharmacy.

### Locking of Pharmacy Areas:

- A. All areas occupied by the Pharmacy shall be capable of being locked by key or combination, to prevent access by unauthorized personnel by force.
- B. Keys may only be in the possession of:
  - 1. Licensed pharmacists employed by CCRMC & HC
- C. Locks in the Pharmacy must be rekeyed:
  - 1. When keys are lost
  - 2. In case of theft
  - 3. With changes in personnel, if determined to be necessary

## Restricted Access to the Pharmacy (Traffic Control):

- A. No person other than a pharmacist, pharmacy technician, intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in the pharmacy wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged.
- B. Medical staff, Nursing Services, administrative, Environmental Services and other facility personnel are authorized admission to the pharmacy in relation to their duties and only while **under the supervision of a Pharmacist**.
- C. The Pharmacy shall limit nonessential traffic (by medical service representatives, visitors, and others).
- D. The Nursing Supervisor may enter the Pharmacy Night Locker **ONLY**, during the hours when no Pharmacist is present only if patient need exists and the medication cannot be obtained elsewhere in the hospital. If the needed medication is only stocked in the Pharmacy and administration to the patient cannot wait until Pharmacy opens, the on-call Pharmacist must be contacted to come in to dispense the medication.

## Pharmacy Lock-Up Procedures:

- A. Pharmacy lock-up procedures shall ensure that drugs are secure, and that the Pharmacy is free of hazardous conditions. Lock-up procedures shall include, but shall not be limited to, ensuring that:
  - 1. Controlled drugs are secure
  - 2. Non-essential lights and electrical equipment are turned off
  - 3. All doors are locked
  - 4. The alarm is set
- B. The Pharmacy door shall be locked at all times.
- C. The Pharmacist will be the only person with a key to the working controlled substance drawers.
- D. Pharmacy Administration is in sole possession of the key to circumvent the security of the narcotic vault in the event of a disaster or major system failure in order to provide adequate patient care.

## Alarm System:

- A. The alarm system for all Pharmacy locations is monitored by Denalact Alarm Company. A list of contact personnel will be provided to them by the Director of Pharmacy and updated as necessary.
- B. In the event of an alarm, they will contact the Pharmacist-in-Charge, or Pharmacist designee, from the list. This individual will rectify the situation as appropriate and as necessary.
- C. If that person cannot be reached, they will then contact the Director or the Assistant Director of the Pharmacy for resolution of the problem.

## Theft or Break-Ins:

- A. Any theft, break-in or unexplained loss shall be reported to the Pharmacy Director immediately.
- B. The Pharmacy Director shall ascertain the loss and file all necessary reports, in accordance with hospital policy and applicable federal and state laws.

## Reports:

- A. The Pharmacy Director shall report controlled substance losses, as appropriate, according to Pharmacy [Policy for Reporting Diversion of Controlled Substances](#).

## RELATED LINKS:

Pharmacy [Policy for Reporting Diversion of Controlled Substances](#)

## REFERENCES:

- A. TJC Standard EC.02.01.01
- B. CMS CoP § 482.13(c), 482.23(c), 482.25(a)(b), 482.41(a)(b)(c)
- C. California Pharmacy Law Business and Professions Code Sections 4116, 4117, 4135

## APPROVALS:

Patient Care Policy and Evaluation Committee: 12/2022

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]	09/2025
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	07/2025
	Shideh Ataii: Director Of Pharmacy Svcs	06/2025

## Standards

No standards are associated with this document



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Next Review	2 years after approval

Owner	Michael De Peralta: Respiratory Care Services Mgr
Area	Respiratory

## Policy For Neonatal High Flow Nasal Cannula

### POLICY STATEMENT:

The Respiratory Care Practitioner will deliver high flow nasal cannula as ordered using hospital-approved equipment. High-flow nasal cannula oxygen therapy delivers a heated and humidified blend of air and oxygen at flow rates surpassing a patient's inspiratory demand. High-flow nasal cannula oxygen therapy is administered to critically ill neonates with respiratory failure due to its comfort, simplicity in setup, and low incidence of nasal trauma. High flow nasal cannula may be initiated in the delivery room, [NICU level II nursery](#), or emergency room.

### RELATED LINKS:

Procedure for Neonatal High Flow Nasal Cannula

### REFERENCES:

- A. *GUIDELINE FOR THE USE OF HIGH FLOW NASAL CANNULA OXYGEN THERAPY (OPTIFLOW OR AIRVO) IN CHILDREN WITH BRONCHIOLITIS OR AN ACUTE RESPIRATORY ILLNESS*. (n.d.). <https://apps.worcsacute.nhs.uk/KeyDocumentPortal/Home/DownloadFile/1726>
- B. Huang, Y., Zhao, J., Hua, X., Luo, K., Shi, Y., Lin, Z., Tang, J., Feng, Z., Mu, D., & Evidence-Based Medicine Group, Neonatologist Society, Chinese Medical Doctor Association (2023). Guidelines for high-flow nasal cannula oxygen therapy in neonates (2022). *Journal of evidence-based medicine*, 16(3), 394–413. <https://doi.org/10.1111/jebm.12546>
- C. Contra Costa County Health Services Nursing Department Policy for Nursing Care of the Infant Receiving Oxygen Therapy.

## Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	09/2025
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	07/2025
	Michael De Peralta: Respiratory Care Services Mgr	06/2025

## Standards

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Owner	Michael De Peralta: Respiratory Care Services Mgr
Area	Respiratory

## Policy for Artificial Airway Management

### POLICY STATEMENT

The management of artificial airways—including endotracheal and tracheostomy tubes—is essential for maintaining airway patency, minimizing tracheal trauma, and preventing aspiration of secretions in intubated patients. Artificial airway care includes, but is not limited to:

1. Securing the airway device to prevent dislodgement or migration
2. Effective removal of secretions
3. Adequate humidification of inspired gases
4. Appropriate and timely suctioning
5. Continuous monitoring for airway obstruction
6. Routine cuff pressure management to reduce aspiration risk and prevent mucosal injury

Healthcare providers must also recognize and respond to potential hazards and complications associated with artificial airways. These include, but are not limited to:

1. **Respiratory:** Hypoxia/Hypoxemia, Respiratory Arrest, Pulmonary Atelectasis, Bronchospasm/Bronchoconstriction
2. **Trauma:** Tissue Trauma to the Trachea and/or Bronchial Mucosa, Pulmonary Hemorrhage/Bleeding
3. **Infection:** Local or systemic infection related to airway or suctioning practices
4. **Cardiovascular:** Cardiac Dysrhythmia/Arrest, Hypertension/Hypotension, Elevated Intracranial Pressure
5. **Mechanical:** Interruption of Mechanical Ventilation

# GUIDELINES:

To ensure consistent and safe management of artificial airways, the following guidelines shall be observed:

1. This policy encompasses both endotracheal and tracheostomy tube care.
2. All staff must be trained in airway management protocols and emergency response procedures.
3. Airway care techniques must adhere to current evidence-based clinical standards and institutional practices.
4. Monitoring and documentation of airway status, cuff pressures, and secretion management must be performed routinely.
5. Staff must remain vigilant for early signs of complications and escalating care as necessary.

# RELATED LINKS:

Procedure for Artificial Airway Management

# REFERENCES:

- A. American Association for Respiratory Care (AARC). (2022). *Clinical Practice Guidelines: Artificial Airway Suctioning*. Retrieved from <https://www.aarc.org/wp-content/uploads/2022/10/cpg-artificial-airway-suctioning.pdf>.
- B. Dougherty, J. M., & Paxton, J. H. (2024). Recent technological advances in airway management. *Current Emergency and Hospital Medicine Reports*, 12, 32–37. <https://doi.org/10.1007/s40138-024-00285->
- C. Johnson, K. L. (Ed.). (2024). *AACN procedure manual for progressive and critical care* (8th ed.). Elsevier.
- D. Zhu, G., Wang, X., Cao, X., Yang, C., Wang, B., Ang, Y., & Duan, M. (2024). The effect of different endotracheal tube cuff pressure monitoring systems on postoperative sore throat in patients undergoing tracheal intubation: A randomized clinical trial. *BMC Anesthesiology*, 24, Article 115. <https://doi.org/10.1186/s12871-024-02499-5>

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [SP]	09/2025

Medical Director	Initha Elangovan: Exempt Med Stf Physician	08/2025
	Michael De Peralta: Respiratory Care Services Mgr	08/2025

## Standards

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Owner	Michael De Peralta: Respiratory Care Services Mgr
Area	Respiratory

## Policy for Neonatal Mechanical Ventilation Management

### ~~POLICY STATEMENT:~~

### POLICY STATEMENT:

Mechanical ventilation is an essential life-saving measure for critically ill newborns, both preterm and full-term. Intubation and invasive mechanical ventilation are indicated in cases of severe respiratory failure, which can be identified by markedly impaired oxygenation and alveolar ventilation, decreased respiratory effort, and, in some cases, circulatory failure. Patients requiring mechanical ventilation will receive care as outlined:

- A. Mechanical ventilators should only be set-up and placed on patients by Respiratory Care Practitioner (RCP).
- B. Mechanical ventilator adjustments should only be performed by an RCP.
- C. An RCP may initiate pre-approved ventilator settings for initial ventilation. However, the RCP must secure an official physician's order at the earliest opportunity.
- D. Proper documentation of all ventilator assessments and parameter adjustments must be performed at the time of assessment or time of change and by the individual initiating the parameter change.
- E. Mechanical ventilator must be cleaned and setup when ventilator is discontinued.

## **GUIDELINES:**

### **GUIDELINES:**

To provide guidelines and standards for the initiation, cleaning, monitoring and assessment, and documentation of mechanical ventilation.

## **RELATED LINKS:**

### **RELATED LINKS:**

Procedure for Neonatal Mechanical Ventilation Management

## **REFERENCES:**

### **REFERENCES:**

- A. Chakkarapani, A. A., Adappa, R., Mohammad Ali, S. K., Gupta, S., Soni, N. B., Chicoine, L., & Hummler, H. D. (2022). "Current concepts in assisted mechanical ventilation in the neonate" - Part 2: Understanding various modes of mechanical ventilation and recommendations for individualized disease-based approach in neonates. *International journal of pediatrics & adolescent medicine*, 7(4), 201–208. <https://doi.org/10.1016/j.ijpam.2020.11.002>
- B. Elsevier – *Clinical Skills Mechanical Ventilation: Neonate (Respiratory Therapy)*. (2025). Elsevier.health. <https://elsevier.health/en-US/preview/mechanical-vent-neonate><https://elsevier.health/en-US/preview/mechanical-vent-neonate>
- C. American Association for Respiratory Care. (n.d.). AARC - Neonatal ALI Guideline. In *American Association for Respiratory Care* (pp. 1–5). [https://www.aarc.org/wp-content/uploads/2020/03/neonatal\\_ventilation\\_000.pdf](https://www.aarc.org/wp-content/uploads/2020/03/neonatal_ventilation_000.pdf) **(MD Reviewed on 07/31/2025)**

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Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [SP]	09/2025
Medical Director	Initha Elangovan: Exempt Med Stf Physician	08/2025
	Michael De Peralta: Respiratory Care Services Mgr	07/2025

## Standards

No standards are associated with this document



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Owner Michael De Peralta:  
Respiratory Care Services Mgr  
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## Policy for Continuous Nebulizer Therapy

### POLICY STATEMENT:

The Respiratory Care Practitioner will initiate continuous nebulizer therapy as ordered and monitor the patient until the therapy ends. To provide standardization guidelines for the administration of continuous nebulization therapy (CNT).

### ~~PURPOSE STATEMENT:~~

~~To provide standardization guidelines for the administration of continuous nebulization therapy (CNT).~~

### RELATED LINKS:

Procedure for Continuous Nebulizer Therapy

### REFERENCES:

- A. Fleisher, G., & Ludwig, S. (2010). Textbook of Pediatric Emergency Medicine (6th ed.). Philadelphia, Pennsylvania: Lippincott, Williams, & Wilkins.
- B. Peters, S. (2007, January). Continuous bronchodilator therapy. Chest, 131(1), 286-9. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/17218588>

### APPROVALS:

Approved By PCP&E

Approved by Med Executive Committee

## Approval Signatures

Step Description	Approver	Date
Joint Conference Committee	John Gioia: Board of Supervisor	Pending
Medical Executive Committee	Sarah E. Mcneil [SP]	09/2025
Patient Care Policy and Evaluation Committee	Vijay K. Bhandari [SP]	07/2025
	Michael De Peralta: Respiratory Care Services Mgr	06/2025

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Owner Michael De Peralta:  
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## Policy for Airway Clearance Therapy

### ~~POLICY STATEMENT:~~

~~Normal airway clearance requires a patent airway, a functional mucociliary escalator, and an effective cough. Any abnormality that alters airway patency, mucociliary function, strength of the inspiratory or expiratory muscles, thickness of secretions, or effectiveness of the cough reflex can impair airway clearance and caused retention of secretions. The primary goal of airway clearance therapy is to help mobilize and remove retained secretions, with the ultimate goal to improve gas exchange, promote alveolar expansion, and reduce the work of breathing.~~

### ~~GUIDELINES:~~

~~To provide safe guidelines for the clearance/removal of secretions from the lungs of patients with excessive inflammation due to ineffective mucociliary clearance and bacterial infection.~~

### ~~RELATED LINKS:~~

### POLICY STATEMENT:

Effective airway clearance depends on a patent airway, an intact mucociliary escalator, and an efficient cough mechanism. Disruption in any component—such as airway obstruction, impaired ciliary motion, weakened respiratory musculature, altered secretion viscosity, or an ineffective cough reflex—can lead to mucus retention and compromise pulmonary function.

The primary objective of airway clearance therapy is to mobilize and eliminate retained secretions, thereby improving ventilation–perfusion matching, enhancing gas exchange, promoting alveolar

expansion, and reducing the work of breathing.

This policy outlines standardized interventions to support airway clearance for patients with acute and chronic conditions associated with mucus retention and impaired secretion

## **GUIDELINES:**

These guidelines establish safe and evidence-based practices for facilitating airway clearance in patients experiencing secretion retention due to:

- : Ineffective mucociliary transport mechanisms
- : Bacterial colonization or active infection
- : Airway inflammation with excess mucus production

Interventions must be selected based on:

- : Individual patient assessment
- : Severity of disease process
- : Clinical goals (e.g., secretion clearance, gas exchange improvement)
- : Contraindications outlined in section III

Care should be guided by current recommendations from the American Association for Respiratory Care (AARC) and manufacturer Instructions for Use (IFUs) for all airway clearance devices.

## **RELATED LINKS:**

Procedure for Airway Clearance Therapy

## **REFERENCES:**

- ~~A. Lester, M.K., Flume, P.A., Airway-clearance-therapy guidelines and implementation, Respir Care. 2009 Jun; 54(6):733-50.~~
- ~~B. Hess DR. The evidence for secretin clearance techniques, Respir Care 2001; 46(11):1276 – 1293~~
- ~~C. Egan, Donald F., Fundamentals of Respiratory Care, Mosby Publishing, 1999~~

Procedure for Cough Assist System

Procedure for Oscillation and Expansion Therapy

Procedure for High-Frequency Chest Wall Oscillation

## **REFERENCES:**

- A. American Association for Respiratory Care. (2013). Effectiveness of nonpharmacologic airway clearance therapies in hospitalized patients. Respiratory Care, 58(10), 1669–1678. <https://www.aarc.org>

- B. [Baxter International Inc. \(2022\). \*Volara System Instructions for Use\*. https://www.baxter.com](https://www.baxter.com)
- Hillrom. (2021). [Synclara Cough System Instructions for Use. https://www.hillrom.com](https://www.hillrom.com)
- C. [Trudell Medical International. \(2021\). \*Aerobika® OPEP Device Instructions for Use\*. https://www.trudellmed.com](https://www.trudellmed.com)
- D. [Belli, S., Prince, I., Savio, G., Paracchini, E., Cattaneo, D., Bianchi, M., Masocco, F., Bellanti, M. T., & Balbi, B. \(2021\). Airway clearance techniques: The right choice for the right patient. \*Frontiers in Medicine\*, 8, Article 544826. https://doi.org/10.3389/fmed.2021.544826](https://doi.org/10.3389/fmed.2021.544826)
- E. [Centers for Disease Control and Prevention. \(2022\). \*Guidelines for disinfection and sterilization in healthcare facilities\*. https://www.cdc.gov/infectioncontrol/guidelines](https://www.cdc.gov/infectioncontrol/guidelines)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Sarah E. Mcneil	Pending
Patient Care Policy & Evaluation Committee	Vijay K. Bhandari [SP]	09/2025
Medical Director	Initha Elangovan: Exempt Med Stf Physician	08/2025
	Michael De Peralta: Respiratory Care Services Mgr	08/2025

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