VENTURA COUNTY MEDICAL CENTER

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CONFIDENTIAL

Medical Executive Committee Document Approvals

July 2024

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VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*12/1/1986*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*6/25/2024*
Next Review:	*3 years after approval*
Owner:	*Todd Flosi, MD: Associate Chief Medical Officer, VCMC & SPH*
Policy Area:	*Administrative - Patient Care*
References:	

100.059 Medications for Opioid Use Disorder in Adults

POLICY:

~~The prescribing of methadone for opioid detoxification is restricted and must be within state licensure and federal regulations. The policy recognizes that VCMC/SPH does not maintain a license to conduct methadone detoxification. However, patients with medical/psychiatric conditions and narcotic addiction may require changes to their methadone dosage during their hospital stay.~~

~~Methadone may also be initiated for relieving acute withdrawal symptoms from opiate use disorder while arranging for the patient's referral for treatment for a maximum of 72 hours. If the patient has not been on methadone and is admitted for another medical/psychiatric reason but is interested in medication assisted treatment (MAT), any provider may initiate methadone therapy under the 72-hour rule.~~

Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) prescribes and administers medications for opioid use disorder (MOUD) such as methadone, buprenorphine, buprenorphine-naloxone, and naltrexone in compliance with federal and state regulations.

ABBREVIATIONS/DEFINITIONS:

A. ADM: Addiction Medicine

B. Buprenorphine* in this policy refers to FDA approved buprenorphine products (i.e., buprenorphine and buprenorphine-naloxone) for opioid use disorder.

C. CFR: Code of Federal Regulations

D. DEA: Drug Enforcement Administration

E. FDA: Federal Drug Administration

F. Federal Register is the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents.

G. LP: Licensed Practitioner is an individual who is licensed and qualified to direct or provide care, treatment, and services in accordance with state law and regulation, applicable federal land and regulation, and organizational policy(TJC 2023).

H. MAT: Medication-Assisted Treatment is the use of medications in combination with counseling and behavioral therapies, which is effective in the treatment of opioid use disorders and can help some

people to sustain recovery.

I. MOUD: Medications for Opioid Use Disorder

J. OTP: Opioid treatment program is an accredited treatment program with SAMHSA certification and Drug Enforcement Administration registration to administer and dispense opioid agonist medications that are approved by the FDA to treat Opioid Use Disorder. To locate an OTP, click on the following link: Find Treatment

K. OUD: Opioid Use Disorder

L. SAMHSA: Substance Abuse and Mental Health Service Administration is the agency within the U.S. Department of Health and Human Services that leads public health efforts to advance the behavioral health of the nation.

M. SOTA: State Opioid Treatment Authority. For more information, click on the following link: Role of SOTA

BACKGROUND:

There are three medications that are FDA approved for the treatment of OUD as part of MAT.

A. Methadone is a long, activating, schedule II, opioid agonist that reduces opioid cravings and withdrawal and blunts/blocks the effects of opioids. Methadone is also FDA approved for pain management.

B. Buprenorphine* is a schedule III opioid partial agonist that helps reduce opioid cravings and withdrawal. Buprenorphine has increased safety in cases of overdose and there is a lower potential for misuse.

C. Naltrexone is an opioid antagonist that blocks the effect of opioids and must be used after the patient has completed withdrawal management (formerly known as detoxification).

For many years, access to Medications for Opioid Use Disorder (MOUD) has been restricted; however, efforts to expand access to MOUD has been changing rapidly during COVID and the rise of Telehealth.

PROCEDURE:

A. Methadone may be administered to ~~hospitalized~~ patients ~~only~~in the emergency department (ED) and hospital under the following three conditions:

1. Methadone Continuation of ~~Outpatient Maintenance~~Medication Assisted Therapy ~~- The patient is enrolled in an opioid treatment program~~ (~~OTP~~MAT) ~~such as a methadone clinic and methadone is prescribed to continue MAT.~~

   a. The patient is enrolled in an opioid treatment program (OTP) such as a methadone clinic, and methadone is prescribed to continue MAT.

   b. ~~Provider~~LP shall verify that the patient is enrolled in a program or clinic.

   c. ~~Provider~~LP shall document in the medical record the dosage regimen, the name and telephone number of the program or clinic where the patient is enrolled, and the name of the employee of the clinic or program providing the information.

   d. ~~Provider~~LP shall not prescribe methadone if the provider is unable to verify enrollment in an OTP or verify the actual dose regimen.

      i. Alternative opiates may be prescribed and administered to prevent withdrawal

      ii. Consultation with an Addiction ~~Specialist~~Medicine (ADM) Physician may be of assistance.

   e. If the patient's condition requires a change in the dosage regimen, approval from an Attending

Physician is required.

f. Pharmacist shall confirm that the provider has both contacted the OTP and verified the methadone maintenance dose before the order can be verified for inpatient administration.

g. Consultation is recommended at discharge with the OTP such as the outpatient methadone maintenance program or clinic regarding the treatment plan to assure appropriate post-hospital care.

2. Methadone Initiation for Opiate Use Disorder ~~- If the patient is not currently on methadone but is admitted for a primary medical/psychiatric diagnosis other than opiate use disorder, the provider may offer methadone MAT or detoxification for the management of opiate use disorder.~~

a. If the patient is not currently on methadone but is admitted with symptoms of opioid withdrawal, the LP may offer methadone MAT or Withdrawal Management.

b. The ~~provider~~LP shall obtain a urine toxicology~~, ECG~~ and Patient Drug Monitoring Program CURES report prior to initiation of methadone therapy. An ECG should be considered.

c. ~~Within 72 hours, an~~An Addiction ~~Specialty~~Medicine (ADM) consultation ~~should~~may be obtained.

d. The ~~provider shall not discharge the patient with methadone for opiate use disorder and~~LP needs to ensure adequate follow up at a local ~~narcotic~~opioid treatment program or clinic.

e. Pharmacist shall confirm that the provider is ordering methadone MAT for opiate use disorder before verifying the order. ~~Once confirmed, the pharmacist shall enter a hard stop of 72 hours from the time of the first dose and document this action in a clinical intervention.~~

~~Compliance with the 72 hour rule shall be monitored to ensure the following:~~

~~i. Not more than one day's medication may be administered or given to a patient at one time.~~

~~ii. This treatment does not exceed 72 hours and is not renewed nor extended.~~

3. Methadone for Pain Management ~~- If the patient is on methadone for pain management and is admitted, that dose will be titrated according to pain control parameters.~~

a. ~~Patients treated in the Emergency Department who are enrolled in a methadone maintenance program with verification and require methadone, prescribe methadone as medically necessary for pain management and/or maintenance prescription.~~Methadone for pain management may be continued and/or initiated based on pain.

b. Opiate withdrawal can be prevented or managed by pharmacological interventions other than methadone.

c. Pharmacist shall confirm that the provider is ordering methadone for pain management ~~before verifying~~and that an Attending or ADM has approved the order.

4. Inpatient Pharmacy will not dispense methadone for outpatient use.

B. Buprenorphine* may be administered to patients in the ED and hospital under the following conditions

1. Buprenorphine* continuation of MAT.

a. Admitting LP shall verify and document that the patient is using buprenorphine* by performing a California Department of Justice Patient Data Monitoring Program (PDMP) report or by confirming with patient.

2. Buprenorphine* Induction

a. Buprenorphine* may be initiated for relieving acute withdrawal symptoms from opiate use

disorder.

b. Admitting LP should follow standard induction practice for buprenorphine*. This includes using a Clinical Opiate Withdrawal Score (COWS).

3. Long acting injectable (LAI) buprenorphine (e.g., Sublocade) shall only be prescribed by ADM Attending LPs and ADM Fellows. LAI buprenorphine requires REMS (Risk Evaluation and Mitigation Strategy) Program enrollment and compliance.

4. Concurrent use of buprenorphine* with benzodiazepines, barbiturates, and sedatives can cause respiratory depression and should be used with caution.

5. The Admitting LP shall obtain urine toxicology to evaluate exposure to other substances or opiates. Buprenorphine* will NOT cause a positive result for generic opiate screen in toxicology.

6. The Admitting LP should ensure adequate follow-up at discharge

a. The Admitting LP should ensure a prescription for a buprenorphine* is written as indicated.

b. The Admitting LP should ensure the patient discharges with training on the use of and a prescription for naloxone.

C. Naltrexone may be administered to patients in ED and the hospital.

1. LP must verify that the patient has completed Withdrawal Management prior to initiating therapy to avoid precipitated withdrawal.

References

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All revision dates: 6/25/2024, 5/2/2019, 11/1/2015, 8/1/2015, 4/1/2012, 5/1/2006, 6/1/2000

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medicine Committee	Tracy Chapman: Director, HCA Medical Staff Administration	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	5/24/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	5/7/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	5/7/2024
Policy Owner	Todd Flosi, MD: Associate Chief Medical Officer, VCMC & SPH	5/7/2024

VENTURA COUNTY
HEALTH CARE AGENCY

Origination:	*7/1/2004*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*6/25/2024*
Next Review:	*3 years after approval*
Owner:	*Gwendolyn Vontoure: Director Perioperative Services*
Policy Area:	*Administrative - Patient Care*
References:	

100.062 Universal Protocol for Preventing Wrong Site, Wrong Person, Wrong Procedure Incidents

POLICY:

To provide steps to assist in minimizing avoidable risks during invasive or surgical procedures. The expected outcome is the patient's procedure is performed on the correct site, side and level.

It is the policy of Ventura County Medical Center/Santa Paula Hospital that the following steps be completed before every invasive or surgical procedure, unless noted on the exceptions list. This policy shall be followed for all invasive or surgical procedures in all patient care departments.

PROCEDURE:

SURGERY/OPERATING ROOM:

A. The correct procedure ~~and~~ site~~/side~~ and laterality will be verified by the following means:
   1. Verbal identification by the patient and/or family
   2. Surgical consent/informed consent
   3. History and physical
   4. Physician's orders
   5. Surgery schedule

B. The above documents along with patient/family identification must indicate the same type and site~~/side of surgery~~ laterality. If any of the above documents disagree or have a discrepancy regarding the patient, procedure or site, the discrepancy must be resolved prior to the procedure being carried out.

C. The preoperative ~~registered nurse~~Registered Nurse (RN) will identify the patient and verify the surgery and site~~/side~~ laterality.

D. The ~~holding area~~Preoperative RN and the circulating RN will ensure all preoperative required documentation is located in the patient's chart.

E. Preoperative Verification Process:

   Verification of the correct person, procedure, and site should occur (as applicable)

   1. At the time the surgery/procedure is scheduled.

2. At the time of admission or entry into the facility.
3. Anytime the responsibility for care of the patient is transferred to another caregiver.
4. With the patient involved, awake and aware, if possible.
5. Before the patient leaves the preoperative area or enters the procedure/surgical room.

F. Marking the operative site

1. The mark will be the surgeon's initials at the site for surgery.
2. Make the mark at or near the incision site. Do NOT mark any non-operative site(s) unless necessary for some other aspect of care.
3. The mark must be positioned to be visible after the patient is prepped and draped.
4. The mark must be made using a marker that is sufficiently permanent to remain visible after completion of the skin prep, yet not tattoo the skin. Adhesive site markers will not be used as the sole means of marking the site.
5. The method of marking and the type of mark should be consistent throughout the organization and age sensitive.
6. At a minimum, mark all cases involving laterality, multiple structures (fingers, toes, lesions) or multiple levels (spine). Note: In addition to preoperative skin marking of the general spinal region, special intraoperative radiographic techniques may be used for marking the exact vertebral level.
7. The person performing the procedure shall perform the site marking.
8. Marking must take place with the patient involved, awake and aware, if possible.
9. Final verification of the site mark must take place during the "time out."
10. If a patient refuses site/side marking, the staff will provide the patient with information to understand why site marking is appropriate and desirable, and the implications of refusing the site/side marking. The patient can then make an informed decision.

G. Exemptions

1. Single organ cases (e.g., Cesarean section, cardiac surgery).
2. Interventional cases for which the catheter/instrument insertion site is not predetermined (e.g., cardiac catheterization).
3. Teeth – BUT, indicate operative tooth name(s) on the documentation OR mark the operative tooth (teeth) on the dental radiographs or dental diagram.
4. Premature infants, for whom the mark may cause a permanent tattoo.
5. Spinal surgery and site/side will be verified as above. The circulating RN will also ask the patient in which leg he/she has pain. Once in the operating room (OR), the Surgeon will make the incision and mark the vertebral space with an instrument and have x-ray taken. The Surgeon will interpret the x-ray and verify the site before proceeding.
6. In emergency situations, when a physician has determined that delay is likely to compromise the patient's condition, completion of the Surgical Safety Checklist may be waived. All steps may be omitted in a life-threatening emergency.

H. Briefing is conducted with all members of the surgical team and the patient, prior to induction. The surgical team shares esential information to include: introductions, patient identification, using 2 patient

identifiers [Name, Medical Record Number (MRN)], procedure, procedure site, site markings, consents, and verification of applicable tissues, implants, radiographic studies and equipment.

I. "Time Out" is conducted immediately before skin incision or start of the procedure if no incision is indicated, in the location where the procedure will be done, just before starting the procedure, requiring the participation of all team members during the critical pause, in which all activities in the operating room must be suspended, except in the case of a life-threatening emergencies. ~~It must involve the entire operative team, use active communication, and there should~~After the completion of the time out it shall be ~~no talking during the time out by other team members in order to ensure all members clearly hear the information. After the completion of the time out it shall be~~ documented using the Electronic Health Record (EHR) - Surgical Safety Check List that includes:

1. Correct patient identity.
2. Correct site~~/side~~ and laterality are identified and marked.
3. Consent form is present and ~~accurate~~verified.
4. Agreement on the procedure to be done.
5. Correct patient position.
6. Sterile indicator criteria met.
7. Confirm all relevant records, images, equipment and implants are present.
8. If applicable, confirm antibiotic prophylaxis and potential time requirement for required re-dosing.
9. Anticipated critical events including expected duration, anticipated blood loss, and critical or non-routine steps.
10. Fire Risk Assessment

~~A debriefing must be performed prior to the patient leaving the OR to include:~~

J. Debrief-all team members must participate in a surgical debriefing prior to the patient leaving the operating room, which includes:

1. Confirmation of estimated blood loss (EBL)
2. Confirmation of the surgical procedure name
3. Wound class verification
4. Verification of sponge, sharps, and instrument counts
5. Specimens including #, tests ordered
6. Equipment problems to be addressed.
7. Administration of Local Anesthetic
8. Patient Disposition and Key concerns for recovery

K. A Time Out must be performed before each procedure, if two procedures are performed at the same time.

L. Procedures including, but not limited to, nerve blocks and central vascular access lines performed prior to surgery by Anesthesia will adhere to the "time-out" process.

~~1. Completion of correct counts~~

~~2. Speciments including #, tests ordered~~

~~3. Equipment problems to be addressed.~~

~~4. Wound Classification~~

~~J. A Time Out must be performed before each procedure, if two procedures are performed at the same time.~~

~~K. Procedures including, but not limited to, nerve blocks and central vascular access lines performed prior to surgery by Anesthesia will adhere to the "time-out" process.~~

INVASIVE PROCEDURES IN NON-OPERATING ROOM SETTINGS, INCLUDING BEDSIDE PROCEDURES

A. Site marking must be done for any procedure that involves laterality, multiple structures or levels.

B. Verification, site marking and "time out" procedures will be consistent throughout the organization as stated above, including any location where invasive procedures are done. This is to be done regardless of location such as Emergency Room, Intensive Care Unit, RADIOLOGY or other areas.

C. **Exception:** Cases in which the individual doing the procedure is in continuous attendance with the patient from the time of decision to do the procedure and consent from the patient through to the conduct of the procedure may be exempted from the site marking requirements. The requirement for a "time out" final verification still applies.

~~DOCUMENTATION~~

DOCUMENTATION

A. Verification of invasive procedure or surgery site/side will be documented in the following areas:

1. Preop checklist
2. Surgical Consent
3. Intraoperative Patient Care Plan
4. Anesthesia Record
5. Surgeon's Post-operative Note
6. Ambulatory Care and Bedside Procedure Universal Protocol for Correct Patient, Procedure Site/Side "Time Out" EHR (Inpatient and Ambulatory Care setting only)

B. A pre-procedure checklist is completed prior to invasive procedures except certain routine procedures such as venipuncture, peripheral vascular access placement, or insertion of a nasogastric tube or indwelling urinary catheter.

C. If an adverse event occurs:

1. Immediately notify the Supervisor, Surgical Services Clinical Nurse Manager, Chief Nurse Executive and the Medical Director.
2. The Circulating RN will be relieved with another RN as quickly as possible.
3. The Circulating RN will complete a Notification Form.
4. The physician or surgeon performing the procedure will notify the patient and family. The Director of Surgery may participate in this notification.

~~References:~~

References:

http://bulletin.facs.org/2016/10/revised-statement-on-safe-surgery-checklists-and-ensuring-correct-patient-correct-site-and-correct-procedure-surgery/

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All revision dates: 6/25/2024, 6/9/2020, 2/15/2018, 5/1/2016, 5/1/2013, 1/1/2012, 6/1/2010, 5/1/2006, 1/1/2005

Attachments

Universal Protocol Checklist

Approval Signatures

Step Description	Approver	Date
Medical Staff Committees: Medicine & Surgery	Tracy Chapman: Director, HCA Medical Staff Administration	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	6/13/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	5/29/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	5/29/2024
Policy Owner	Gwendolyn Vontoure: Director Perioperative Services	5/29/2024

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*3/1/2016*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*6/25/2024*
Next Review:	*3 years after approval*
Owner:	*Danielle Gabele: Chief Nursing Executive, VCMC & SPH*
Policy Area:	*Administrative - Patient Care*
References:	

100.201 Sepsis Management Policy

POLICY:

Sepsis is the leading cause of death in non-cardiac intensive care units in the United States. Mortality rates are higher that those of trauma, stroke and myocardial infarction. Studies have demonstrated ~~a significant reduction in sepsis~~that early recognition and treatment significantly decreases mortality ~~through the use of early aggressive management of severe sepsis, immediately after recognition~~rates.

To improve care and reduce sepsis mortality for patients at Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH)~~, a~~ a multidisciplinary Sepsis ~~Task Force~~Committee was ~~formed in 2012~~restarted in 2022. The following policy has been revised to reflect updated requirements for the Centers for Medicare and Medicaid Services~~, the Department of Health and Human Services~~ and The Joint Commission. In addition, the policy refers to non-obstetric adult patients, 18 years and older. Please note that if any potential sepsis criteria symptoms are presented in obstetric patients, ~~the nurse will notify the physician.~~refer to OB.76 Maternal Sepsis Policy.

PROCEDURE:

DEFINITIONS

The following definitions and guidelines reflect the CMS SEP-1 Core Measure requirements. Care for each patient should be individualized to optimize care.

A. **Systemic Inflammatory Response Syndrome (SIRS):**

A severe systemic response to a condition (as trauma, an infection, or a burn) that provokes an acute inflammatory reaction indicated by the presence of 2 or more of a group of symptoms including:

• ~~temperature~~Temperature greater than 100.9 F or less than 96.8 F~~;~~
• ~~heart~~Heart rate greater than 90 bpm~~;~~
• ~~respiration~~Respiration rate greater than 20 BPM ~~**OR** a reduced concentration of carbon dioxide in the arterial~~
• White blood~~, and;~~
~~• white blood~~ cell count ~~greatly decreased or increased or consisting of more~~greater than ~~ten percent immature neutrophils;~~
~~• systolic blood pressure (SBP) less than 90 mm/Hg;~~

~~• mean arterial pressure (MAP) less than 65 mm/Hg **OR** a SBP decrease of more than 40 mm/Hg from baseline;~~
~~• white blood cell count greater than~~ 12,000 or less than 4,000~~;~~
~~• bands~~ or greater than 10%~~.~~
immature neutrophils

B. **Sepsis:** Presence of infection ~~and presence of~~with 2 or more SIRS - ~~2~~see abnormal vital signs from above. ~~A patient screens positive for sepsis if the above criteria are met. *See Appendix A*~~

C. **Severe Sepsis:** Qualifies when sepsis criteria and at least one sign of organ dysfunction or hypoperfusion are present.

Signs of organ dysfunction may include the following:

• ~~lactate~~Lactate level greater than 2 mmol/L~~;~~
• ~~platelets~~Platelets less than 100,000/dL
• PTT more than 60 seconds~~;~~
• INR more than 1.5 seconds~~;~~
• ~~bilirubin~~Bilirubin greater than 2 mg/dL~~;~~
• ~~creatinine~~Creatinine greater than 2 mg/dL **OR** a urine output less than 0.5 ml/kg/hr for 2 hours~~.~~

Signs of hypoperfusion may include 2 readings of the following:

• ~~systolic~~Systolic blood pressure (SBP) less than 90 mm/Hg;
• ~~mean~~Mean arterial pressure (MAP) less than 65 mm/Hg, **OR** a SBP decrease of more than 40 mm~~/~~ Hg from baseline.

D. **Septic Shock:** ~~Severe~~When severe sepsis criteria ~~and a~~is met with lactate ≥ 4 mmol/L ~~or~~**&/or** persistent hypotension (SBP < 90 mm~~/~~ Hg, MAP < 65, SBP decrease more than 40 mm~~/~~ Hg from baseline) is identified within one hour of completion of an intravenous fluid (IVF) bolus of 30 ml/kg fluid by 2 blood pressure readings.

SEPSIS CARE

~~A. **Sepsis Screening:**~~

~~a. **Emergency Department Adult Patients** shall undergo sepsis screening on arrival. Patients that screen positive for sepsis, shall have lactate testing done at the time of the positive screen. The nurse (RN) shall order a "ED Triage Sepsis Adult Power Plan," in the patient's Electronic Health Record (EHR), per Standardized Nursing Procedure.~~

~~b. **Inpatient Adult Patients** are to be screened at least once a shift while hospitalized. The primary nurse shall draw an initial lactate per provider admission orders, at the time of a positive sepsis screen.~~

~~B. **Sepsis Care:** The following guidelines reflect the CMS Core Measure requirements. Care for each patient should be individualized, to optimize care.~~

~~a. A patient who meets criteria for severe sepsis/septic shock, shall have blood cultures drawn prior to antibiotic infusion and appropriate antibiotics infused within 3 hours of the specified time criteria for severe sepsis/septic shock.~~

~~b. In addition, every patient who meets criteria for septic shock shall also receive a 30 ml/kg crystalloid~~

~~infusion, started within 3 hours, vasopressors (if persistent hypotension within one hour of completion of crystalloid infusion), with reassessment of volume status and tissue perfusion within 6 hours of the specified time criteria for septic shock.~~

~~C. **Rapid Response Code Sepsis:** A Rapid Response Code Sepsis will be called for patients with initial hypotension criteria and/or lactate ≥ 4.0 mmol/L, in addition to a positive sepsis screen.~~

~~The following individuals are notified when a rapid response code sepsis is activated:~~

~~• ICU attending and resident;~~
~~• ER nurse and physician;~~
~~• pharmacy, lab, respiratory therapy, radiology, paging;~~
~~• ICU nurse manager, nursing supervisor;~~
~~• Trauma Support Nurse (TSN), and performance improvement liaison.~~

~~The Emergency Department code sepsis will be a silent page. The Inpatient Department code sepsis will be an overhead "Rapid Response Code Sepsis" page.~~

~~D. **Quality Improvement:** The Quality Assessment & Performance Improvement (QAPI) department shall assist in data reporting requirements for presentation to the Sepsis Committee. Data will be used by the Sepsis Task Force and the QAPI department, to further support improvement and staff education efforts, related to sepsis care.~~

A. **Sepsis Screening:** patients who meet 2 or more SIRS criteria with or without hypotension, shall undergo sepsis screening to assess if suspected/confirmed infection is present. For patients that screen positive for sepsis, a lactate order will be automatically generated by Cerner; unless one is already present.

B. **Code Sepsis:** When a patient screens positive for sepsis with a lactate ≥ 4.0 mmol/L **&/or** hypotension, a Code Sepsis will be paged. The Emergency Department (ED) code sepsis will be a silent page, while the Inpatient Department code sepsis will be an overhead page.

- The following individuals are notified when a Code Sepsis is activated/paged:

  • ICU Resident at VCMC; ICU Attending at SPH
  • ED Nurse and Physician; *when in ED*
  • Nursing Supervisor
  • Respiratory Therapy
  • Radiology
  • Lab
  • Quality Department Liaison

C. **SEP-1 Bundle Elements:** CMS guidelines require implementation of the following time sensitive interventions once severe sepsis/ septic shock identification.

- Within the first 3 hours of severe sepsis/septic shock identification:
  - Initial Lactate
  - Blood Cultures (10 minutes apart and from two separate locations)
  - Antibiotics (intravenous or intraosseos)
  - If hypotensive **&/or** Lactate ≥ 4 then 30ml/kg IV crystalloid fluids bolus (normal saline or lactated ringers) to be administered. The rate must be greater than 125 ml/hr. Multiple mini

bolus are acceptable. If less than 30ml/kg ordered, license practitioner to document reason why.

- Within 6 hours of severe sepsis/septic shock identification:
  - Repeat lactate level if initial lactate result >2 (Cerner automatically orders to repeat in 4 hours)
  - If patient receives crystalloid fluids:
    - Assess and document BP x 2 within the hour after the targeted fluids finished.
    - License practitioner to assess and document a repeat volume status and tissue perfusion assessment post fluid bolus administration.

D. **Quality Improvement:** The Quality Assessment & Performance Improvement (QAPI) department shall assist with data collection/ abstraction and report SEP-1 bundle compliance to the Sepsis Committee. The Committee will review cases, bundle compliance, identify gaps and initiate performance improvements projects to improve patient care and outcomes.

Emergency Department Personnel Duties:

Non-obstetric patients 18 years and older

A. ~~ED Triage or Primary Nurse:~~

1. ~~Assess the patient for sepsis using "Sepsis Screening Tool Part 1" in the EHR. **If down time, nurse to use current Sepsis Clock example. See Appendix D: Sepsis Assessment Tool and Clock Documentation Form.* Current forms can be located on DocuShare.~~
2. ~~If it is a positive sepsis screening, RN to initiate a "ED Triage Sepsis Adult" Power Plan."~~
3. ~~The following will be done, as indicated:~~
   a. ~~**Lactate result < 2 (sepsis):** The nurse will continue the "Sepsis Screening Tool Part 2" and assess for criteria regarding organ dysfunction.~~
   b. ~~**Lactate > 2 but < 4, and/or organ dysfunction new to patient (Severe Sepsis):** The nurse will continue the "Sepsis Screening Tool Part 2," notify the physician/advance practice provider (APP) that the patient has met the criteria for severe sepsis and consult with the provider regarding the following:~~

      ~~• additional orders for diagnostic testing;~~
      ~~• blood cultures;~~
      ~~• broad spectrum antibiotics.~~

      ~~Notify the physician/APP if a patient's SBP < 90, Lactate ≥ 4 or if SBP decreases ≥40 mm Hb from baseline.~~
   c. ~~**Severe Sepsis Care:** The nurse will collect two blood cultures prior to antibiotics, administer broad spectrum antibiotics and a IVF bolus, if ordered, by a physician/APP.~~
   d. ~~**Lactate ≥ 4 and/or Initial Hypotension (Septic Shock):** The nurse will page a *Rapid Response Code Sepsis* (silent page in ER) and continue the sepsis screening tool part 2 and consult with the physician/APP regarding the following:~~

      ~~• additional orders for diagnostic testing;~~

~~• blood cultures;~~
~~• broad spectrum antibiotics;~~
~~• 30ml/kg IV fluid bolus of Lactated Ringers or Normal Saline.~~

~~e. **Septic Shock Care:** The nurse will collect two blood cultures prior to antibiotics, administer broad spectrum antibiotics and administer 30ml/kg IV NS/LR fluid bolus, if ordered by a physician/APP.~~

~~Recheck blood pressures every 5 minutes until stable (SBP > 90 or MAP > 65) within the hour following IVF bolus completion, with a minimum of 2 recorded blood pressures.~~

~~4. If the phlebotomist is unable to draw lactate in a timely manner, the nurse shall draw lactate.~~

ED Triage or Primary Nurse:

1. **Emergency Department Adult Patients** who meet 2 or more SIRS criteria with or without hypotension, shall undergo sepsis screening to assess if suspected/confirmed infection is present. For patients that screen positive for sepsis, a lactate order will be automatically generated by Cerner; unless one is already present. **If down time nurse to use Sepsis Clock and Assessment paper form. See Appendix A: Sepsis Assessment Tool and Clock Documentation Form*
2. If sepsis screen is positive, EDN Power Plan (2+ Systemic Inflammatory Response Syndrome) is available for ED RN to initiate when more orders are needed to meet the needs of the patient. *See ER.42 Standardized Nursing Procedures in the Emergency Department policy.*
3. ED Nurse to follow SEP-1 Bundle Elements as outlined above in *Sepsis Care C. SEP-1 Bundle Elements.*
4. If the phlebotomist is unable to draw lactate in a timely manner, the nurse shall draw lactate.

B. ER Phlebotomist (Nurse at SPH):
   1. Draw lactate sample and ~~give~~provide to the Respiratory Therapist for testing.
   2. If lactate > 2, lactate is to be redrawn within 4 hours. If unable to draw the patient in a timely manner, the nurse will be requested to draw lactate.

C. Respiratory Therapist:
   1. Test the lactate sample(s) report result(s) to the primary nurse, regardless of result.
   2. Lactate ≥ 4 (critical lab) to be reported to the primary nurse and/or ~~Charge Nurse~~charge nurse.

D. ~~Physician/APP~~License Practitioner: In addition to other clinically indicated diagnostic testing and treatment, the following sepsis bundle components are to be ordered if there are no contraindications:
   1. Intravenous access~~;~~.
   2. Two sets of blood cultures ~~(10 minutes apart and from two separate locations)~~ and prior to antibiotics being initiated~~;~~.
   3. Broad spectrum antibiotics to be administered within 3 hours of the severe sepsis time. ~~Antibiotics to be administered within 3 hours of the severe sepsis time;~~
   4. Patients with SBP < 90 mm Hg, ~~Lactate~~lactate ≥ 4 or ~~if~~ SBP decreases ≥ 40 mm ~~Hb~~Hg from baseline,~~will~~ to have a fluid bolus administered~~,~~ of 30 ml/kg IV ~~NS/LR~~crystalloid fluids (normal saline or lactated ringers). Multiple mini bolus are acceptable. If IV ~~antibiotics~~antibiotic(s) is administered that are ~~administered that are~~ mixed with ~~NS or LR~~crystalloid fluids and the rate is > ~~126~~125 ml/hr, fluids may apply to the target fluid ~~may apply to the target fluid~~ amount~~;~~.

a. If the crystalloid fluid volume ordered is less than the volume required, a license practitioner must document why the target ordered volume is less than 30 ml/kg.

5. Initiate vasopressors in ~~any patient that has~~patients with persistent hypotension~~,~~ post 30ml/kg IV NS/ LR fluid bolus~~;~~.
6. If the patient ~~the patient~~ meets criteria for septic shock, then ~~the Physician/APP is to complete the "Septic Shock Assessment"~~a license practitioner to assess and document a repeat volume status and tissue perfusion assessment post fluid bolus administration, and within ~~the~~ 6 hours ~~post~~from septic shock identification~~; see Appendix D~~. A ~~note containing the below reassessment criteria, within the 6 hours post septic shock identification, will also be acceptable. Either option "a." or "b." will meet the reassessment criteria requirement.~~repeat volume status and tissue perfusion assessment may consist of any one of the following three:
   a. License practitioner documentation attesting to performing or completing a physical examination, perfusion (re-perfusion) assessment, sepsis (severe sepsis or septic shock) focused exam.
   b. ~~"Sepsis focus exam was completed"; this attests~~ License practitioner documentation indicating that at least 5 of the following were assessed: Vitals (HR, B/P, temp and RR), cardiopulmonary assessment, capillary refill, skin color exam, peripheral pulses, urine output, &/or SaO2 or SpO2.
   c. One of the following to be completed: ScvO2 or SvO2, CVP, Bedside CV Ultrasound, Passive Leg Raise or Fluid Challenge.

Inpatient Unit Personnel Duties:

Non-obstetric patients 18 years and older

A. ~~Inpatient Nurse:~~

~~1. Assess the patient for sepsis using "Sepsis Screening Part 1" in the EMR. *If down time nurse to use Sepsis Clock and Assessment paper form. See Appendix D: Sepsis Assessment Tool and Clock Documentation Form~~

~~2. If it is a positive sepsis screening, the RN will order *Lactate Blood Gas - RT* as a nurse initiate-no cosign, per the physician/APP admission orders. Nurse to draw initial lactate. If a nurse is unable to draw lactate in a timely manner, the phlebotomist shall draw lactate.~~

~~3. The following will be done, as indicated:~~

~~a. **Lactate result < 2 (sepsis):** The nurse will continue the sepsis screening tool part 2 and assess for organ dysfunction criteria.~~

~~b. **Lactate > 2 but < 4, or organ dysfunction new to patient (Severe Sepsis):** The nurse will continue the sepsis screening tool part 2, notify the physician/APP that patient has met the criteria for severe sepsis and consult with the provider regarding the following:~~

~~• additional orders for diagnostic testing;~~
~~• blood cultures;~~
~~• broad spectrum antibiotics.~~

~~Notify the physician/APP if a patient's SBP < 90, Lactate ≥ 4 or if SBP decreases ≥40 mm Hb~~

~~from baseline.~~

~~c. **Severe Sepsis Care:** The nurse will collect two blood cultures prior to antibiotics, administer broad spectrum antibiotics and a IVF bolus, if ordered by the physician/APP.~~

~~d. **Lactate ≥ 4 and/or Initial Hypotension (Septic Shock):** The nurse will page a *Code Sepsis Rapid Response* (silent page) and continue the sepsis screening tool part 2 and consult with the physician/APP regarding the following:~~

~~• additional orders for diagnostic testing,~~
~~• blood cultures,~~
~~• broad spectrum antibiotics,~~
~~• 30ml/kg IV fluid bolus of Lactated Ringers or Normal Saline.~~

~~e. **Septic Shock Care:** The nurse will collect two blood cultures prior to antibiotics, administer broad spectrum antibiotics and administer 30ml/kg IV NS/LR fluid bolus, if ordered by a physician/APP.~~

~~Recheck blood pressures every 5 minutes until stable (SBP > 90 or MAP > 65) with in the hour following IVF bolus completion, with the minimum of 2 recorded blood pressures.~~

Inpatient Nurse:

1. Patients who meet 2 or more SIRS criteria with or without hypotension, shall undergo sepsis screening to assess if suspected/confirmed infection is present. For patients that screen positive for sepsis, lactate order will be automatically generated by Cerner; unless one is already present. **If down time nurse to use Sepsis Clock and Assessment paper form. See Appendix A: Sepsis Assessment Tool and Clock Documentation Form*
2. Nurse to follow SEP-1 Bundle Elements as outlined above in *Sepsis Care C. SEP-1 Bundle Elements*.
3. Nurse to facilitate lactate draw as soon as possible when the patient meets positive sepsis criteria.

B. Phlebotomist (nurse at SPH night shift):

~~1. If a nurse is unable to draw lactate in a timely manner, the phlebotomist shall draw lactate.~~

1. Draw lactate sample and provide to the Respiratory Therapist for testing.
   If lactate > 2, lactate is to be redrawn within 4 hours.
2. If unable to draw the patient in a timely manner, escalate to the charge nurse.

C. Respiratory Therapist:

1. Test the lactate sample(s) and report the result(s) to the primary nurse.
2. Lactate ≥ 4 (critical lab) to be reported to the primary nurse and/or Charge Nurse.

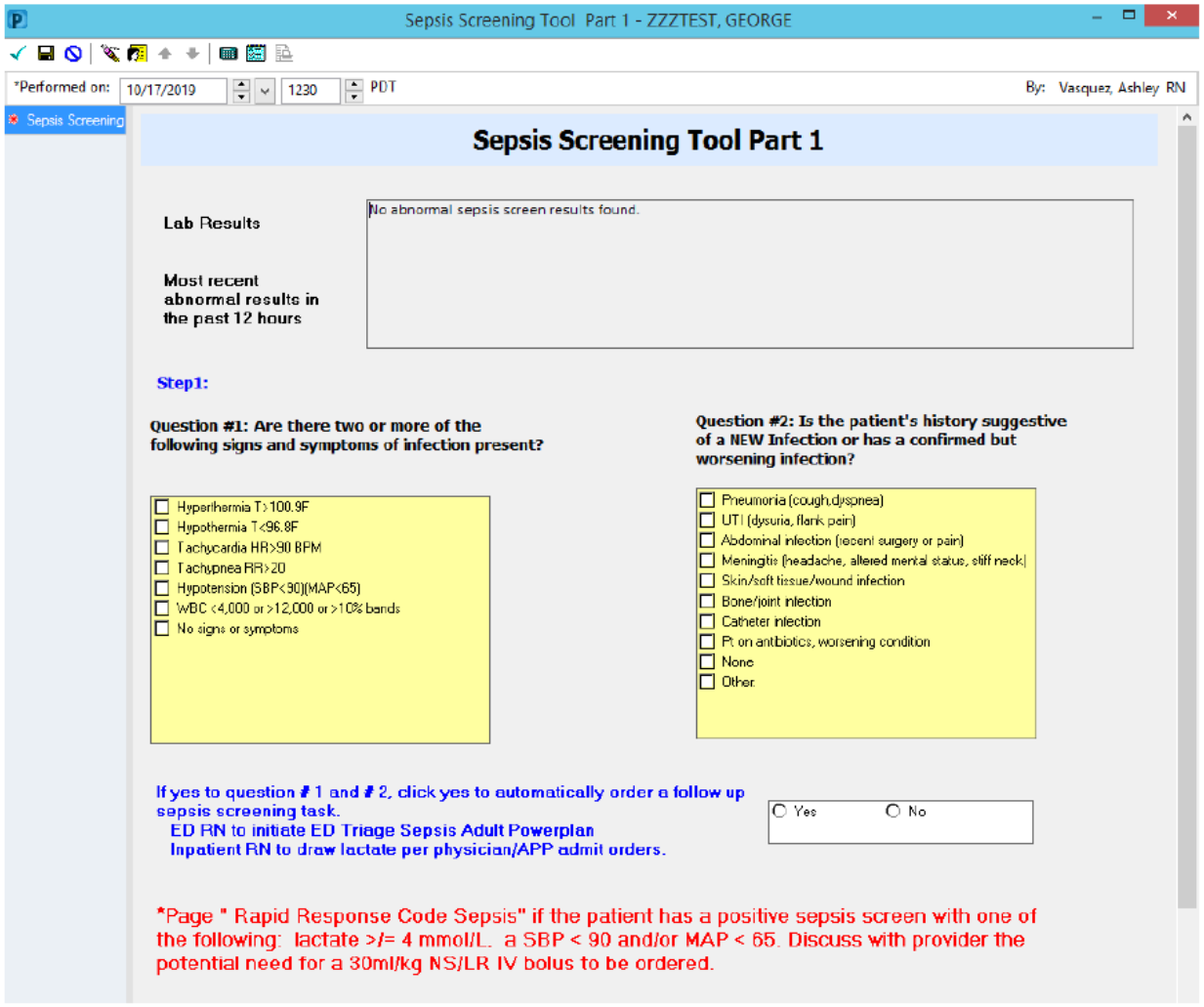
D. ~~Physician/APP~~License Practitioner: In addition to other clinically indicated diagnostic testing and treatment, the following sepsis bundle components ~~will~~are to be ordered if there are no contraindications:

1. Intravenous access~~;~~.
2. Two sets of blood cultures ~~(10 minutes apart and from two separate locations)~~ and prior to antibiotics being initiated~~;~~.
3. Broad spectrum antibiotics to be administered within 3 hours of the severe sepsis time. ~~Antibiotics will be administered within 3 hours of the severe sepsis time;~~

4. Patients with SBP < 90 mm Hg, ~~Lactate~~lactate ≥ 4 or ~~if~~ SBP decreases ≥ 40 mm ~~Hb~~Hg from baseline, ~~will~~to have a fluid bolus administered~~,~~ of 30 ml/kg IV ~~NS/LR~~crystalloid fluids (normal saline or lactated ringers). Multiple mini bolus are acceptable. If IV ~~antibiotics~~antibiotic(s) is administered that are ~~administered that are~~ mixed with ~~NS or LR~~crystalloid fluids and the rate is >~~126~~ 125 ml/hr, fluids may apply to the target fluid ~~may apply to the target fluid~~ amount~~;~~.
    a. If the crystalloid fluid volume ordered is less than the volume required, a license practitioner must document why the target ordered volume is less than 30 ml/kg.
5. Initiate vasopressors in ~~any patient that has~~patients with persistent hypotension~~,~~ post 30ml/kg IV NS/LR fluid bolus~~;~~.
6. If the patient ~~the patient~~ meets criteria for septic shock, then ~~the Physician/APP is to complete the "Septic Shock Assessment"~~a license practitioner to assess and document a repeat volume status and tissue perfusion assessment post fluid bolus administration, and within ~~the~~ 6 hours ~~post~~from septic shock identification~~; see Appendix D~~. A ~~note containing the below reassessment criteria, within the 6 hours post septic shock identification, will also be acceptable. Either option "a." or "b." will meet the reassessment criteria requirement.~~repeat volume status and tissue perfusion assessment may consist of any one of the following three:
    a. License practitioner documentation attesting to performing or completing a physical examination, perfusion (re-perfusion) assessment, sepsis (severe sepsis or septic shock) focused exam.
    b. ~~"Sepsis focus exam was completed"; this attests~~License practitioner documentation indicating that at least 5 of the following were assessed: Vitals (HR, B/P, temp and RR), cardiopulmonary assessment, capillary refill, skin color exam, peripheral pulses, urine output, &/or SaO2 or SpO2.
    c. One of the following to be completed: ScvO2 or SvO2, CVP, Bedside CV Ultrasound, Passive Leg Raise or Fluid Challenge.

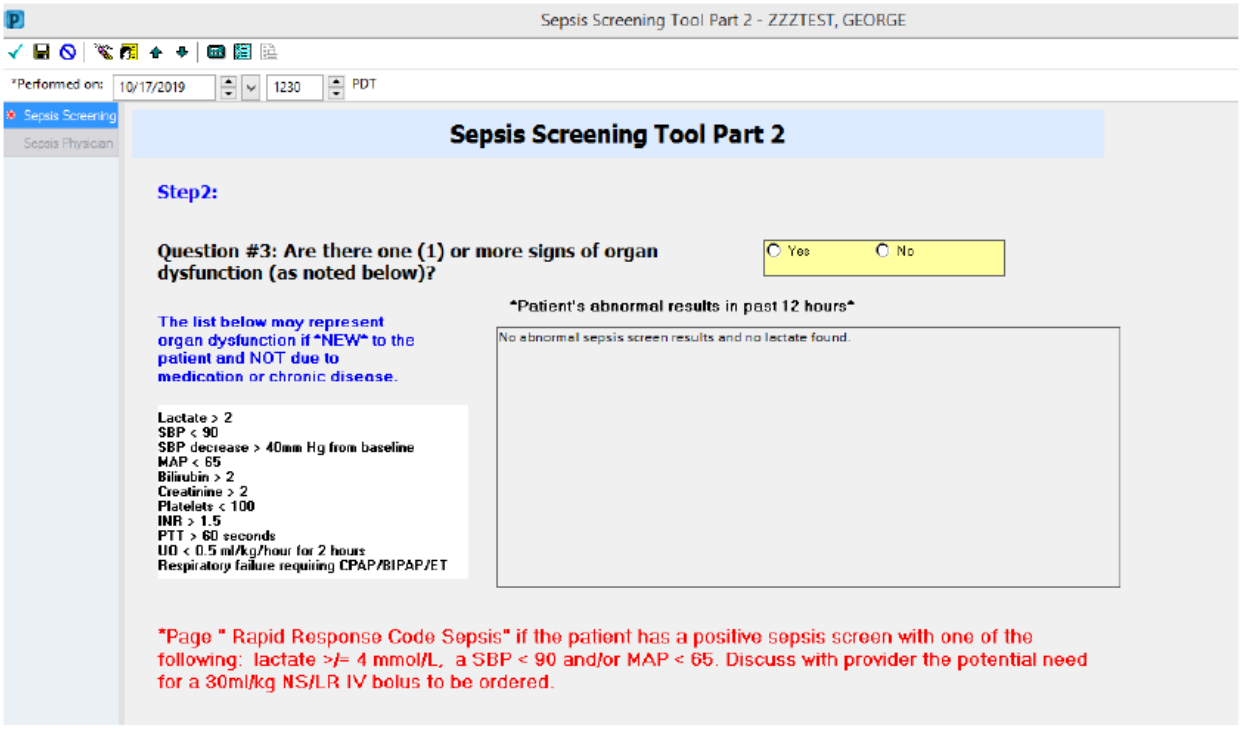
~~APPENDIX A: Sepsis Screening Tool Part 1~~

Appendix A- Sepsis Screening Tool Part 1



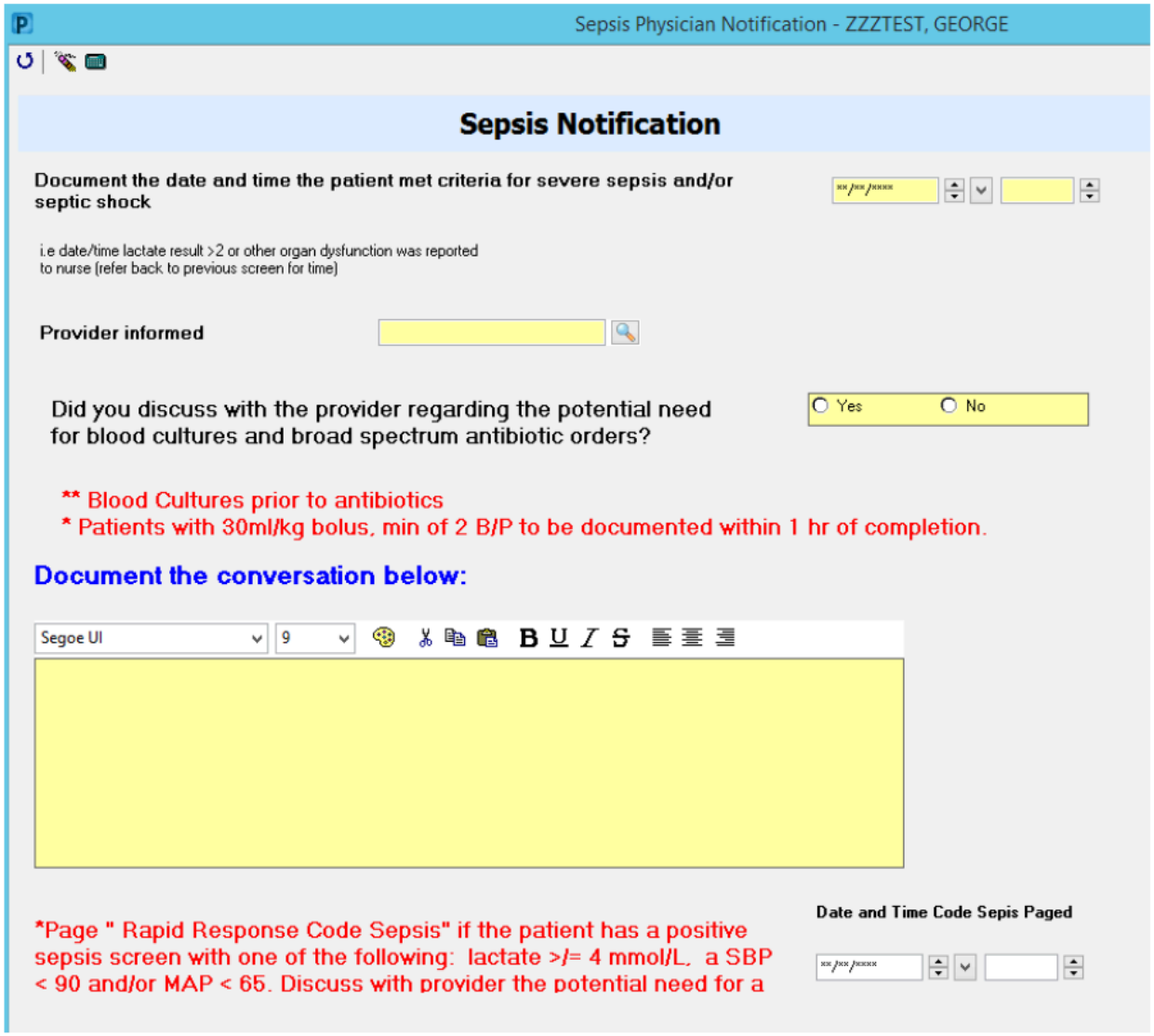
~~APPENDIX B: Sepsis Screening Tool Part 2~~

Appendix B- Sepsis Screening Tool Part 2



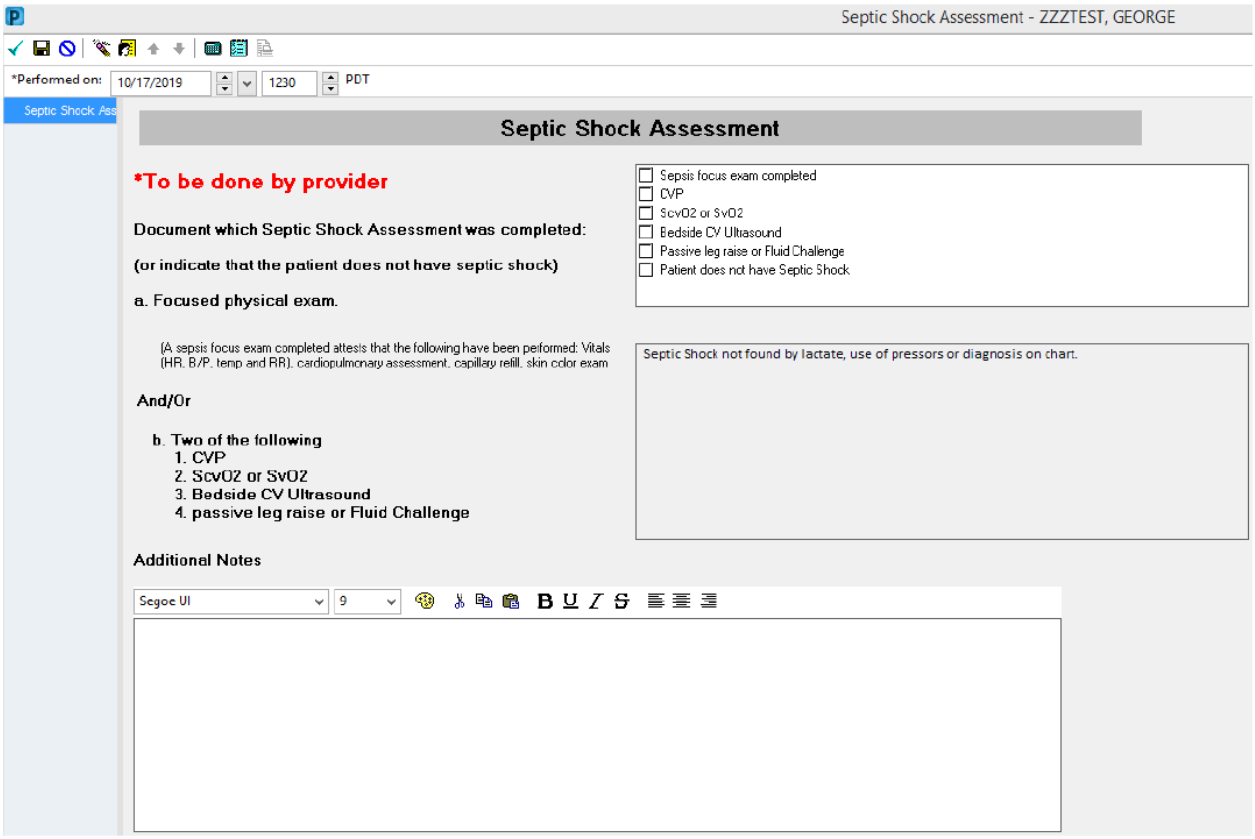
~~APPENDIX C: Sepsis Notification~~

Appendix C- Sepsis Notification



~~APPENDIX D: Septic Shock Assessment~~

Appendix D- Septic Shock Assessment



~~APPENDIX E: Sepsis Assessment Tool and Clock Documentation Form~~

Appendix E

SEPSIS ASSESSMENT TOOL AND CLOCK DOCUMENTATION

Positive Sepsis Screen: Date: _____ Time: _____ **Location:** VCMC SPH Unit: _____

Please complete ALL steps and assure that BOTH signatures are present.

Step 1: Sepsis screening assessment

Vital Signs

Temp:_____

HR:_____

BP:_____

RR:_____

Question 1: Are there 2 or more of the following signs and symptoms of infection present?

☐ Hyperthermia (T > 100.9°F) ☐ Hypothermia (T < 96.8 °F) ☐ Tachycardia (HR > 90 bpm) ☐ Tachypnea (RR > 20)
☐ Hypotension (SBP < 90)(MAP<65) New to PT ☐ WBC < 4,000 or > 12,000 or bands > 10% ☐ No signs or symptoms

Question 2: Is the patient's history suggestive of a NEW Infection or has a confirmed but worsening infection?

☐ Pneumonia (*cough, dyspnea*) ☐ UTI (*dysuria, flank pain*) ☐ Abdominal infection (*recent surgery, pain*)
☐ Meningitis (*headache, altered, stiff neck*) ☐ Skin/soft tissue/wound infection ☐ Bone/Joint infection
☐ Catheter infection ☐ Pt on antibiotics, worsening condition ☐ None ☐ Other:_____

Step 2: Draw lactate. *To be drawn if YES to the questions above.*

Intervention		Time	Sepsis Guidelines
Draw Lactate	☐ *Refused*		Lactate = Green top on ice. Give sample to Respiratory Therapist. ☐ *Failed attempt to draw*
Lactate Result: _____mmol/L			If lactate result is < 2 mmol/L: See Step 3-4 to assess for severe sepsis or septic shock criteria. If lactate is > 2 and < 4 mmol/L: Severe Sepsis criteria is met (based on lactate alone) If lactate is > 4 mmol/L: *Page a CODE SEPSIS; patient meets severe sepsis & septic shock.*

Step 3: Assess for severe sepsis criteria.

Severe sepsis is met when the patient has any of the following that are new to patient:

☐ LA > 2 ☐ SBP < 90 ☐ SBP decrease > 40 mmHg from patient's baseline* ☐ MAP < 65 ☐ Bilirubin > 2 ☐ Creatinine > 2 ☐ Platelets < 100
☐ INR > 1.5 ☐ PTT > 60 s ☐ Urine output < 0.5 ml/kg/hr for 2 hours. ☐ Acute Respiratory Failure (CPAP/BIPAP)* *reason for it required from MD

Did patient meet any of the above criteria for severe sepsis? ☐No ☐Yes *If so, at what time?* Date: _____ Time:_____

	Intervention		Time	Sepsis Guidelines
To be done within 3 hours of severe sepsis time	**1st Blood Culture drawn**	☐ *Refused*		To be done before any antibiotics are administered. ☐ *Failed attempt to draw*
	2nd Blood Culture drawn	☐ *Refused*		To be done before any antibiotics are administered ☐ *Failed attempt to draw*
	IV antibiotic_____	☐ *Refused*		MUST be started within 3 hours of severe time and after blood cultures collected.
	30 ml/kg IV NS/LR bolus Kg_____ x 30 ml= _____ml	☐ *Refused*	↑ ↓	Must be started within 3 hours. IVF bolus is only required if patient has initial hypotension (SBP < 90, MAP < 65), **and/or** a lactate > 4 mmol/L, **and/or** has a SBP decrease > 40 mmHg from baseline.
	Blood pressure MUST be checked twice in the hour after completion of 30ml/kg bolus			Time _____ BP _____ MAP _____ Time _____ BP _____ MAP _____
Done in 4 hrs	**Repeat Lactate result*** *if initial lactate was > 2 _____mmol/L	☐ *Refused*		To be done within 4 hours of when severe sepsis time was met and only if initial LA was > 2.

Step 4: Assess for septic shock criteria.

Septic Shock is met when the patient has met severe sepsis criteria and has a lactate of > 4 **and/or** has persistent hypotension in the hour after the initial 30ml/kg bolus was completed. ☐ LA > 4 ☐SBP < 90 ☐MAP < 65 ☐ SBP decrease > 40 mmHg from baseline** ** reason for it required from MD

Did the patient meet any of the above criteria for septic shock? ☐No ☐Yes *If so, at what time?* Date: _____ Time:_____

	Intervention		Time	Sepsis Guidelines
To be done within 6 hours of septic shock time	**Vasopressor given?** *Name:*_____	☐ *Refused*		Shall be started within 6 hours of Septic Shock Start time if the patient's hypotension did not respond to initial fluid resuscitation. Goal is MAP > 65 mmHg.
	Documentation that a Septic Shock Focused Examination was reviewed, performed or attested to be performed by MD/APN/PA.			**Option A:** "Sepsis focus exam was completed"; This attests that at least 5 of the following were assessed: Vitals (HR, BP, temp and RR), cardiopulmonary assessment, capillary refill, skin color exam, peripheral pulses, urine output, &/or SaO2 or SpO2. **Option B:** ONE of the following: ScvO2 or SvO2, CVP, Bedside CV Ultrasound, Passive Leg Raise or Fluid Challenge.

Step 5: Was a Code Sepsis called? ☐No ☐Yes ☐ N/A Required if patient has a positive sepsis screen and a lactate > 4 mmol/L, **and/or** has a SBP < 90 New to patient, **and/or** has a SBP decrease > 40 mmHg from baseline.

Time Code Sepsis was called:		Call paging to report a code sepsis.

Primary Nurse Signature:_____Date: _____ Time:_____

Physician/APN/PA Signature:_____Date:_____ Time:_____

SEPSIS ASSESSMENT AND CLOCK DOCUMENTATION

* S E P S I S *

VCHCA-516-093 (11/2019)

VENTURA COUNTY HEALTH CARE AGENCY

Patient Label
or
Two Patient Identifiers

~~APPENDIX F: Sepsis Cheat Sheet~~

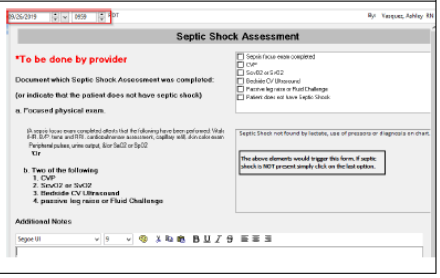
Appendix F

VCMC/SPH Sepsis Cheat Sheet v5.7

revised 8/28/19

The following definitions and guidelines reflect CMS Core Measure Requirements. Care for each patient should be individualized to optimize care.

	SIRS	SEPSIS 10-20% Mortality Rate	SEVERE SEPSIS 20-40% Mortality Rate	SEPTIC SHOCK 40-80% Mortality Rate
DEFINITIONS	Systemic Inflammatory Response Syndrome (SIRS) Must have at least 2 of the following: • Temp < 96.8 F • Temp > 100.9 F • HR > 90 • RR > 20 • WBC < 4,000 • WBC > 12,000 • Bands > 10%	SIRS + Infection/ Suspected Infection	SIRS + Infection/Suspected Infection + Organ Dysfunction Must have at least 1 of the following: • Lactate > 2 • SBP < 90 ** • SBP decrease > 40 mm Hg from baseline ** • MAP < 65 ** • Bilirubin > 2 * • Creatinine > 2 * • Platelets < 100 * • INR > 1.5 * • PTT > 60 seconds * • UO < 0.5 ml/kg/hour for 2 hours * • Respiratory failure (requiring CPAP/BIPAP/ET) * *new for patient **2 values to qualify as initial hypotension.	SIRS + Infection/Suspected Infection + Organ Dysfunction + Lactate ≥ 4 and/or Persistent hypotension within the 1 hr post bolus What is persistent hypotension? (per CMS) When there are two consecutive b/p's in the 1 hour post bolus completion with no improved b/p's within that hour. • SBP < 90 • MAP < 65 • SBP decrease of more than 40 mm HG from patients baseline
TO DO LIST	Recognize & Assess for infection	Order & draw lactate within 30 minutes of recognition	W/in 3 hours of meeting severe sepsis or septic shock: 1. Initial Lactate level. 2. Blood cultures before antibiotics. 3. Broad spectrum antibiotics within 3 hours. 4. IF initial hypotension &/or lactate ≥ 4 start LR/NS 30ml/kg bolus *(rate of 126ml/hr or greater), Assess and document BPx3.* W/in 6 hours of meeting septic shock 1. Start Vasopressors if persistent hypotension is present post IVF bolus completion. 2. Septic Shock Assessment form MUST be completed. • If septic shock elements are present and within the eligible time window, a SmartZone alert (red triangle) with direct link to the form will appear in the right upper corner of your PowerChart patient window. Click on the alert text to fill out the form. • Form may also be found in Ad-Hoc under "Physician Forms" folder, or "All Items -> Patient Care -> Septic Shock Reassessment Form". • Note that you can back-date the form if needed.	W/in 4 hours of meeting severe sepsis or septic shock: 1. Repeat Lactate Level if initial >2 (Cerner automatically orders). 2. IF patient received bolus: assess & document BP x3 w/in hour that the bolus completes. **Done to assess if patient has persistent hypotension, thus qualifying as Septic Shock.**



References

1. ~~The Joint Commission (2018). Specifications Manual for National Hospital Inpatient Quality Measures; v5.4.~~
2. ~~Lippincott Procedures. Sepsis, Emergency Patient Care; February 2019.~~
3. ~~Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, Quality Net (2018). Specifications Manual for National Hospital Inpatient Quality Measures v5.4.~~
4. ~~Rhodes, et al. (2016) Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016; Critical Care Medicine. 2017 Mar;45(3):486-552.~~
1. Centers for Medicare and Medicaid Services (CMS) (2023). Version 5.15a - specifications manual for discharges 01/01/24 - 06/30/24 (updated December 2023). *Quality reporting center.* https://qualitynet.cms.gov/inpatient
2. Lippincott Procedures (2023, Aug 21). *Sepsis, emergency patient care.* https://journals.lww.com/ccmjournal/fulltext/2021/11000/executive_summary__surviving_sepsis_campaign_.14.aspx
3. Evans, L., et al., (2021). Executive summary: surviving sepsis campaign: international guidelines for the

management of sepsis and Septic Shock 2021. *Critical care medicine.* 49(11), pp 1974-1982. DOI: 10.1097/CCM.0000000000005357

All revision dates: 6/25/2024, 11/13/2019, 9/23/2019, 6/28/2019, 9/27/2018, 3/1/2016

Attachments

Appendix A - Sepsis Assessment Tool and Clock Documentation Form.pdf
Appendix B - Sepsis Cheat Sheet
Appendix C - Administration of IV Antimicrobials
Appendix D - Sepsis Core Measure Requirement.pdf
Appendix E - Sepsis Clock Guidelines.pdf

Approval Signatures

Step Description	Approver	Date
Medical Staff Committees: ED & Medicine	Tracy Chapman: Director, HCA Medical Staff Administration	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	5/13/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	4/26/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/26/2024
Policy Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/26/2024

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*1/1/2012*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*6/5/2024*
Next Review:	*3 years after approval*
Owner:	*Judy Borenstein: VCMC - Nursing*
Policy Area:	*Cancer Program*
References:	

CA.10 Cancer Registry Conferences

POLICY:

It is the policy of Ventura County Medical Center/Santa Paula Hospital to have a multi-disciplinary team approach to planning, providing and evaluating the care of patients with cancer. To this end, Cancer Conferences and Committee meetings are held on a regular basis.

PROCEDURE:

Cancer Committee:

The Cancer Committee is a standing committee which reports to the Medical Executive Committee. Committee minutes are maintained and meetings scheduled by the Cancer Registrar and maintain legal confidentiality. The Cancer Committee meets quarterly and is the leadership component of the Cancer Program. It is multidisciplinary in nature, and includes representatives from all the medical specialties and allied health professionals. The Committee's physician composition includes at least one board certified physician representative from surgery, medical oncology, radiation oncology, diagnostic radiology, and pathology, as well as the cancer liaison physician and other specialty physicians as appropriate. Non-physician members must include administration, nursing, social services, Cancer Registry, clinical research, ~~rehabilitation~~ and other department/service representatives, as appropriate.

A. Cancer Committee responsibilities include:

1. Develop and evaluate the annual goals and objectives for the clinical, educational, and programmatic activities related to cancer.
2. Promote a coordinated, multidisciplinary approach to patient management.
3. Ensure that educational and consultative cancer conferences cover all the major sites and related issues.
4. Assure that an active supportive care system is in place for patients with cancer, their families, and oncology staff.
5. Monitor quality management and improvement through completion of quality management studies that focus on quality, access to care and outcomes.
6. Promote clinical research.
7. Develop and monitor the Cancer Survivorship Program

8. Supervise the cancer registry, and ensure accurate and timely abstracting, staging, and follow-up reporting.
9. Perform quality control for the cancer registry.
10. Encourage data usage and accurate data reporting.
11. Uphold medical ethical standards.

Cancer Conferences (Tumor Boards):

1. Multidisciplinary Tumor Board Cancer Conferences are held ~~alternating~~the first and third Monday's each month. A minimum of two cases are presented at each meeting for consultative and educational purposes.
2. The Cancer Committee establishes the Multidisciplinary attendance requirements to include physician representatives from Medical Oncology, General Surgery, Diagnostic Radiology, Pathology, Radiation Oncology, and other appropriate disciplines, attend/participate in this activity. These physician specialties are expected to attend at least 80% of the meetings each year.
3. The number of cases presented is a minimum of 15% of the annual analytic case load with at least 80% of the presented cases being prospective. Prospective cases include:
    - Newly diagnosed and treatment not yet initiated
    - Newly diagnoses and treatment initiated, but discussion of additional treatment is needed.
    - Previously diagnosed, initial treatment completed, but discussion of adjuvant treatment or treatment for recurrence or progression is needed.
    - Previously diagnosed, and discussion of supportive or palliative care is needed.
4. The Cancer Conference Coordinator monitors discussion of the required areas:
    - Discussion of clinical and/or pathological stage
    - Treatment planning using evidence-based national guidelines
    - Options and eligibility for research study enrollment
    - Options and eligibility for genetic testing
    - Options and eligibility for supportive care services

    ~~The Cancer Conference Coordinator~~
5. Purely didactic lectures are limited to 25 percent of conference frequency. Copies of the agenda and sign-in sheets are kept in the Cancer Registry.
6. The Cancer Conference Coordinator must evaluate and report annually to the Cancer Committee the following required elements 1) Cancer case conference frequency 2) Multidisciplinary physician specialty attendance 3) Number of cases presented and percentage of prospective cases 4) Elements of discussion for each case, including, but not limited to Staging, Treatment planning, options for clinical study enrollment, options or genetic testing, options and eligibility for supportive care services. 5) An action plan to resolve any areas that do not meet the requirements of the program's policy and procedure.

Reference:

Optimal Resources for Cancer Care 2020 Standards

All revision dates:	6/5/2024, 8/23/2021, 2/9/2021, 2/12/2020, 4/28/2016

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Tracy Chapman: Director, HCA Medical Staff Administration	pending
Cancer Committee	Judy Borenstein: VCMC - Nursing	6/18/2024
Cancer Program Manager	Judy Borenstein: VCMC - Nursing	6/5/2024

VENTURA COUNTY
HEALTH CARE AGENCY

Origination:	*12/1/1989*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*5/11/2021*
Next Review:	*3 years after approval*
Owner:	*Julia Feig: Clinical Nurse Manager, Emergency Services*
Policy Area:	*Emergency Services*
References:	

ER.23 Immediate Care of Patients with Toxic Exposures in the Emergency Department

POLICY:

A. To provide decontamination of Emergency Department (ED) patients with exposures to toxic substances and evaluation for further medical treatment.

B. To ensure the safety of health care workers, patients and visitors in surrounding areas.

C. To prevent further environmental contamination.

D. To prevent contamination of the ED staff, patients and visitors.

PROCEDURE:

A. In the event of known or suspected toxic exposure, the Hazardous Materials response team must be notified through the Ventura City Fire Department by dialing 911.

B. The ED physician will be notified of the incident. The ED Charge Nurse will be notified and obtain information as it becomes available regarding the type of toxic exposure, severity , duration of exposure, number of victims and any associated injuries. The ED Charge Nurse will notify Nursing Administration, Security, and Maintenance to secure the area.

C. When known, the type of toxin involved should be researched via MSDS online so appropriate treatment and/or antidotes may be initiated in the field.

D. As needed and directed by management, the Charge Nurse will initiate internal or external disaster protocol (see Emergency Operations Plan).

E. The ED will not initiate patient care until the toxic substance is identified.

EQUIPMENT

A. Portable freestanding privacy curtains as needed

B. ACLS equipment as needed

C. Barriers (Security to set up)

D. Portable light source if at night

E. Two-way radios

F. Additional equipment as needed

PROCEDURE

A. Upon arrival of a patient who has been contaminated with a toxic substance, or upon discovery that a patient already in the ED has experienced a toxic exposure, or if staff or visitors are suffering from toxic exposure, they should be taken outside to the designated DECONTAMINATION SITE and the Facilities Maintenance Department will be notified to set-up a Decon Tent.

B. ED staff will not initiate patient care until the exposure is identified and decontamination is identified.

C. ED Charge Nurse will assign appropriate staff to the triage/decontamination area.

D. As soon as a contaminated patient is identified, Ventura City Fire Department shall be notified by dialing 911. An emergency request for the HAZMAT team should be made, providing as much information as possible about the incident.

E. Access to the decontamination site must be limited by the placement of appropriate barriers and Security personnel, but no closer than 200 yards to the site.

F. Facilities Maintenance will set-up the decontamination tent as directed by House Supervisor or Administration.

G. When it is safe to transfer the patient into the hospital, the patient must be lifted onto a clean, non-contaminated gurney.

H. Definitive treatment of the patient may then continue inside the facility, after going through decontamination.

I. Any visitors of the Hospital or staff that become contaminated will follow the decontamination procedure.

DOCUMENTATION

Documentation of all above activities shall be reflected in the patient's Electronic Health Record in addition to the standard documentation of all medical events.

In addition, an incident report shall be filed per event.

All revision dates: 5/11/2021, 6/1/2011, 6/1/2006, 12/1/2004, 11/1/2001, 1/1/1995, 10/1/1992, 12/1/1989

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Emergency Department Committee	Tracy Chapman: VCMC - Med Staff	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	5/3/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	5/3/2024

Step Description	Approver	Date
Policy Owner	Julia Feig: Clinical Nurse Manager, Emergency Services	5/3/2024

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Owner:	*Julia Feig: Clinical Nurse Manager, Emergency Services*
Policy Area:	*Emergency Services*
References:	

ER.47 Treatment of Patients with Radiation Contamination

POLICY:

To provide clear guidelines for the treatment of radiation contaminated patients at Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) in order to limit exposure to staff, patients and the facility.

PROCEDURE:

A. In cases of known or suspected radioactive contamination of patients:

1. Notify the Fire Department of the location of the incident by calling 911. Their hazardous materials response team will coordinate the on-scene management of the incident. Ideally, the incident commander of the Fire Department will contact the Emergency Department (ED) charge nurse from the field to provide an update regarding the extent of contamination.
2. The ED staff physician will be notified, as he/she will be involved in the medical care of the victims.
3. The ED charge nurse should also be notified and immediately try to obtain information about the incident including the type and extent of radiation, duration of exposure, injuries involved, and number of victims. The charge nurse should report information, as it becomes available, to the staff physician, the Nursing Supervisor and the Radiation Safety Officer.

B. Radiation contaminated patients:

1. The number of staff members exposed to radiation-contaminated patients should be limited whenever possible. In certain instances, it may be necessary to have several teams of patient care staff care for the patient on a rotating basis as to limit the total time of exposure to a contaminated patient.

C. Receiving of prospective radiation contamination patients

1. The ED will be evacuated of non-essential persons. The evacuation will be lifted only when deemed appropriate by the Radiation Safety Officer.
2. The Maintenance Department will be notified to turn off any air conditioning and/or ventilation systems in the area.
3. Security will be paged and requested to be present in the ED for aid in evacuation and to maintain control of the area.

D. Set-up of controlled receiving area

1. The control area will be designated and radiation labels will be used to isolate this area. Absorbent paper will be placed in this area and taped securely to cement. The papered area shall be large enough to accommodate gurneys, disposable hampers and working space for attendants. Protective clothing, including gloves, shoe covers, gown, cap, and mask, should be made available at this area. Fire and ambulance will be instructed to park at the extreme east portion of this lane. The Nuclear Medicine Technician will carry out an initial survey of the victim inside the ambulance. If there is no evidence of external contamination and no likelihood of subsequent contamination to hospital staff, the patient will be brought directly into the ED for emergency care. If there is any external contamination or break in the patient's skin or otherwise, the patient will be decontaminated by the Fire Department before being admitted to the ED.
2. All attendants, equipment, and vehicles used in transport and treatment of the patient will remain in the control area for subsequent survey and decontamination, if necessary. The Radiation Safety Officer will attach radiation labels to the vehicles and equipment waiting to be surveyed or may direct Security staff to do so.

E. Patient brought into the ED without previous surveying:

1. Whenever possible, the patient will be brought to the shower room on a gurney and this room will then be considered contaminated. If possible, all equipment necessary for care will be brought into this room and will remain there. Persons in attendance of the victim will remain in the room until the Radiation Safety Officer clears them. The room shall be labeled with radioactive warning signs and those entering the area voluntarily should wear protective clothing. Decontamination will take place in this room, if necessary.
2. If more than one patient requires emergency care prior to survey and/or decontamination, the overflow area may be used. Similar restrictions to staff and equipment will be in effect for this area. All areas in which patients are brought will be considered contaminated and labeled as such. Radiation Safety Officer will conduct survey and make clear area when deemed safe.

F. Multiple patients who do not require emergency treatment

1. VCMC Only: At the discretion of the staff ED physician, patients may be sent to the Morgue for decontamination prior to being admitted to the ED. Additionally, transport staff and equipment may be requested to be transported to the Morgue via the outside entrance for decontamination. This will be supervised by the Radiation Safety Officer who may then release patients as needed.

G. Decontamination required prior to admittance to ED

1. Decontamination may be initiated in the control area. Decontamination will take place under the guidelines listed in this protocol. All equipment and protective clothing used by staff in the decontamination process will remain in the control area until adequate disposal is possible. All materials used should be placed in radioactive waste bags and should remain in quarantine area at all times.
2. Ambulance staff and equipment will be dismissed when cleared by Radiation Safety Officer. It will be recommended that all persons who come in contact with a contaminated patient have a shower and fresh change of clothing.
3. For specific decontamination measures of various body areas, see Attachment A.

H. Waste Disposal

1. Samples of contaminated water shall be collected and held in plastic containers when possible for

sampling and appropriate disposal as deemed necessary by the Radiation Safety Officer.

2. Any product used to contain fluids during decontamination should be carefully placed in disposable plastic bags.
3. Contaminated disposable supplies should remain in control area until it has been decontaminated and cleared by the Radiation Safety Officer.
4. Contaminated equipment should remain in the control area until it has been decontaminated and cleared by the Radiation Safety Officer.
5. The Radiation Safety Officer is responsible for the proper disposal and handling of all radioactive waste.

I. Notification of appropriate authorities

1. The Radiation Safety Officer shall be responsible for notifying the California Department of Health Services and Radiological Safety Department of all incidents involving radiation contamination.

J. EQUIPMENT

All equipment listed below is to be kept in a common location in the ED physicians' room and may be transported to the control area as necessary during a suspected radiation contamination incident.

1. Disposable gloves
2. Shoe covers
3. Surgical caps
4. Surgical masks
5. Surgical full-length jumpsuits
6. Four (4) liters of sterile normal saline
7. Sterile wash basins
8. Sterile scrub brushes
9. Radioactive labels and ribbons
10. Absorbent pads
11. Absorbent paper
12. Masking tape
13. Scissors
14. Radioactive plastic bags for disposal
15. Specimen boxes, jars
16. Goggles

K. DOCUMENTATION

1. All procedures, measurements, treatments, responses to treatment, and names of staff involved in direct care of the radiation contamination patient shall be recorded in the patient's ED record and shall become part of the permanent record.
2. A log of all patients transferred to the hospital or admitted to the ED shall be kept with the date, time of admission, patient ID information and log number.

L. KEY POINTS

1. Radiation Safety Officers

   Physician
   VCMC: Dr. William Pace: 652-6185 (home number available through hospital Paging)

   Nuclear Medicine Technician (Radiation Safety Officer)
   Miguel Jimenez: 652-6185 (home number available through hospital Paging)
   ***Geiger counter is with the above persons.

2. Responsibilities of hospital staff
   a. Radiation Safety Officer
      i. Immediately upon notification of possible contamination, contact the ED charge nurse to determine all known details of the situation.
      ii. Report to the ED and, with the aid of the Nuclear Medicine Technician, determine that the following materials are available:
         1. Appropriate radiation survey meters.
         2. Radioactive labels, tape or ribbon, to establish barriers around control area.
         3. All available radiation monitoring devices for use by ED staff.
         4. Adequate protective clothing for all those entering the control area.
   b. Supervise the set-up of a control area at the east end of the ED entrance.
   c. Determination of need for decontamination
      i. If there is no external contamination and no likelihood of subsequent contamination to hospital staff attending the patient, the patient should be brought directly into the ED.
      ii. If there is any sign of external contamination upon breaking of the patient's skin, the patient should be decontaminated before being admitted to the hospital providing there are no life threatening injuries and it is deemed safe by the ED staff physician to undergo decontamination prior to care.
   d. Monitor the vehicle, driver, attendants and any equipment which are used in the transport of a contaminated patient to the hospital. If decontamination is necessary, they may be directed to the Morgue area prior to release from the hospital grounds.
   e. Radiation caution may be attached to the door of each vehicle used, as well as to all equipment used in transport of patients.
   f. If there is a possibility of radiation exposure to hospital staff, the Radiation Safety Officer will have the following responsibilities:
      i. When appropriate, provide the ED staff with radiation monitoring devices, ensure proper use, and follow-up on use.
      ii. Ensure that all persons (except patients) entering the decontamination site wear scrub suits, surgical masks, caps, gloves and shoe covers and other protective apparel, if necessary.
         1. For minor decontamination, only some of the protective items may be deemed

necessary.

2. Ensure that all protective clothing worn by staff is removed before leaving the decontamination site, even if only briefly, and is placed in the proper barrels for disposal.

iii. Continue to update the ED staff on radiation protection measures that should be taken as the situation changes.

iv. When exposure is finished, collect all monitoring devices from all persons to whom they have been issued, and arrange for evaluation of the exposure.

v. Oversee clean-up measures and arrange for safe disposal of contaminated items.

g. Where possible external contamination is involved, ensure that all the following items are saved, labeled with the name of the patient and the body location as well as the time and date:

i. All clothing (including clothing from the ambulance) is surveyed and discarded in a manner suitable to the contamination. If clothing is not contaminated, it can later be returned to the patient.

ii. All metal objects, including belt buckles, dental plates, etc.

h. Guidelines for the handling of external contamination:

i. The patient's clothing should all be removed as this will contain the bulk of external contaminating substances. This should be surveyed and discarded in a manner suitable to the contaminated. If the clothing is not contaminated, it can later be returned to the patient.

ii. Clean the skin with copious amounts of soap and water as often as is sufficient to remove all contamination. A soft brush or gauze pad may be used with care as to not break the patient's skin. Barriers need to be surveyed and decontaminated, if necessary. In no instance, should the hair be shaved, as this may cause internal contamination.

iii. All materials used in the decontamination process must be treated as though they were contaminated and will therefore remain in the decontamination area until they are surveyed and appropriately disposed.

i. Guidelines for handling internal contamination:

i. Internal contaminants may be trapped in the respiratory system or in the GI system. Moistened applicators may be used to obtain samples from the nares and mouth in suspected cases of internal contamination. These levels of radioactivity should be recorded.

ii. All open wounds should be surveyed with an appropriate survey meter, and if any contamination is found, the wound should be considered contaminated.

iii. All contaminated wounds should have specimen taken with cotton tipped applicator which should then be placed in individual envelopes with the patient's name, date and location of specimen.

iv. Decontamination of wounds should be undergone with copious amounts of irrigation, using sterile saline, and when appropriate, surgical debridement may be necessary. Consultation with attending physicians should be made if surgical debridement is deemed necessary.

v. Area should be resurveyed until radioactivity is less than 2x background, at which point patient should be deemed safe for entrance into the ED.

j. ED Staff Physician

i. When contamination is minor, patient should be decontaminated in the control area prior to admittance into the ED. Medical treatment may begin in the decontamination area.

ii. When contamination is considered major and presents a serious hazard to ED staff, it is preferred that the patient be taken to the Family Care Center via the outside entrance for decontamination procedures. Also, the Radiation Safety Officer may be used in making a decision as to decontamination prior to admittance to the ED. Medical care may be initiated in the Family Care Center when possible and in such instance all supplies will be transported to the Family Care Center under the supervision of the staff physician. It will be at the discretion of the ED treatment area. This decision should be based upon the need for immediate medical or surgical care of a life threatening injury.

iii. During a major contamination incident or a disaster, when the ED is at capacity, contaminated patients who are not in immediate need for medical care should be taken to the Family Care Center for decontamination prior to treatment.

k. Responsibilities of ED Charge Nurse

i. Obtain as much information as possible about the situation:

1. Type of contamination.
2. Extent of contamination (dose).
3. Field decontamination, if any.
4. Number of victims involved.
5. Nature of injuries, if not limited to radioactive contamination.

ii. Notify the following areas and staff:

1. Appropriate staff and ED physician
2. Hospital Administration (notify hospital Security)
3. Radiology Technician on duty

iii. Maintain log of all persons being transferred to hospital with prospective contamination

l. Senior member of Radiology Department present in hospital:

i. Notify the Radiation Safety Officer of the situation.

ii. VCMC Only: Inform the nuclear technician of the situation and instruct them to meet the Radiation Safety Officer in the ED.

iii. Work with the Radiation Safety Officer, as needed.

M. Contaminated Corpses:

1. Goal: Limit the spread of contamination within the hospital, protect transport staff and staff in the Coroner's Office.
2. If advised by the Radiation Officer, remove and double bag clothing.
3. If advised by the Radiation Officer, wash body as appropriate.
4. The corpse should be double body bagged.
5. A prominent label attached to the body bag indicates the corpse is contaminated and the nature of

the contaminant.

6. On the label place the name and number of the ED staff or person in the field who the Coroner or Pathologist can call for more information about the nature of contamination.

N. Reporting Requirements

1. Occupational Illness or Injury

   a. Illnesses or injuries occurring in the course of employment must be reported by the treating physician in a "Physician's First Report of Occupational Illness or Injury."

All revision dates: 12/1/2013, 6/1/2006, 11/1/2004, 1/1/1995, 10/1/1992

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Emergency Department Committee	Tracy Chapman: VCMC - Med Staff	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	5/3/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	5/3/2024
Policy Owner	Julia Feig: Clinical Nurse Manager, Emergency Services	5/3/2024

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*4/1/2017*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*7/10/2024*
Next Review:	*3 years after approval*
Owner:	*Julia Feig: Clinical Nurse Manager, Emergency Services*
Policy Area:	*Emergency Services*
References:	

ER.50 Hazmat Shower and Tent Use

POLICY:

It is the policy of Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) to provide care to patients who may have been exposed to hazardous materials, biological, chemical or radiological contamination, while simultaneously ensuring the safety of the Code Triage-Decontamination Response Team members, other hospital personnel and protect the hospital environment from contamination.

PROCEDURE:

This plan provides recommendations for protecting healthcare personnel and decontaminating victims who are known or suspected of being exposed or contaminated with a hazardous substance. The presence of a hazardous substance on a victims' skin, clothing or hair could jeopardize the health and safety of hospital personnel, other staff and visitors. Providing decontamination (decon) and medical care for victims exposed to a hazardous substance requires specialized training as specified in Occupational Safety and Health Standards 29 CFR 1910.120, 29 CFR 1910.132, 29 CFR 1910.134, and many other federal, state and industry standards. While this plan provides guidance for a majority of patient decontamination situations which could occur in a hospital setting, it is not all encompassing; thus optimal results will be based on sound knowledge and skills, team consensus and expert consultation.

RECOGNITION and INITIAL ACTIONS:

Contaminated victims may arrive with pre-notification or unexpectedly. When pre-notification is received, the reporting party should be transferred to the Emergency Department (ED) Charge Nurse, who will obtain pertinent information prompted on the Hazardous Material Incident Risk Assessment. The ED Charge Nurse will assign appropriate staff to the Decontamination Unit. A Decontamination Unit Leader will be identified. The Hazardous Materials response team must be notified through the Ventura City Fire Department by dialing 911 for VCMC and Santa Paula Fire Department and/or Ventura County Fire for SPH. When known, the type of toxin involved should be researched via a phone call to SDS fax on demand at (800) 451-8346 so appropriate treatment and/or antidotes may be initiated in the field. A Code Orange will be initiated to alert the hospital Hazardous Materials response team. If indicated, a Code Triage may be initiated.

Potentially contaminated patients will be refused entry inside a hospital facility until they are properly decontaminated.

A. If a contaminated patient is identified inside the hospital:

   1. Avoid physical contact keeping 3-6 ft. from the patient.

2. Redirect patient out of the hospital to a designated patient staging area.
3. Notify ED Charge Registered Nurse (RN) of the situation.
4. Provide privacy and have patient remove and contain clothing and personal items.
5. Arrange for transportation to the appropriate Decontamination Area.
6. Isolate the affected hospital area, until it is determined to be free of contamination.
7. Watch for other potentially contaminated patients.

B. If a contaminated patient arrives by ambulance or other vehicle:
   1. Keep the patient in or near the vehicle
   2. Redirect the vehicle to the appropriate Decontamination Area, if needed.
   3. Notify the ED Charge RN of the situation.
   4. Provide privacy and have patient remove and contain clothing and personal items if not already accomplished.
   5. Direct all other individuals and vehicles away from the Decontamination Area, except assigned Decontamination Unit personnel.

C. The following interventions may be implemented prior to decontamination in life threatening situations. Physicians and other hospital personnel involved must wear appropriate Personal Protective Equipment.
   1. Airway management
   2. Bleeding control
   3. Tension pneumo/hemothorax management
   4. Antidote administration

POLICY: THE DECONTAMINATION DECISION

The Decontamination Unit Leader or another assigned Unit member will obtain additional information from the patient, bystanders, or responders. The extent of decontamination to be performed will be based on (see Decontamination Algorithm):

1. Patient ALARA (**A**s **L**ow **A**s **R**easonably **A**chievable) exposure to contaminate: ALARA (5-15 minutes) vs. the critical nature of the victim's presentation.
2. The extent and source of contamination: light gas or vapor exposure vs. heavy liquid or solid contamination.
3. The toxicity of the hazardous substance and the route of exposure (inhalation, ingestion, absorption, injection)

Removal of clothing is the first and fastest way to reduce the level of contamination of victim(s). Removed clothing must be placed in a bag that is tied off.

1. **Dry decon:** includes removal of contaminated clothing, placing clothing into a tied off bag, cleaning the face, hands, neck, exposed areas of skin with a wet wipe, and changing into a clean set of clothes.
2. **Wet decon:** includes removal of contaminated clothing, placing clothing into a tied off bag, liberally washing exposed skin, hair with water and soap, rinsing and changing into a clean set of clothes.

Hospital Decontamination Units utilize three (3) general types of patient decontamination.

1. Dry Decontamination – Remove patients' clothing. Wash hands, face, and hair with wet wipes.
2. As Low As Reasonably Achievable (**ALARA**) – Remove patient's clothing
    a. Wash with soap and water (or other decontamination solution as directed) for a minimum of 1 minute. Face and wounds first
    b. Rinse continuously with water for a minimum of 1 minute
    c. Wash with soap and water for a minimum of 1 minute
    d. Rinse continuously withy water for a minimum of 1 minute
    e. Detect for residual contaminant if applicable
    f. Dry and redress

    NOTE: If unacceptable contaminant levels or significant signs and symptoms persist, consider repeating decontamination sequences.
3. Emergency Decontamination – Remove patient's clothing
    a. Wash with soap and water (or other decontamination solution as directed) for a minimum of 1 minute. Face and wounds first.
    b. Rinse all areas of body thoroughly.
    c. Rinse again all areas of suspected contamination.
    d. Dry and redress.

    Note: Decontamination to ALARA should be considered after patient is stabilized

PROCEDURE: PATIENT DECONTAMINATION

A. **Single Person Decontamination Shower**
    1. MINIMUM STAFF PROTECTION IN CHEMICAL DECONTAMINATION:
        a. Level D is the minimum level of personal protective equipment (PPE) required for securing, isolating, and denying entry of an ambulatory victim. It includes but is not limited to:
            i. LIQUID SPLASH PROTECTION
                1. Full face shield
                2. Hood or hair covering
                3. Gloves
                4. Water-repellant gown
                5. Water ~~repellant~~repellent boots / shoes covers
            ii. RESPIRATORY PROTECTION
                1. No respiratory protection needed for chemical decontamination.
        b. These PPE recommendations provide minimal protection, and act primarily as a barrier in the following situations:
            i. No staff contact or exposure to the contaminant is anticipated.
            ii. The chemical is known and is a low risk contaminant.

iii. Decontamination should be performed outdoors or in a well ventilated area.

iv. The patient must be ambulatory and able to fully understand and perform self-decontamination.

Single Person Decon Shower Procedure

1. See *Ambulatory Patients* section below under Hazmat Decontamination Tent Procedure.

B. **Hazmat Decontamination Tent**

1. SPECIALIZED STAFF PROTECTION IN CHEMICAL DECONTAMINATION
    a. Specialized Protection PPE Level: C
        i. LIQUID SPLASH PROTECTION
            1. Full face shield
            2. Chemical-resistant gloves
            3. Chemical-resistant suit
            4. Waterproof, chemical resistant boots
        ii. RESPIRATORY PROTECTION
            1. Powered Air Purifying Respirator (PAPR) with loose fitting hood and appropriate filter cartridge
            2. Air Purifying Respirator (APR) with appropriate filter cartridge
            3. Supplied Air Respirator (SAR) with loose fitting hood
    b. These PPE recommendations provide the specialized hazardous materials protection in the following situations:
        i. Non-ambulatory patients or ambulatory patients requiring direct assistance.
        ii. Potential or actual staff contact or exposure to the contaminant is anticipated.
        iii. For decontamination purposes, Level C is adequate unless there is a known contraindication for the filter cartridge in the PAPR or APR.

Hazmat Tent Decon Procedure

1. **Ambulatory Patients**
    a. Direct patient to Decon Staging Area.
    b. Children should be kept with their parents if at all possible; if no parent or older sibling is available then a Decon Team member should provide needed assistance to a child
    c. Patient should be given Personal Decon set as soon as it is available and be given rapid instructions on its use (**Hot Zone**).
        i. The kit stays with the patient as they proceed through the process.
        ii. Open up the bag – it has three parts.
        iii. Take out the plastic bags now.
        iv. Patient should quickly remove all clothing putting valuables into the clear plastic bag and clothing into large bag then put both bags into 3rd bag and cinch tight w/ tag number in pak.

Patient should put numbered tag around their neck and wear it through decon and treatment.

d. The clothing bag should be set aside in secure area.

e. If staff available, patients name and number should be recorded on Patient Decon Record.

f. Patient should continue forward into the Decon Sector with remaining part of Personal Decon Kit (**Warm Zone**).

g. Patient should quickly rinse themselves from head to toe with water using either the hand held sprayer, garden hose or shower head.

h. Patient should next wash with soap and wash cloth or brush from the kit in a systematic fashion cleaning open wounds first and then in a head to toe fashion for 5 minutes when the agent is non persistent and 8 minutes when a persistent or unknown agent is involved. Discourage the patient from rubbing too vigorously while washing. Eye irritation may require the use of a topical anesthetic first before irrigating.

i. The Decon Team should closely observe each victim to ensure they are thorough in washing themselves. Particular attention should be made to ensure they wash the axilla, creases, folds and hair. Help should be offered as necessary.

j. Once the washing is completed then each patient should thoroughly rinse themselves (this should require about a minute to complete).

k. Decon soap bars, wash cloths, brushes and sponges should be put into a nearby trashcan and NOT carried into the Cold Zone.

l. After the rinse/wash/rinse cycle is complete the patient should next proceed to the towel off area and complete drying off and leave towel in trashcan (**Cold Zone**).

m. Following drying off the patient should put on the patient gown and proceed to the Triage Nurse for rapid assessment and assignment to a Treatment Sector.

n. Additional treatment will be limited only to those interventions deemed life-saving by the Decon Officer and /or physician. Antidote administration should be done via the IM route after cleaning the affected area first.

o. Decon Team members should be alert to the possibility that an ambulatory patient may clinically deteriorate and require immediate removal to the Non Ambulatory Sector via backboard, stretcher or wheelchair.

2. **Non-Ambulatory Patients**

a. Patient should be brought to the Decon Staging Area and tended to by a minimum of 4 decon personnel.

b. Each patient should be put onto a backboard or ~~EMS~~ stretcher w/ the pad removed.

c. All patient clothing should be removed and valuables put into the clear plastic bag and clothing into large bag then put both bags into 3rd bag and cinch tight w/ tag number in ~~pak~~pack. Clothing should be cut away where necessary (**Hot Zone**).

d. Attention should be paid to minimizing the aerosolization spread of particulate matter by folding clothing inside out as removal is being done and dabbing the skin with sticky tape and or vacuuming.

e. Patient should have their clothing bag tag around their neck and wear it through decon and treatment.

f. The clothing bag should be set aside in secure area if staff available, patients name and number should be recorded on Patient Decon Record.

g. While resting the backboard on saw horses or other device or with patient on ~~EMS~~ stretcher the patient should quickly be rinsed from head to toe with water using either the hand held sprayer, garden hose or shower head; protection from aspiration of the rinse water should be initiated (**Warm Zone**).

h. Next, the patient should be washed with soap and either a brush or wash cloth in a systematic fashion cleaning airway first followed by open wounds then in a head to toe fashion for 5 minutes when the agent is non persistent and 8 minutes when a persistent or unknown agent is involved. Avoid rubbing too vigorously.

i. The patient should be rolled on their side for washing of the posterior head, neck, back, buttocks and lower extremities by 2- 4 personnel; attention to a possible neck injury should be given.

j. Careful attention should be given to washing the voids and creases such as the ears, eyes axilla, and groin.

k. Topical eye anesthetic maybe required for effective eye irrigation to be done.

l. The patient should then be rinsed in a head to toe fashion that minimizes contamination spread for about one minute. Overspray or holding the rinsing device too close so as to irritate the skin should be avoided.

m. Decon Team members should be alert to the probability that the non-ambulatory patient may require airway, breathing and circulation (ABC~~'s~~) support (airway positioning, suctioning, O2 administration, spinal stabilization etc.) and administration of life saving antidote administration by intramuscular injection (IM) injection. If intravenous (IV) therapy is needed the extremity site for the IV should be decontaminated quickly before the IV is started. If IV therapy is needed the patient should be pulled out of line in the Decon Corridor but remain in the Decon Sector. Cardiopulmonary resuscitation (CPR ~~or~~) or advanced cardiac life support (ACLS) intervention should not be started unless there are no other patients awaiting decontamination

n. The patient should be dried off, put into a hospital gown and transferred to a clean backboard (or clean off and dry the board they are on if additional boards are not available). Patients on ~~an EMS~~a stretcher should be transferred to a clean backboard (**Cold Zone**).

o. Decon soap bars, brushes and sponges should be put into a trashcan and not carried into the Cold Zone. ~~O2 materiel~~Supplemental oxygen materials should remain in the Decon Sector

p. The patient should be taken to the Triage Nurse for rapid assessment and assignment to area in the Treatment Sector.

3. **PATIENTS WITH SPECIAL NEEDS**

a. Glasses/Contact Lenses

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

ii. Contact lenses should be removed and placed in the valuables portion of the clothing bag.

b. Canes/ Walkers

i. Patients who use walking assist devices may retain them but, the devise must be washed with

soap and water during the decon process before being allowed into the Treatment Sector.

ii. Patients who are unsteady standing and or walking should be given a walker upon entry into the Decon Corridor. The walker should be used to assist with ambulation until they get to the end of the line when it should be retrieved, deconned and returned to the front of the Decon Corridor for the next patient who needs it.

c. ~~PIC~~Peripherally Inserted Central Catheter (PICC) Lines/ Saline Locks

i. Unless contaminated PIC lines and saline locks should be covered with ~~Tegoderm~~Tegaderm or Saran wrap before the area is decontaminated.

ii. Contaminated PIC lines or saline locks should be removed before being decontaminated. After the area is cleaned a dressing should be applied until in The Treatment Sector where antibiotic ointment and a new bandage should be applied.

d. Hearing Aids

i. Hearing aids CANNOT be immersed or otherwise be soaked with water. Thus, they should either be removed and placed in the valuables portion of the patient's clothing bag or if they must be used by the patient because there is no hearing without them they should be carefully wiped off with a slightly saline moistened 4x4 gauze, dried off, put into a clear plastic bag and handed to the patient. The cleaned hearing aid is NOT to be worn until the patient has completed the decon process (including washing the ears) and is in the Treatment Sector.

e. Dentures

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

ii. If the oral cavity is contaminated then the dentures should be removed, placed in a clear plastic bag with the patient's name or clothing identification number placed on it. The dentures should later be decontaminated in accordance with instructions received from the Poison Center and/or a dentist. The patient's mouth should be decontaminated with mouthwash or saline that is gargled and safely spit out into a bio-hazard bag.

f. Law Enforcement Officers with Weapons

i. In most cases law enforcement personnel who have been injured on the scene will have had their gun(s) removed before arrival and given to a fellow officer. However, if that is not the case the weapon should be left in the holster and the gun belt removed by a Decon Team member and placed in a clear plastic bag labeled with the patient's name and/or clothing number. The bag should then be passed to the Treatment Sector where it should be given to a fellow officer or hospital Security Officer for safe keeping until it can be given to a representative of the injured officers department. **THE GUN SHOULD BE LEFT IN THE HOLSTER IF AT ALL POSSIBLE.** If the gun must be removed it should be handled by a Decon Team member familiar with firearms, rendered safe, placed in a clear plastic bag marked with the patient's name and/or clothing identification number and given to a fellow officer or hospital Security Officer in the Treatment Sector.

ii. Decon Team personnel should be aware that often times an officer may have a backup weapon usually found in a holster near the ankle, in their pocket, in a ballistic vest or near an armpit. The holster with the weapon in place should be removed and secured as described above.

iii. An officer's gun belt may also contain items that could prove dangerous if allowed to get in the wrong hands. Thus, the belt should be collected and separately bagged ASAP and passed to a

fellow officer or hospital Security Officer in the Treatment Sector. ~~**DECONNING**~~**THE DECONTAMINATION OF AN OFFICER'S WEAPON AND/OR GUN BELT WILL BE THE RESPONSIBILITY OF THE POLICE DEPARTMENT.**

iv. If the Officer is wearing a ballistic vest it must be removed prior to undergoing decon. The vest is usually easily removed by loosening the Velcro straps and then pulling the vest apart and then off the patient. It should then be placed in a large plastic bag identified with the patient's name and /or clothing number on it and then passed to a fellow officer or Hospital Security Officer in the Treatment Sector.

HAZARDOUS WASTE STORAGE, DISPOSAL CRITERIA & RECORD KEEPING

Refer to Administrative Policy 106.035 for information on storage, disposal and record keeping Hazardous materials at VCMC and SPH.

DECONTAMINATION UNIT STAFFING

Facilities Maintenance, Security, and Environmental Services (EVS) staff have the primary responsibility of staffing the mobile decontamination facility (tent). A minimum of 5 trained staff members are required to effectively implement any decontamination operation. In the event of a large scale event, Decontamination Triage will be required, which will require an additional two trained clinical staff members to perform.

NOTE: This plan assumes a minimum of five (5) trained staff members are available to perform decontamination activities. If there is an insufficient number of trained staff available, call 9-1-1 and request assistance from Fire Department(s).

ReddiNet, or Ventura County Emergency Medical Services (EMS) agency at 805-981-5301 should also be immediately advised of situation.

DECONTAMINATION FACILITIES AND EQUIPMENT

Ventura County Medical Center and Santa Paula Hospital are equipped with facilities and equipment in which to implement limited individual and mass decontamination.

Primary Decontamination Area:	Exterior Shower in ED
Mobile Decontamination Tent:	External 2 lane tent

NOTE: Mobile facility should only be utilized when primary decontamination capabilities are exceeded.

DECONTAMINATION UNIT STRUCTURE AND OPERATIONS

The Incident Command System will be utilized as the basic structure for all hazardous materials decontamination operations. The Decontamination Unit will consist of a Decontamination Unit Leader, Decontamination Operations Team, and Decontamination Support Team, when possible. In the case of multiple patients, a Decontamination Triage Team may also need to be established. The Hazardous Materials Technical Specialist will serve as a subject matter expert in person or by telephone on all decontamination

operations.

A written After Action Report (AAR) will be completed on all hazardous materials decontamination operations. For large scale decontamination efforts, a standardized, written Incident Action Plan will be completed. The Incident Action Plan will consist of the following:

- Hazardous Material Incident Risk Assessment
- Decontamination Incident Action Plan
- Decontamination Medical Monitoring and Debriefing Form

The Decontamination Unit Leader is appointed by the Incident Commander or Emergency Department Charge Nurse and organizes and directs decontamination operations. The Unit Leader is responsible for conducting pre and post incident briefings. The Unit Leader oversees hazardous substance identification, security and set up of the decontamination area, donning and doffing of personal protective equipment, and implementation and termination of decontamination procedures, including the completion of documentation. The Team Leader will brief the Hazardous Materials Technical Specialist on the nature of the incident, patient condition, protection and procedures implemented and clean up/containment measures taken. Once it has been determined which decontamination process is required, the Emergency Treatment Area (ETA) will be configured.

The Decontamination Operations Team is primarily responsible for the actual decontamination of the patient(s). The minimum team will consist of two operations trained team members and one safety observer. The Operations Team will also assure security and control of the Decontamination Reduction Zone. The Operations Team will attend all briefings, supervise and assist with patient decontamination, and perform initial cleanup of the area. The Decontamination Ops Team is required to have medical monitoring performed pre and post incident.

The Decontamination Support Team will consist of a minimum of two operations trained staff members. Support personnel will assist the Operations Team with medical monitoring, equipment set up, and donning/doffing of personal protective equipment. Support personnel will monitor the Operations Team and patients during decontamination, providing equipment and supplies as necessary. The Support Team will receive the patient after decontamination and perform hazardous materials monitoring as directed before transferring care to other Emergency Department staff.

The Decontamination Triage Team, IF NEEDED, will consist of a minimum of two (2) clinical providers trained to operations level. The Triage Team is responsible for sorting patients based on level of contamination/exposure vs. severity of injury. Triage personnel will reevaluate and direct patients to a wet decontamination area or secondary treatment area based on degree of the symptom resolution after dry decontamination.

Security and/or law enforcement will serve as the decontamination area control team. A Security officer will be designated for area security and traffic direction as necessary. The Security officer will assure an appropriate chain of custody for any evidence and patient property as coordinated with the Hazardous Materials Technical Specialist and jurisdictional law enforcement officials.

The Ventura City Fire Department serves as the response team for inside city limits; Ventura County Fire Department may assist as requested. Emergency response personnel are trained at the technician level to meet competencies as outlined in NFPA 472 standards. These standards include control techniques, use of personal protective equipment, and containment equipment, and other specialized resources. Hazardous Materials Team response vehicles are equipped with emergency response reference materials, guidebooks and specialized equipment, including computers and data management software. In the event that Ventura County Medical Center and Santa Paula Hospital staff at this level are not available, mutual aid will be

requested to fulfill this role.

HAZARDOUS SUBSTANCE IDENTIFICATION

Hazardous substance identification is a critical activity that provides a foundation for safe and effective staff protection, patient decontamination, and subsequent patient treatment. While the Decontamination Unit Leader alongside the Hazmat Medical Technical Specialist are ultimately responsible for substance identification, input should be solicited from other team members and emergency department physicians as necessary. The Hazardous Material Incident Risk Assessment will be utilized to determine initial characteristics of the involved hazardous substance and the extent of decontamination.

The Hazardous Material Incident Risk Assessment will be completed to document the chemical name, physical form, exposure symptoms, clinical effects, emergency treatment, compatibilities, and personal protection equipment needed.

A minimum of three (3) valid resources will be used to determine Substance Identification. Acceptable resources include:

- NIOSH databases
- Emergency Response Guide
- Shipping papers
- Safety Data Sheets
- Pharmacists
- ChemTrec – (800) 424-9300
- Micromedex/TOMES
- Radiation Emergency Assistance Center/Training site – (865) 422-8737
- City of Ventura Fire Department HAZMAT Team
- County of Ventura Fire Department HAZMAT Team

Local Area Contacts/Resources

- Local law enforcement – 9-1-1
- Local Federal Bureau of Investigation/Ventura – (805) 642-3995 or (310) 477-6565
- Fire/Rescue – 9-1-1
- Ventura County Public Health Department – (805) 981-5331
- Ventura County Emergency Medical Services Agency – (805) 981-5301
- Ventura County Office of Emergency Services-Sheriff's Department - (805) 654-2551
- State of CA, Environmental Protection Agency – (800) 300-2193
- State of CA, Department of Toxic Substances Control – (818) 551-2800

PERSONAL PROTECTION and SAFETY

During a hazardous materials decontamination operation the principles of hazard reduction, contamination avoidance, and personal protection are used in combination to enhance safety for the patient and members of the decontamination unit. Personal protective equipment must be carefully selected to meet the needs identified in the substance identification process. PPE ensembles are composed of different levels of chemical protective clothing combined with respiratory protection. Ventura County Medical Center and Santa Paula Hospital decontamination operations will utilize the following levels of protection based on the substance Identification process.

NOTE: All hospitals in Ventura County have been provided Level C PPE ensembles via Health Resources and Services Administration (HRSA) Funding. All hospitals are stocked with Level D PPE. For any substance identified wherein LEVELS A OR B PPE are required for staff protection, the local fire department MUST be contacted to provide LEVEL A OR B support services. Ventura County Medical Center and Santa Paula Hospital do not maintain Level A or B personal protective equipment.

LEVEL C – Splash protection with air purifying respirator. This ensemble at a minimum will include a CPF 2 level chemical suit (Operations Team) or CPF 1 (Support Team), high efficiency particle arresting (HEPA) mask

and goggles, over boots, nitrile gloves. A half or full face air purifying respirator, or power air purifying respirator with appropriate cartridges will provide a higher level of protection and will be available at the discretion of the Decontamination Unit Leader. If the contaminant is suspected to be biological or radiological in nature, a ~~TYVEK~~100% synthetic material suit made from high-density spunbound polyethylene fibers (brand name: Tyvek) may be utilized as an alternative.

LEVEL D – Splash protection without respiratory protection. This ensemble at a minimum will include a CPF 1 level or ~~TYVEK~~Tyvek suit, goggles, nitrile exam gloves and over boots.

As a standard the Support Team will wear no less than one level lower than the operations team during a decontamination operation. Decontamination Unit staff should be encouraged to use higher levels of protection when significant levels of contamination are suspected, substance toxicity is high, or team consensus dictates.

Medical Monitoring will be performed on all Decontamination Ops team members prior to donning and after doffing of personal protective equipment. As a minimum temperature, blood pressure, pulse rate and respiratory rate will be included in medical monitoring and will be recorded on the Medical Monitoring Debriefing Form (see attachments). Donning of PPE may be denied to any team member based on established exclusionary criteria.

Heat stress is a potential complication of donning chemical protective clothing. Team members must pre-hydrate with water prior to and after decontamination operations.

Appropriate air monitoring will be implemented during decontamination operations to assure that the appropriate personal protective equipment is being utilized, and to reduce the possibility of vapor exposure.

Decontamination team members who will be serving as a decontamination operations or support team member will complete a medical evaluation to include Respirator Screening Questionnaire annually with the Occupational Health Department. In addition, fit test will be completed annual on any tight fitting respirators to be utilized during decontamination operations.

Attachments:

A. Hazmat Decontamination Algorithm
B. Medical Monitoring Debriefing Form: PAPRs
C. Hazardous Materials Incident Risk Assessment Form
D. OSHA Respirator Donning Medical Evaluation Form

References

EMSA California. (2005). Patient Decontamination Recommendations for Hospitals. Retrieved from

http://www.emsa.ca.gov/Media/Default/PDF/emsa233.pdf

OSHA. (2017). Hazardous Waste: Decontamination. Retrieved from https://www.osha.gov/SLTC/hazardouswaste/training/decon.html

WHO. (2014). Initial Clinical Management of Chemically Contaminated Patients. Retrieved from http://www.who.int/environmental_health_emergencies/deliberate_events/Initial_Management_of_Contaminated_Patients.pdf

All revision dates: 7/10/2024, 4/1/2017

Attachments

A: VCMC & SPH Hazmat Decontamination Algorithm
B: VCMC & SPH Medical Monitoring Debriefing Form: PAPRs
C: VCMC & SPH Hazardous Materials Incident Risk Assessment
D: VCMC & SPH Respirator Donning Medical Evaluation Form

Approval Signatures

Step Description	Approver	Date
Emergency Department Committee	Stephanie Denson: Interim Manager, Medical Staff Office	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/10/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/10/2024
Policy Owner	Julia Feig: Clinical Nurse Manager, Emergency Services	7/10/2024

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*7/10/2024*
Effective:	*N/A*
Last Approved:	*N/A*
Last Revised:	*N/A*
Next Review:	*N/A*
Owner:	*Julia Feig: Clinical Nurse Manager, Emergency Services*
Policy Area:	*Emergency Services*
References:	

ER.52 Suicidal Ideation Patient Safety Precautions in the Emergency Department

POLICY:

Ventura County Medical Center (VCMC) and Santa Paula (SPH) Emergency Departments (~~ER~~ED) will identify patients at risk of self harm and provide a safe environment of care for those assessed to be be at risk due to suicidal ideation.

DEFINITIONS:

1. Line of Sight - a straight line along which an observer has unobstructed vision.
2. Observer - an assigned health care worker, or provider, posted to maintain continuous visual observation of the patient.

PROCEDURE:

Registered nurses (RNs), or Licensed independent providers (Physicians, Nurse Practitioners, or Physician Assistants), will identify patients at risk for serious self-harm due to suicidal ideation.

A. **Admission**

1. Prior to admission:

a. Remove all sharp objects.

b. Remove unnecessary monitor cables, unnecessary cords, shoe laces, and equipment .

c. Remove the telephone.

d. Remove call bell cord and utilize push buttons.

e. Remove bottles/containers of solutions.

f. Limit linen in room, ensure linen cabinet is locked.

g. Remove trash can and place outside of the room.

h. Remove ~~O2~~oxygen tank from under bed.

i. Anything that can be removed from head wall, should be removed.

j. Bedside cart, tables and trays should be removed from the ~~rom~~room.

k. Gloves should be removed.

l. Remove any additional furniture from room .

m. If hand sanitizer can be removed, remove bottle from room.

n. Place a sign on the door stating visitors must report to the nurse's station prior to entering room.

o. Visitors are not permitted to take anything into room; this includes what may be in their pockets which could be used to cause harm. The physician may order "No Visitors" if appropriate and necessary for patient safety.

p. Patient belongings are searched upon arrival for potential self-harm items or contraband

q. If assistance is needed to perform this function, upon request of the nurse ~~the~~, law enforcement or security may help

2. On admission to room ~~RN responsibilities~~, the registered nurse is responsible for:

a. Explain to the patient & family that the patient is on suicide precautions for their safety

b. Immediately place patient on constant 1:1 observation

i. Patient will remain 1:1 until a psychiatrist determines it is unnecessary

ii. The patient safety attendant should be the same gender as the patient whenever possible

iii. Family members are not permitted to provide 1:1 observation

c. Assist patient into paper scrubs or hospital gown with buttons

d. Search all belongings, including pockets in clothing and purse/bags:

i. This is to be done by two VCMC/SPH employees in the patient's presence

ii. Items which can be used for self-harm include but are not limited to:

- Belts
- Shoelaces
- Cell phones/phones
- Magazines (staples)
- Ties
- Necklaces
- Medications brought by the patient (~~OTC~~over the counter and prescription)
- Other dangerous items~~-~~ but not limited to: i.e. glass, scissors, knives, razors, nail files, belts, electrical appliances/cords, lighters, scalpels, cleaning chemicals, ink pens worn around the neck, shoe laces, alcohol foam, compact with mirror, phone cord or any items which could be used to harm patient/ staff

iii. Contraband will be turned over the VCMC/SPH Security:

- Knives
- Any device which can lead to significant bodily harm

iv. Law enforcement can/will remove:

- Illicit drugs
- Guns

- Any illegal weapons

v. Explain to the patient that we are doing this for their safety and according to policy

vi. If the patient's physical person is searched, a staff member of the same gender as the patient must assist in carrying out the search

vii. May request security or law enforcement to assist with searching

~~viii. Family members are not permitted to provide 1:1 observation~~**viii. Family members are not permitted to provide 1:1 observation**

e. Enter/confirm diet order includes comment:

i. When ordering meals no sharp objects are placed on tray.

B. Assessment:

1. Patients must be assessed by RN on admission, each shift and with any reported change in behavior:

~~a. Patients must be assessed by RN on admission, each shift and with any reported change in behavior:~~

i. The last time the patient had thoughts about hurting him/herself

ii. The way the patient thought about doing this

iii. How the patient was able to stop him/herself from doing this

iv. If psychotic, ask if the voices tell the patient to harm him/herself and if other people may be trying to harm to the patient

2. *If patient is found to be at risk for serious self-harm due to suicidal ideation upon assessment by RN, immediately place patient on *Suicide Precautions and notify physician and get an order for Suicide Precautions*.

C. Interventions:

1. **Suicide Precautions* will be initiated upon suspicion of serious self-harm due to suicidal ideation or determination by provider.

~~2. **Suicide Precautions* will be initiated upon suspicion of serious self-harm due to suicidal ideation or determination by provider~~

~~3~~2. *Suicide Precautions* will remain in effect until a provider evaluates the patient and deemed them no longer at risk. *A providers' order must be obtained to discontinue suicide precautions.

~~4~~3. Based on physician discretion, if the patient requires chemical restraint, if they are a danger to themselves or others and are not alert to person, place and time or extreme agitation.

~~5~~4. Refer to Restraint policy based on physician order

~~6~~5. Consult ED physician for behavioral issue.

~~7~~6. Charge nurse will:

a. Place patient in preferred room with security supervision or safety attendant

b. Arrange break times and periodically check to validate constant surveillance of patient.

c. Verify that safety attendant knows patient is on Suicide Precautions and reviews the Suicidal Patient Policy.

d. Notify security for any patient behavior escalation, such as disputes or disturbances.

8. Primary Nurse will:

a. Verify practitioner's order for *Suicide Precautions*.

b. Assess patient for risk of serious self-harm due to suicidal ideation each shift.

c. Inform patient of suicide precautions, including items prohibited in the patient's room, and explain patient's plan of care for that shift.

d. *Patient is restricted to room unless determined by psychiatrist that ambulation is beneficial and safe.

e. Collaborate with safety attendant to address patient's safety care needs for the shift.

f. Search patient's room and belongings on admission and at the beginning of each shift to remove potentially harmful items. Contents of patient's belongings will be documented in the patient's chart. Another VCMC employee must serve as a witness during the search. RN-RN ~~handoff~~hand off should include care nurse of off-going shift and on-coming shift:

i. Every search or seizure will be documented. Documentation will include:

- Scope of search
- Reason for search
- Procedures in search
- Description of any property seized
- Account of disposition of seized property

g. Potentially harmful items include: glass, scissors, knives, razors, nail files, belts, electrical appliances or cords- including telephone cords, lighters, scalpels, cleaning chemicals, ink pens worn around the neck, shoe laces, medications (either prescription or over the counter), alcohol foam, consider any item which could be used to cause harm to patient or staff. Any items identified as contraband will be handled according to the Suicidal Patient Policy.

h. All visitors will check with primary/charge nurse prior to entering the room. A sign will be placed on the patient's door instructing the visitors to check at the front desk. For any packages brought by visitors to patient, permission will be requested to search these packages for potentially harmful items. If harmful items are noted, they will be removed and given to the visitor to take home when they leave. If permission is not provided, the packages will not be allowed into the patient's room.

i. Primary nurse will observe patient taking all medications. Collaborate with Pharmacist to obtain liquid medications when possible. Check patient's mouth to verify that medication was swallowed. Do not leave medications at the patient's bedside or with the safety attendant.

j. When ordering meals no sharp objects are to be placed on tray. Verify this order is accurate.

k. Document patient behavior and inappropriate language every shift and with any change in behavior.

l. If patient needs to be restrained, there must be ~~a standing~~an order from the physician.

9. The assigned observer will:

a. Patients require **continuous line of sight**.Patients should be watched for signs of possible or actual intentional or unintentional harm to self, unpredictable behaviors that place the patient at risk of injury, and rapid changes in the patient's ability to think clearly.

b. Check in with primary nurse upon arrival to the unit. Review the guidelines for working with patients on Suicide Precautions. Pre-arrange break times at the beginning of the shift, one 30 minute lunch break, with the charge nurse and communicate with charge nurse to assure continuous coverage for the patient. Give report to next safety attendant upon their arrival.

c. Introduce yourself to patient and explain how long you will be with them. Identify how you will meet their patient care needs.

d. Get report from the primary nurse about what care the patient will require during your shift.

e. Complete all patient care as listed below but not limited to:

i. Vital signs (to include blood pressure, temperature, respirations, and pulse) and complete intake and output.

ii. Personal care: bathing, mouth, skin, hair care and linen change.

iii. Assist with ambulation, turn and position every 2 hours, range of motion.

iv. Assist with meals.

v. Perform accuchecks (once competency is complete)

vi. Observe standard precautions, contact, and respiratory isolation.

vii. Offer bedpan, urinal, and collect test specimens as requested.

viii. Provide hourly documentation of the patient.

f. Never leave the patient alone in the room. Patient must be in eyesight at all times. Do not allow the patient to go off the unit, except for ordered and prearranged tests that have been cleared by the primary nurse. Patients on suicide precautions are not allowed to go off the unit to smoke.

g. Families cannot observe the patient, only a hospital employee. Do not leave the patient alone with a family member or visitor.

h. If a patient must leave the unit for a test or procedure, you must accompany them. Notify the primary nurse before leaving the unit with the patient. You must remain in the room if the patient has visitors.

i. Wait for scheduled breaks and relief person. Do not leave the patient unattended at the end of your shift. You MUST wait to leave until the next patient care attendant arrive.

j. Doors to patient’s room and bathroom must remain open at all times. Use curtain to ensure patient’s privacy.

k. Always remain between the patient and the door. Sitting on the opposite side of the room from the door puts you at risk of harm if the patient becomes violent, and could permit the patient to elope from the room.

l. Notify primary nurse of changes in patient behavior immediately. Behavior that requires immediate attention such as a change in level of alertness, pulling at IV lines, tubes, restraints, verbal threats, yelling, or refusal to comply with requests must be reported to the patient's primary nurse.

m. Use the call light when needed. If necessary and urgent, yell for assistance.

n. Remain alert at all times. Notify the nurse if you become sleepy. You are not allowed to sleep in the room.

o. Check meal tray before and after the patient eats for presence of utensils. All trays should only contain paper and plastic dinnerware. Make sure all dinnerware is returned to the tray and discarded and notify

primary nurse if items are missing.

p. Promote a safe and caring environment. Remain calm at all times.

q. Give primary nurse feedback on patient response to nursing interventions.

r. Maintain patient confidentiality.

s. Tell the patient what you are going to do before you do it.

t. Avoid giving advice to the patient. Do not argue with the patient. Tell the patient to discuss problems or feelings with the doctor or nurse.

u. Do not become a "pal" with the patient, try to "cheer up" the patient, burden the patient with tales of your personal life, or have the patient become your friend. Do not share personal information with the patient. Let the patient know you are uncomfortable if questioning becomes too personal.

v. Focus your activities on the patient. Do not use cell phones or electronic gadgets. No reading, eating or drinking in patients room.

w. Use the patient's room phone or your work phone only to call for resources. Check with the nurse to find out what activities you could do with the patient, such as watching TV, drawing or writing, playing cards or games, etc.

x. Do not wear hair down, dangling earrings, neckties, ink pens around the neck, or other objects, which could be used to injure the patient or staff.

y. Ensure no items such as tourniquets, syringes, and/or needles are left in the room.

z. Refer visitors to nurse if they bring belongings, packages, etc.

10. Hand-off process:

a. If patient is admitted to another unit (i.e. Inpatient Psychiatric Unit) through the Emergency Department with suicide precautions in place, a patient attendant or other competent personnel must accompany patient to the unit from the ED.

b. No patient will be discharged from the ED without being accompanied by security or law enforcement and primary nurse.

c. Patient belongings which are determined to have potential for self-harm, will not be handed back to patient until Suicidal Precautions are discontinued or items are sent home with family. Final disposition of patient items will be documented and included in verbal hand-off to receiving unit.

All revision dates:

Attachments

No Attachments

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*3/1/2009*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*7/5/2018*
Next Review:	*3 years after approval*
Owner:	*Matt McGill: Director, Imaging Services*
Policy Area:	*Imaging Services*
References:	

IS.28 Patient Transport to Imaging Services

POLICY:

Ventura County Medical Center and Santa Paula Hospital (VCMC/SPH) Imaging Services staff will take all reasonable precautions to prevent patients from falling during transport.

PROCEDURE:

A. The ambulatory status of each patient will be assessed. Patients that are functionally ambulatory (patients are functionally ambulatory if they normally walk without assistance at home and they are not debilitated with illness or medication at the time of the stay) can walk to a different department; those that are not will be taken by wheelchair or gurney respective of their condition. In addition, two or more people will assist with transfers of nonambulatory patients,
    i. Assessment of the patient will take into account:
        1. The ambulatory status of the patient.
        2. The possibility of an altered status resulting from the medication.
        3. The possibility of an altered status due to illness.
        4. The possibility of decreased strength from a period of non-ambulation.
        5. Any other condition affecting strength and coordination.
B. All inpatients will be transported to the CT scanners via a gurney to wheelchair only. All inpatients will be transported to MRI scanner Zone 3 via MRI-safe gurney or MRI-safe wheelchair only.
C. VCMC/SPH employees will use the safety rails on wheelchairs, gurneys and lifts used for transporting patients to and from the scanner.

All revision dates: 7/5/2018, 4/1/2012

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medicine Committee	Tracy Chapman: VCMC - Med Staff	pending
Imaging Services	Matt McGill: Director, Imaging Services	6/4/2024
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	3/13/2024

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*11/1/2004*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*4/11/2024*
Next Review:	*3 years after approval*
Owner:	*Jennifer Ferrick: Director, Peds/ PICU & NICU*
Policy Area:	*NICU*
References:	

N.29 High Risk Infant Follow-Up Program (HRIF)

POLICY:

To define admission criteria for the High Risk Infant Follow-Up (HRIF) Program/Clinic.

PROCEDURE:

Admission to the HRIF Program is defined by a specific set of criteria established by California Children's Services (CCS) for the purpose of evaluating the growth and development of infants at risk for developmental delays. Age of infants eligible for the HRIF Program can be at anytime after birth up to the child's third birthday. Referrals for follow-up are made as problem areas are identified.

A. **Medical Eligibility:**

Entry in to the HRIF Program is limited to those infants who meet the following medical eligibility requirements and who have met CCS medical eligibility criteria for NICU care or had a CCS eligible medical condition during their stay in a CCS-approved NICU, even if they were never CCS clients during their NICU stay.
Also, the program is available to infants who have a CCS eligible medical condition on discharge.

An infant shall be medically eligible for the HRIF Program when the infant:

1. Met CCS medical eligibility criteria for NICU care, in a CCS-approved NICU (regardless of length of stay) (as per Numbered Letter 05-0502, Medical Eligibility in a CCS-approved NICU).

   Or

2. Had a CCS eligible medical condition in a CCS-approved NICU (regardless of length of stay), (as per California Code of Regulations, Title 22, Section 31800 through 41872, CCS Medical Eligibility Regulations).

   And

1. The birth weight was less than 1500 grams or the gestational age at birth was less than 32 weeks.

   Or

2. The birth weight was 1500 grams or more and the gestational age was 32 weeks or more and one of the following criteria was met during the NICU stay:

a. Cardiorespiratory depression at birth (defined as pH less than 7.0 on an umbilical blood sample or a blood gas obtained within one hour of life) or an Apgar score of less than or equal to three at five minutes or an Apgar score less than 5 at 10 minutes.

b. A persistently and severely unstable infant manifested by prolonged hypoxia, acidemia, hypoglycemia and/or hypotension requiring pressor support.

c. Persistent apnea which required medication (e.g. caffeine) for the treatment of apnea at discharge.

d. Required oxygen for more than 28 days of hospital stay and had radiographic finding consistent with chronic lung disease.

e. Infants placed on extracorporeal membrane oxygenation.

f. Infants who received inhaled nitric oxide greater than four hours for persistent pulmonary hypertension of the newborn.

g. Congenital heart disease requiring surgery or minimally invasive intervention.

h. History of documented seizure activity. or receiving antiepileptic medication at time of discharge

i. Evidence of intracranial pathology, including but not limited to, intracranial hemorrhage (grade II or worse), periventricular leukomalacia, cerebral thrombosis, cerebral infarction, developmental central nervous system (CNS) abnormality or "other" CNS problems associated with adverse neurologic outcome.

j. Other problems that could result in a neurologic abnormality (e.g. history of CNS infection, documented sepsis, bilirubin in excess of usual exchange transfusion level, cardiovascular instability, hypoxic ischemic encephalopathy, et cetera).

B. **Age Eligibility:**

The child shall be eligible from birth up to the child's third birthday.

C. **Residential Eligibility**:

The Ventura County CCS Program is responsible for determining whether the parent or legal guardian of a HRIF Program applicant is a resident of Ventura County per CCS policy.

D. **Financial Eligibility**:

A financial eligibility determination is not required for the HRIF Program when services are authorized and funded as diagnostic services, i.e. infant not eligible for the CCS Program.

PROCEDURE

A. Infants meeting the eligibility criteria are admitted to the HRIF Program.

B. A comprehensive history and physical examination including neurologic assessment usually performed at approximately 4 to 6 months, 9 to 12 months, and 18 to 36 months of age. Exams up to a total of 3 during the 3-year eligibility period may be completed by a physician or a nurse practitioner under the direction of a physician.

C. A developmental assessment (equivalent to Bayley Scale of Assessment). Usually performed at approximately 4 to 6 months, 9 to 12 months and 18 to 36 months of age. Each assessment, up to a total of 3 during the 3-year eligibility period may be performed by a physician, nurse practitioner, physical

therapist, occupational therapist, or developmental specialist who has trained in the evaluation of motor and sensory development of high risk infants.

D. A family psychosocial assessment performed by either a CCS paneled social worker or a CCS paneled nurse specialist with expertise in family psychosocial assessments.

E. Hearing evaluation will be done on all infants discharged from the NICU. All HRIF outpatient hearing screening services will be performed by a Newborn Hearing Screening Program (NHSP)-certified Outpatient Infant Hearing Screening Provider or a CCS-approved Type C Communication Disorder Center.

   1. Infants who did not pass the inpatient screening will be referred by the NICU to a Type C Communication Disorder Center for a diagnostic hearing evaluation.
   2. Infants who passed an initial hearing screen but who are at risk for developing a progressive or late-onset hearing loss (see N.L. 20-1299) should receive a diagnostic hearing evaluation every six (6) months.

F. An ophthalmologic assessment, performed by a CCS-approved ophthalmologist with experience and expertise in the retinal examination of the preterm infant. The assessments are to be done in accordance with American Academy of Pediatrics Policy Statement "*Screening Examination of Preterm Infants*" *Pediatrics*, Vol. 131: Number 1. January 2013 and until the ophthalmologist determines the child is no longer at risk for developing retinopathy or prematurity.

G. The HRIF Coordinator shall be a CCS-approved: pediatrician or neonatologist, PNP, nurse specialist, psychologist, social worker, physical therapist, or occupational therapist. The PNP only requires CCS-approval when functioning in the CCS HRIF program as a HRIF Coordinator. The Coordinator has the key role in follow-up and coordination of services for eligible infants and children. The specific responsibilities of the coordinator are:

   1. Coordination
      a. Serve as the primary person coordinating neonatal HRIF services among the County CCS Programs, other HRIF Programs located in CCS-approved Regional, Community and Intermediate NICUs, State CMS Regional Offices, clients/families, and others in matters related to the client's HRIF services.
      b. Participate in NICU discharge planning process or multidisciplinary rounds.
      c. Ensure identification of HRIF eligible clients according to HRIF eligibility criteria and request authorizations from County CCS Program or Regional Offices.
      d. Ensure copies of the authorizations are distributed to HRIF team members and consultants.
      e. Gather medical reports and assessments for review by team members and prepare a summary report.
      f. Ensure that a copy of the summary report is sent to the County CCS Program or Regional Office.
      g. Confer with parents regarding services provided and results of clinical evaluations and assessments of their infant or child.
      h. Assist families in establishing a Medical Home for the infant or child,
      i. Assist clients/families in making linkages to the necessary medical and social services.
      j. Ensure there is a system in place to follow-up with families including those who have missed

appointments. Collect documentation of the reason for missed appointments and develop a plan of action for improving the HRIF Program adherence for evaluations and assessments.

k. Provide coordination between the HRIF Program and the infant's or child's (pediatric) primary care physician, specialists and County CCS Program or Regional Office when appropriate.

l. Coordinate HRIF services with the County CCS Program and Regional Offices and other local programs.

m. Coordinate follow-up service needs among the CCS-approved Regional, Community and Intermediate NICUs within the community catchment area and with those NICUs that provide CCS referrals to their agency.

2. Client Referral Services and Follow-Up

   a. Ensure and document referrals are made to the Early Start (ES) Program for children who meet ES eligibility criteria.

   b. Ensure referrals are made to the Regional Center when services are appropriate.

   c. Ensure referrals to HRIF diagnostic consultations and assessments are made with CCS-approved providers.

   d. Provide referral and resource information for other social and developmental programs within the community as required.

3. Educational Services Program

   a. Provide education and outreach about the HRIF Program and services, clinical care, required documentation on transfer, and referral options, including outreach to NICUs with which there is a NICU Regional Cooperation Agreement to CCS-approved Community and Intermediate NICUs and other community referral agencies, as appropriate.

   b. Develop and provide education to parents and family members about the high risk infant's medical condition(s), care and treatment, special needs and expected outcomes of care.

   c. Provide education to parents and family members about the system of care and services (including social services) available to help them nurture, support and care for the high risk infant.

H. **Providers for HRIF Program:**

All providers rendering services for HRIF shall be CCS paneled providers (nurse practitioners and developmental specialists do not require paneling).

IMPLEMENTATION

A. **HRIF Authorization:**

The CCS Medical Consultant/Director or designee shall authorize specific HRIF outpatient services based on the request for HRIF diagnostic services for NICU infants who were authorized by CCS.
(HRIF services requested for those HRIF eligible infants who are eligible for the CCS Program may be authorized and funded as treatment services.) See CCS guidelines for HRIF Program Authorization.

B. **HRIF Provider Claiming and Reimbursement:**

HRIF services are reimbursable only to CCS paneled/approved providers listed in the directory of the

HRIF NICU SCC who have been authorized to provide services to the HRIF eligible child. See CCS guidelines for HRIF Claims and Reimbursement. See attached CCS Billing Guidelines for the HRIF Program.

ORGANIZATION OF HRIF CLINIC/SCOPE OF CARE

A. **Description of Service:** The HRIF Clinic provides specialized Pediatric Outpatient care. The care provided in this clinic is care that is not routinely provided in the primary care physician's office. Continuity of care is paramount in the care of children.

B. **Location:** Physical Therapy Department
Address: 3212 Loma Vista Road, Ventura, CA 93003
Phone Number: 805-648-9980

C. **Staffing:**

1. Neonatologist
2. Secretarial support/Medical Office Assistant (MOA)
3. Registered Nurse
4. Developmental/Physical Therapist/Occupational Therapist
5. Medical Social Worker (MSW) or by referral on an as needed basis
6. A Registered Dietitian by referral on an as needed basis

D. **Responsibilities of Staff:**

1. **Responsibilities of Neonatologist:**
    a. History and physical examination including neurological evaluation.
    b. Coordinates Interdisciplinary conference.
    c. Conferences with infant's family/primary caretaker regarding services provided and results of clinical evaluations and assessments.
    d. Oversees coordination of appropriate specialty referrals (e.g. dietary, orthopedic, neurologic, pulmonary, ophthalmology, endocrine).
    e. Oversees coordination of documentation, summary and reports. (Formulates statistics for CCS reporting.)
    f. Respects the confidentiality of the patient at all times.
    g. Recommends NICU clients to be seen in HRIF and ensures appropriate clients are assigned to be followed as per CCS guidelines.
2. **Responsibilities of Secretary:**
    a. Schedules appointment to HRIF at time of discharge from NICU and as ordered by Neonatologist/PT/OT.
    b. Ensures that a copy of the Discharge Summary and Discharge Progress Notes are in the HRIF Chart.
    c. Prepares clinic medical record chart for HRIF clinic appointment. Pulls charts for following week appointments. Audits charts for payment source. Reviews CCS SAR (Service Authorization

Request) paperwork and need for any extensions.

d. Types and distributes yearly HRIF schedule to all team members. Does follow up reminders as needed.

e. Confirms authorization prior to HRIF Clinic.

   i. Insurance clients – checks with insurance and confirms authorization.

   ii. Medi-Cal clients – completes paperwork for TAR (Treatment Authorization Request) authorization.

   iii. CCS – assists coordinator with obtaining SAR.

f. Mails reminder of HRIF Clinic appointment 2 weeks prior to appointment with confirmation information and map as needed.

g. Phones family day before HRIF Clinic appointment to confirm.

h. Orders inpatient medical record the day before clinic.

i. Registration of HRIF clients.

j. Assists with correspondence and communication with agencies working with the family as directed by neonatologist, physical therapist or registered nurse.

k. Filing.

l. Makes up billing sheets.

m. Maintains supplies and equipment as needed.

n. Inputs billing into STAR Plus (hospital billing computer system) and maintains billing files.

o. Respects the confidentiality of the patient at all times.

3. **Responsibilities of Registered Nurse / HRIF Coordinator:**

   a. Summary report of the HRIF clinic visit.

   b. Records growth parameters: weight, height and head circumference (graphs on growth chart).

   c. Records immunizations.

   d. Records dietary history.

   e. Provides educational information to parents/caretakers regarding general care, safety information and any specialized care for patient.

   f. Instructs parent/caretaker on referrals and appointments.

   g. Documents all interactions.

   h. Maintains supplies and equipment as needed.

   i. Follows up on referrals.

   j. Respects the confidentiality of patient at all times.

   k. Completes the Registration Client Identification face Sheet (see attached A) at the initial visit and submits to CMS Branch.

   l. Completes the Health and Development Status Report (see attached B) at the initial and all subsequent visits and submits to CCS Branch.

   m. Submits a summary report of the HRIF Team visit to the county CCS office, the medical home

provider for the patient and any other providers involved in the patient's care.

4. **Responsibilities of Physical Therapist / Occupational Therapist:**
    a. Developmental Assessment (equivalent to Bayley Scale of Infant Assessment).
    b. Specialty referrals as indicated.
    c. Documentation.
    d. Determines whether on-going PT, OT is needed and obtains necessary referral or authorization.
    e. Respects the confidentiality of the patient at all times.
    f. Education of parents regarding developmental issues.
    g. Referrals to Early Start.
5. **Responsibilities of Social Services:**
    a. All clients/families will be assessed for psychosocial, spiritual, and cultural needs during HRIF Clinic by Medical Social Worker.
    b. Evaluation of the home and family life, the caregiver status, and financial concerns.
    c. Community services and follow-up referrals made.
    d. Documentation.
    e. Reassessments are done as needs arise.
    f. Respects the confidentiality of the patient at all times.
    g. Education of parents regarding developmental issues.
    h. Referrals to PHN.

REFERRALS

A. **Nutrition Referral:**
    1. Diagnosis, feeding habits and growth parameters (weight, length, head circumference and weight for length) will be evaluated by the HRIF teams.)
    2. Referral to the Registered Dietitian may include but is not limited to:
        a. Failure to thrive
        b. Osteopenia
        c. S/P GI surgery
        d. S/P Heart surgery
        e. Symmetrical SGA
        f. Poor feeding of feeding intolerance.
        g. Parent request for nutrition consult.
    3. High Risk Flags:
        a. Growth falling below track on the Babson or HDP growth charts.
        b. Growth parameters fall at/below 2 standard deviations less than mean on Babson Growth Chart or HDP growth charts.

c. Alkaline Phosphotase > 500 Phosphorus <4.5.

d. Gastrostomy fed infant.

e. Any baby on Nutramigen, Pregestimil, Alimentum, Neocate.

4. Referral to RD will be made by Neonatologist/PT/OT/RN/MSW.
5. Evaluation may be done during the HRIF clinic visit with the NICU dietitian. If a separate appointment is needed, schedule through Pediatric Diagnostic Center with pediatric dietitian.
6. Education for nutritional needs is provided by the dietitian and/or health care team.
7. Follow-up evaluations are at the discretion of the RD/Neonatologist.
8. Documentation of nutrition consult is in the medical record.

B. **Referral for follow-up services/consultations/testing:**

1. Follow-up referrals or consultations will be made based on the recommendation of the HRIF team. Consultations and services will be made in compliance with insurance/CCS guidelines.
2. See list of referral services provided (see attached).
3. Referrals documented in clinic record.

SAFETY IN THE HRIF CLINIC

A. Insure a safe environment in the HRIF Clinic for all children/families.

1. Safety procedures in the Rehab manual will be followed.
2. All equipment will be checked by the Biomed department for safety.
3. Sharp objects will not be left in the exam rooms.
4. Corridors will be kept uncluttered.
5. A waiting room will be provided in the Center.
6. All electrical outlets will have safety plugs.
7. Sharps containers will be used as needed.

EDUCATION – PARENTS

A. Education is provided for all parents whose infant or child is seen in the HRIF Clinic. Information will include general and specialized care of children and will be linguistically and culturally appropriate.

B. Education will be available in a variety of venues:

1. Videos
2. Pamphlets
3. Verbal instruction
4. Information is individualized for the needs of the child.
5. Additional resources are available on the child with special needs in the hospital medical library.

APPOINTMENTS / MISSED APPOINTMENTS

A. Initial HRIF appointment to be scheduled prior to discharge. Appointment should be when patient is

approximately 4-6 months of age.

B. If family cancels or does not show for appointment, then family is called to re-schedule patient for next available appointment (HRIF Coordinator and/or designee).

C. If family does not show for two consecutive appointments or cancels for three consecutive appointments, then letter will be sent to PMD notifying of missed appointments and asking them to please assist us with communicating to the family the need to be seen in HRIF Clinic (HRIF Coordinator and/or designee). PMD will be instructed to call HRIF directly to schedule patient for next available appointment.

DISCHARGE FROM HRIF PROGRAM

Those infants who meet the following criteria will be discharged from HRIF Clinic:

A. Successful completion of the evaluation process.

B. Primary care provider will follow developmental milestones.

C. Children who have missed two consecutive appointments and parents are not available by phone or mail.

D. Child has reached 3rd birthday.

E. After 3rd birthday, if developmental delays or concerns persist, may be followed by out-patient PT or OT under another program or referred to another agency.

REFERENCES:

California Children's Services Guidelines 7/03.

DHS Letter 05-0502 May 1, 2002, Medial Eligibility for Care in a CCS Approved Neonatal Intensive Care Unit (NICU) CCS NL 05-0502-ADA.pdf (ca.gov)

Attachment

List of referral services provided:

1. Ophthalmology
2. Neurology
3. Pulmonology
4. Endocrinology
5. Orthopedics
6. Gastroenterology
7. Neuro surgery
8. Nephrology
9. Hematology/Oncology
10. Genetics
11. Children's Hospital Los Angeles
12. UCLA
13. Tri-Counties Regional Center

14. Ventura County Public Health
15. School District

All revision dates: 4/11/2024, 4/9/2024, 4/1/2007, 4/1/2006

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Tracy Chapman: Director, HCA Medical Staff Administration	pending
Pediatrics Committee	Tracy Chapman: VCMC - Med Staff	5/22/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	5/21/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	5/21/2024
NICU	Jennifer Ferrick: Director, Peds/PICU & NICU	5/21/2024
NICU	Melissa Krebs: Director, NICU	4/15/2024

Ventura County Medical Center

Delineation Of Privileges

Dentistry General ~~– Ambulatory Care~~

Name:

Privilege	Requested	Granted	Deferred	Suspended

Initial Criteria:
- DDS or DMD license issued by the Dental Board of California.
- Current DEA Certificate
- Basic Life Support
- Documentation of the provision of care to a minimum of 200 dental patients in the previous year.

Evaluation Requirements:
- Retrospective review of a minimum of 5 cases

Renewal Criteria:
- Documentation of the provision of care to a minimum of 400 dental patients within the previous 2 years.

~~Outpatient~~ Core Privileges: ___ ___ ___ ___
Privileges to admit, evaluate, diagnose and provide treatment to dentistry patients in the outpatient or inpatient setting, including preventative and emergency dental care.

Privileges Include:
- Perform history and physical
- General dental screening and diagnoses
- Oral Prophylaxis
- Dental x-rays
- Routine restorative dentistry
- Biopsy and removal of soft tissue lesions
- Extractions
- Non-surgical endodontics
- Non-surgical periodontal therapies

~~Special~~ Additional Privileges
(Must also meet the criteria above)

Performing Core Privileges Under General Anesthesia in the OR

Additional Criteria for Phase I Orthodontic Treatment:
- Documentation of training
- Documentation of current clinical competnecy

Phase I Orthodontic Treatment ___ ___ ___ ___
Privileges to evaluate and provide interceptive orthodontic treatment.

Privileges include:
- General dental screening and diagnoses
- Palatal expansion
- Maxillary protraction
- Space Maintenance
- Active retainer
- Partial braces

Delineation Of Privileges

Dentistry General ~~– Ambulatory Care~~

Name:

Privilege	Requested	Granted	Deferred	Suspended

ACKNOWLEDGEMENT OF PRACTITIONER:
I have requested only those privileges for which, by education, training, current experience and demonstrated performance, I am qualified to perform, and that I wish to exercise at the Ventura County Medical Center, Santa Paula Campus Hospital and/or with the VCMC Ambulatory Care System. I understand that exercising any clinical privileges granted, I am constrained by hospital and medical staff policies and rules applicable generally and any applicable to the particular situation. I am willing to provide documentation of my current competence for the requested privileges.

Applicant's Signature:

_____ Date: _____

TEMPORARY PRIVILEGE APPROVAL

Department Chief's Signature:

_____ Date: _____

Evaluator Assignment:

_____

[ ] PROVISIONAL [ ] RENEWAL APPROVAL

Department Chief's Signature:

_____ Date: _____

VENTURA COUNTY MEDICAL CENTER
SANTA PAULA HOSPITAL
A Division of Ventura County Health Care Agency

Ventura County Health Care System Oversight Committee
Hospital Administrative Policies & Procedures

August 2, 2024

The following administrative policies were reviewed and recommended for approval by appropriate departments and committees.

1. 106.034 Emergency Management Plan
2. 106.046 Medical Equipment Management Plan
3. L.58 iCASSETTE Fentanyl Urine Test Cassette
4. L.SPH.49 Ketones
5. L.SPH.59 ARK Fentanyl II Assay
6. R.50 Responsibilities of the Respiratory Therapist
7. 101.017 Verification of Current Licensure
8. 101.023 Request for Vacation, Leave of Absence, Administrative Leave
9. 106.012 Locking Hospital Entrances
10. 106.086 Suicidal Environmental Risk Assessment
11. 107.065 Security Screening of Patients and Visitors
12. F.23 Facilities Maintenance Eyewash Station Inspection
13. IS.01 Radiation Safety & Protection Program
14. IS.46 Gamma Cameras Quality Control and Maintenance
15. PH.14 Procurement of Pharmaceuticals
16. PH.45 Monthly Inspections
17. T.20 Guidelines for Care of the Injured Older Adult

VENTURA COUNTY MEDICAL CENTER
SANTA PAULA HOSPITAL
A Division of Ventura County Health Care Agency

Ventura County Health Care System Oversight Committee
Hospital Administrative Policies Procedures - August 2, 2024
Summary of Changes

#	Title	Review Period	Summary of Changes
1	106.034 Emergency Management Plan	Annual	Adding trauma language from gray book.
2	106.046 Medical Equipment Management Plan	Annual	Changed the word "month" to "cycle" in Performance Standards section
3	L.58 iCASSETTE Fentanyl Urine Test Cassette	Biennial	New policy
4	L.SPH.49 Ketones	Biennial	Changed manufacturer for serum QC material.
5	L.SPH.59 ARK Fentanyl II Assay	Biennial	New policy
6	R.50 Responsibilities of the Respiratory Therapist	Biennial	Policy was updated to reflect current standards
7	101.017 Verification of Current Licensure	Triennial	Updated language and department names.
8	101.023 Request for Vacation, Leave of Absence, Administrative Leave	Triennial	Policy reviewed by HR. Revised policy based on HR's current practices and guidelines. Changed owner.
9	106.012 Locking Hospital Entrances	Triennial	Changed from 8:00 pm - to - 9:00 pm, might have been a typo
10	106.086 Suicidal Environmental Risk Assessment	Triennial	Policy reformatted. Timeframe of last SI/SA.
11	107.065 Security Screening of Patients and Visitors	Triennial	Policy was updated to reflect current practices
12	F.23 Facilities Maintenance Eyewash Station Inspection	Triennial	Policy was updated to reflect current practices
13	IS.01 Radiation Safety & Protection Program	Triennial	Updated to include Quality Assurance Test for Nuclear Medicine
14	IS.46 Gamma Cameras Quality Control and Maintenance	Triennial	Policy was update to reflect current practices
15	PH.14 Procurement of Pharmaceuticals	Triennial	Updated Rx Transparent to ConsortiEX and added reference to PH.13 Drug Supply Chain Security Act
16	PH.45 Monthly Inspections	Triennial	Updated to include physical inspection of drugs in automated dispensing cabinet per CA BoP law 1261.6 (h).
17	T.20 Guidelines for Care of the Injured Older Adult	Triennial	New policy with edits to comply with American Collefe of Surgeons recommendations

Status **Active** PolicyStat ID **16042233**

Origination	2/1/2000	Owner	Fernando Medina: Director, Support Services
Last Approved	6/17/2024	Policy Area	Administrative - Environment of Care
Effective	6/17/2024		
Last Revised	6/17/2024		
Next Review	6/17/2025		

106.034 Emergency Management Plan

POLICY:

It is the policy of Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) and Licensed Hospital clinics to develop, maintain and continually update an Emergency Management Plan. The purpose of the Emergency Management Plan is as follows:

A. Designed to support the Hospital Incident Command System (HICS), which is a modification of the Incident Command System (ICS). ICS is the standardized and official emergency response organization adopted by city, county, and state organizations, to permit improved understanding and communications between various government agencies. VCMC/SPH joins an expanding number of health care organizations, by adopting HICS, which will permit improved coordination between other health care facilities and local government agencies.

B. To provide for effective actions which will minimize injuries and loss of life among patients, employees, volunteers, vendors, visitors and contractors during a state of disaster or extreme emergency.

C. To provide procedures for optimal use of our resources during a state of disaster or extreme emergency.

D. To provide a plan, through EMS, of mutual assistance with other hospitals, organizations and agencies for the prompt transfer of victims that we are unable to manage.

The VCMC/SPH Emergency Operations Plan (see attachment) is modeled after the HICS format. The goal is to provide a simplified disaster plan for common response by all departments and units. The specific duty for implementations of these plans is the responsibility of each department manager or supervisor. Plans are tailored to the specific needs and resources of each department.

PROCEDURE:

The Emergency Operations Plan is designed to work in conjunction with the Ventura County Sheriff

Office of Emergency Services (OES), Ventura County Emergency Medical Services (VCEMS) Agency and Public Health. In the event of a large-scale disaster, VCMC/SPH will participate in the coordination between other healthcare facilities, as directed by the Ventura County Sheriff's OES Multi-Hazard Functional Plan and the EMS Agency. The Ventura County Medical Network (REDDINET) system will be used to assist in coordinating emergency response and hospital availability. The HICS plan will also support the medical needs of the surrounding communities.

The Emergency Operations Plan is also designed to activate the resources of Ventura County Ambulatory Care (AC) as needed. If an emergency situation occurs that necessitates assistance by AC, the Incident Commander will contact the AC Administrator-on-Call to initiate the AC Emergency Operations Plan. According to the plan, the Administrator-on-Call will determine whether to assign an AC Liaison to the VCMC ICC who will coordinate the limited mobilization of AC resources or to initiate the Ambulatory Care Incident Command Center to mobilize and coordinate massive resources, in which case an Ambulatory Care liaison would be assigned to the VCMC ICC to facilitate collaboration and coordination.

To permit optimum response and minimize the impact of the emergency on normal operations, the response effort must grow with the threat and then needs to be reduced as soon as emergency conditions permit. This requires rapid assessment of the problem, and the resources available to contain and resolve the emergency. Quickly obtaining current and accurate information enables the incident management team to estimate the potential impact on the facility and initiate plans to meet both facility and community needs.

This Emergency Operations Plan shall be prepared in compliance with the California Administrative Code, Title 17, Title 9 and The Joint Commission, which requires that all hospitals have a written Emergency Operations Plan.

A trauma surgeon from the trauma panel must be included as a member of the hospital's Emergency Management Committee and be responsible for the development of a surgical response to a mass casualty event. The surgical response is detailed in policy *T.13 Multiple Casualty Incident*, and outlines the critical personnel, means of contact, initial surgical triage (including subspecialty triage when appropriate), and coordination of secondary procedures.

Any fire service, law enforcement agency, public health agency or hospital may notify the Ventura County Sheriff's Office of Emergency Services and/or Ventura County Emergency Medical Services (EMS) Agency of any disaster that is known to have produced, or is likely to produce, multiple causalities.

AUTHORITY

A. The Environment of Care Executive Committee appoints a chairperson to be responsible for the management, monitoring and reporting regarding the Emergency Operations Plan (EOP).

B. The Chairperson of the Emergency Management Committee has immediate and complete access to all records that become necessary in carrying out the EOP.

HAZARD VULNERABILITY ANALYSIS

Hazard Vulnerability Analysis is conducted every two years, or sooner as needed.

Results of the Hazard Vulnerability Analysis are obtained through the collaborative efforts of the Emergency Management Committee.

Both natural and man-made disasters could affect this hospital at any time. It is an inherent obligation of those charged with the responsibility for the care of the sick and injured to provide an effective Emergency Operations Plan. This program should ensure the maximum safety and well being of all patients and staff.

DEFINITIONS

Disasters may be "Internal" or "External" to the hospital. Disasters shall be paged over the hospital intercom system and phone page system as "CODE TRIAGE" (15 or more patients/victims, regardless of mechanism or acuity i.e. trauma, chemical exposure, radiation exposure etc., are expected or received for emergency care in the Emergency Department), followed by "External or Internal," (location), (ETA if known) "All visiting hours are now ended, visitors please exit the hospital."

Disasters are defined as follows:

A. **External**
An External disaster occurs outside the hospital complex which affects the local community and which would result in a sudden influx of acutely sick and/or injured patients needing emergency care. Disasters of this type could result from fire, major accident, earthquake, flood, explosion, electrical failure, gas leakage, etc.

B. **Internal**
A disaster occurring within the bounds of the hospital complex with acute injuries, facility damage or significant disruption of service or the threat of potential injuries, due to a major calamity. Disasters of this type could result from fire, explosion, electrical failure, flood, gas leakage, earthquake, threat of an employee walkout, etc.

C. **Bioterrorism/Hazardous Substance**
Bioterrorism is the deliberate release of pathogenic microorganisms (bacteria, viruses, fungi or toxins) into a community. Most likely diseases include smallpox, anthrax, botulism, plague and tularemia, but viral hemorrhagic fever viruses such as Lassa, Marburg and Ebola may also be deliberately introduced. With the exception of smallpox, VHR and the encephalitis viruses, all bioterrorism agents can be treated with antibiotics or toxin antagonists if promptly diagnosed.

The key to rapid intervention and prevention is to maintain a high level of vigilance. Early identification of an outbreak from an unnatural source is essential. Suspicious indicators include increasing numbers of otherwise healthy persons with similar symptoms seeking treatment over a period of several hours, days or weeks, a cluster of previously healthy persons with similar symptoms who live, work or recreate in a common geographical area; an unusual clinical presentation; an increase in reports of dead animals; lower incident rates in those persons protected; an increase number of patients who expire within 72 hours after admission; any person with a history of recent travel to a foreign country presenting with S&S of high fever,

rigors, delirium, rash, extreme myalgias, prostration, shock diffuse hemorrhagic lesions or petechiae; and/or extreme dehydration due to vomiting or diarrhea with or without blood loss.

Decontamination of suspected exposure to a bioterrorism agent or to reduce the extent of external contamination will be coordinated with the Hazardous Materials Team of the Fire Department. The Decon tent will be set-up by our Facilities Dept. as needed.

D. **Emergency Operations Plan**
The Emergency Operations Plan (EOP) is an "all hazards" plan to guide preparations, response, and recovery to emergencies and disaster for Ventura County Medical Center and Santa Paula Hospital. The EOP is a dynamic document that is modified as deficiencies and opportunities for improvement are identified in the evaluation of all emergency response exercises and all responses to actual emergencies.

INITIATION OF CODE TRIAGE

A. Authority to Initiate -- The Hospital Administrator or the Administrator on Duty in conjunction with the Nursing Supervisor and the Emergency Department Charge Nurse have the authority to initiate a Code Triage and activate the Emergency Operations Plan, or other portions of the Plan as deemed appropriate. The person activating the plan serves as Incident Commander until relieved by a Senior Administrator or relinquishes responsibility to another individual.

B. Conditions Necessary to Initiate the Emergency Operations Plan:
    1. Notification of a disaster received from the Ventura County EMS Agency or Office of Emergency Services Emergency Operations Center (EOC).
    2. Any condition that brings a significant number of patients to the Emergency Department or seriously disrupts the quality of services that the facility provides to its patients, staff and communities.
    3. A significant internal disaster.

C. The Initiation Process:
    1. In the event of a disaster, the initial notification will usually be to the Emergency Department. The Emergency Department will immediately notify the Administrator-On-Duty (Administration during the weekdays, Nursing Supervisor all other times).
    2. The Administrator, Nursing Supervisor, or Administrator on Duty reviews the need to establish the Command Center to manage the situation and, where appropriate, activates the disaster plan.
    3. The Administrator, Nursing Supervisor, Administrator on Duty or the Emergency Department Charge Nurse notifies Communications to overhead announce the disaster code: CODE TRIAGE, ER, EXTERNAL OR INTERNAL, or other code as appropriate; activates the Administrative Disaster Call-back as appropriate; notifies those needing to be informed not accessed by the paging system.
    4. Paging, after confirming a complete understanding of the notification requirements, overhead announces:

        "Code Triage, (Internal or ***External), (location) (ETA if known),*** **all visiting hours are**

now ended, visitors please exit the hospital."

5. At that time, paging will notify the appropriate personnel via pagers and cell Phones. Paging may also be instructed by Administration to notify those needing to be informed of disaster that is not accessed by the paging system. After 15 minutes, **"Code Triage in process until further notice"** should be announced by Paging.

D. Upon establishment of the Incident Command Center, located in the Large Auditorium or Academic Family Medicine Residency and Specialty Care Center in the Computer Training Center (Alternate Location) at VCMC and the Library or Nursing Office (Alternate Location) at SPH, an Incident Briefing Form will be developed:

1. The Incident Commander (IC) will be responsible for preparing the Incident Briefing Form (HICS 201), a brief written statement about the nature of the problem, anticipated impact on the staff, and general directions for managers to take in response to the situation.
2. Command Staff and Section Chiefs, or Branch/Unit/Team Leaders and Medical/ Technical Specialists will report to the Incident Command Center to review the Incident Briefing Form and accept assignment by the IC.
3. The IC will provide updated Incident Briefing Forms for departments as often as appropriate and as the situation permits.

STAFF ROLES AND RESPONSIBILITIES (General)

A. **General Guidance to All Staff and Physicians**: In most cases, clinical and support staff will continue their normal duties when a disaster code is called, depending on the level called, unless otherwise directed, such as being identified as a member of the command center staff. When the code is first called, staff should check their fellow staff, patients, families, and visitors; installed utilities and equipment, and if there are no injuries or damage, continue the provision of patient care or report to IC if you are a member of the command center staff. Any injuries or damage must be reported to the command center immediately. All staff and physicians should be prepared for reassignment as directed by their immediate supervisor, depending on the nature of the crisis.

B. **Communications**: The Paging Department staff is responsible for alerting key staff per the procedure and call tree when a Code is called, then providing updates via overhead announcement to all people in the hospital. All staff is responsible to check any communications equipment in their area and report system failures to the command center.

C. **Resources and Assets**: During a crisis, all staff is expected to conserve medical and non-medical supplies to the extent that it can reasonably be done without compromise to patient care. When a disaster code is called, Central Supply is responsible to verify current supply inventories, coordinate with vendors to fill any shortfalls, and be prepared to reallocate supplies as directed by the command center. Disaster Carts will be distributed to the designated areas.

D. **Safety and Security**: All staff and physicians are responsible to communicate any safety or security concerns immediately to the command center, attention the Safety Officer for resolution. All staff and physicians are also responsible in the course of their duties to report to Security anyone claiming to be on staff but without an ID badge and any personnel in, or

attempting to enter, areas they are not authorized to enter.

E. **Utilities Management**: All staff and physicians are expected to reasonably conserve the demand on utilities in a crisis, without undue effect on patient care. All staff and physicians are responsible to immediately report any utility failures to the command center. Facilities department is responsible to manage primary and alternate utilities in an emergency, including the inventory of utility support requirements such as fuel, water, oil, etc.

F. **Patient Clinical and Support Activities**: All staff and physicians are responsible to communicate honestly with patients, visitors, and families, with respect to what they know, but should not speculate on events, situations, or plans unknown to them, but direct the question back to the command center.

STAFF ROLES AND RESPONSIBILITIES (Specific)

A. Initiate Department Call-Back Lists as necessary, based upon such information as:
    1. Nature and severity of the disaster
    2. Number of victims
    3. Type of injuries
    4. Time of day
    5. Current staffing
    6. Condition and availability of the facility, its equipment and materials
    7. Need for evaluation (consider number of patients, status, etc)

B. Medical Staff will remain in location and wait for further instruction. Medical Staff Office will initiate the call back roster as directed by the Medical Director.

C. Personnel/Volunteers will check in at the Labor pool (Located in the Cafeteria Conference Room) at VCMC and Dining Room at SPH as directed.

D. Physicians/Residents will continue their duties until otherwise assigned by Chiefs of Staff or the Medical Director.

E. The ED Physician and/or Nursing Supervisor will keep the Incident Command Center informed of the need for additional personnel to handle incoming victims and initiate the callback list for physicians and staff. Each department will initiate call back as needed or directed and send available personnel to the Labor Pool (Cafeteria Conference Room) at VCMC and (Dining Room) at SPH.

F. Employee Sign-In Section Personnel Time Sheet (HICS 252) to be used for all employees to sign in and out of each Department or Treatment Area.

G. Employee Relief: Schedule employees and assign meal breaks.

H. Resource Use: Document equipment/supplies procured from department and agencies.

I. IC to provide general guidance, resourced in the Incident Response Guide manual (IRG), for the immediate situation.

J. Report Forms: Departments will notify the Command Center within 30 minutes of initial notification, as to their ability to respond, when significant information changes, when fully

staffed, and whenever requested by Incident Command.

K. Use of telephones will be limited to immediate needs of the disaster response.

L. Communications to be addressed by IC and the distribution of radios as needed.

M. In a County-Wise Disaster Event or during Off Business Hours, all personnel shall be ready to report when notified by Administration of immediate supervisor.

N. In the event that all telephone contact is out of service, all personnel shall report to the labor pool (located in the Cafeteria Conference Room) at VCMC and (Dining Room) at SPH for assignment and further instruction.

O. Should evacuation be required, location for all personnel is the Public Health parking lot on Hillmont Rd. to the west of the main hospital at VCMC and Parking Lot E at SPH.

P. All facility employees must wear their authorized employee identification badges at all times while in the facility or on its grounds. Personnel assigned to selected special duties may be required to wear position identification vests, ID tags and/or armbands identifying their disaster job titles.

Q. In the event of a lock-down to the facility or during a disaster, employees will use only the Lab entrance (VCMC) and the front entrance to the Emergency Department (SPH).

R. The Emergency Department Staff will use the Ambulance Bay Entrance (VCMC/SPH).

COMMUNICATION PROCESS AND TRAFFIC FLOW

Refer to Attachment A: Emergency Operations Plan.

EMERGENCY TREATMENT AREA LOCATIONS

Refer to Attachment A: Emergency Operations Plan.

DISASTER CONCLUSION

At the conclusion of the disaster, the Incident Commander will notify paging to overhead announce: CODE TRIAGE ER HAS BEEN CLEARED (**to be repeated twice**).

All HICS disaster supplies will be returned to the section chiefs. The section chiefs will ensure the supplies have been restocked and returned to storage.

EMERGENCY MANAGEMENT COMMITTEE

The Emergency Management Committee includes representatives from various key departments. The Chairman of the Committee will report activities to the Executive Environment of Care Committee and the general Environment of Care Committee. The Emergency Management Committee will meet at least quarterly. Written Drill critique will be filed with Environment of Care Executive Committee. Responsibilities of the Emergency Management Committee are as follows:

A. To coordinate and critique disaster events and drills.

B. To review and update the Emergency Operations Plan.

There will be a minimum of two emergency drills per year, at least 4 months apart, to include one that will have victim scenarios going through the system.

PERFORMANCE IMPROVEMENT

A. Immediately, or as soon as possible, following an actual disaster or drill, an informal critique of the incident will be held with major players to identify problems and successes. Location and time of the critique will be announced near the end of the incident.

B. Each department manager will review response to the disaster (drill) with his or her staff. Items to be included in the critique are as follows:

    1. Evaluation of facilities and department disaster plans and responses.
    2. Identification of any problems encountered.
    3. Recommendation of changes to the disaster plan, procedures, supplies and materials.
    4. Communication/coordination problems.
    5. Patient and staff movement problems.
    6. Other issues as appropriate.

C. The Emergency Management Committee will meet to:

    1. Review the critiques.
    2. Recommend updates to the disaster plans, as appropriate.
    3. Make recommendations on further testing on the disaster plan.

EMERGENCY RESPONSE EXERCISES

A. The hospital activates its Emergency Operations Plan at least twice a year at each site included in the EOP.

    1. The trauma program must participate in two hospital drills or disaster plan activations per year that include a trauma response and are designed to refine the hospital's response to mass casualty events.

B. For each site of the hospital that offers emergency services or is a community-designated disaster receiving station, at least one of the hospital's two emergency response exercises includes an influx of simulated patients.

    1. A pediatric mass casualty incident drill will occur at least every two years.

C. For each site of the hospital that offers emergency services or is a community-designated disaster receiving station, at least one of the hospital's two emergency response exercise include an escalating event in which the local community is unable to support the hospital.

D. For each site of the hospital with a defined role in its community's response plan, at least one of the two emergency response exercises includes participation in a community-wide exercise.

E. Emergency response exercises incorporate likely disaster scenarios that allow the hospital to evaluate its handling of communications, resources and assets, security, staff, utilities and

patients.

F. The hospital designates an individual(s) whose sole responsibility during emergency response exercise is to monitor performance and document opportunities for improvement.

G. During emergency response exercise, the hospital monitors the effectiveness of internal communication and the effectiveness of communication with outside entities such as local government leadership, police, fire public health officials, and other health care organizations.

H. During emergency response exercise, the hospital monitors resource mobilization and asset allocation, including equipment, supplies, personal protective equipment, and transportation.

I. During emergency response exercise, the hospital monitors:

    1. Safety and Security;
    2. Staff roles and responsibilities;
    3. Utility systems, and;
    4. Patient clinical and support care activities.

J. Based on all monitoring activities and observations, the hospital evaluates all emergency response exercise and all responses to actual emergencies using a multidisciplinary process including license independent practitioners.

K. The evaluation of all emergency response exercises and all responses to actual emergencies includes written documentation to identify deficiencies and opportunities for improvement.

L. Deficiencies and opportunities for improvement are communicated to the multidisciplinary Emergency Management Committee.

M. The hospital modifies its Emergency Operations Plan based on its evaluation of emergency response exercise and responses to actual emergencies.

N. Subsequent emergency response exercise will reflect modifications and interim measures as described in the modified Emergency Operations Plan.

O. Communication and documentation of modifications of the Emergency Operations Plan will be documented in the Emergency Management Committee minutes.

EDUCATION

Staff is trained for the emergency roles in the following ways:

A. New hire staff training: During the New Employee Orientation, emergency procedure policy, codes and responsibilities are presented.

B. Annual staff training: Staff is required to complete safety training which includes emergency procedure policy, codes and responsibilities.

C. New hire physician training: During the New Physician Orientation, emergency procedure policy, codes and responsibilities are presented.

D. Incident Command System (ICS 100/200 HC) and NIMS (IS 700) training for hospital personnel who would assume a leadership role in the Hospital Command Center (NIMS Element 9 and 11).

E. National Response Plan (IS 800a) training for persons directly responsible for the Emergency

Management Program (NIMS Element 10)

If Licensed Independent Practitioners volunteer or are transferred into the hospital, they will be oriented, assigned roles, and then proctored by the medical staff in accordance with the procedures established by the Emergency Management Committee according to the Emergency Operations Plan policy -- Disaster/Emergency Volunteer Health Professionals Credentialing.

EVALUATION

At least annually the Emergency Operations Plan will be reviewed and revised, if necessary, by the Emergency Management Committee chair and approved by the Emergency Management Committee. The scope, objectives, and effectiveness of the EOP, as well as the effectiveness of the emergency operations planning activities will be reviewed. The Environment of Care Executive Committee and Administration will approve the review.

All Revision Dates

6/17/2024, 4/17/2024, 12/13/2022, 8/2/2019, 6/1/2016, 2/1/2014, 6/1/2011, 11/1/2010, 12/1/2007, 10/1/2006, 5/1/2006

Attachments

Emergency Operations Plan

Emergency Operations Plan Appendix A 96-Hour Critical Supplies and Strategies for Extension

Emergency Operations Plan Appendix B Hazard Vulnerability Assessment

Emergency Operations Plan Appendix C Emergency Contacts Directory

Emergency Operations Plan Appendix D Emergency Supply Inventory

Emergency Operations Plan Appendix E VCMC HICS Assignments

Emergency Operations Plan Appendix F SPH HICS Assignments

Emergency Operations Plan Appendix G Evacuation Plan & Rally Points

Emergency Operations Plan Appendix H Tarp Tent Set-Up Map

Approval Signatures

Step Description	Approver	Date

Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH [JA]	6/17/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/17/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/17/2024
Emergency Management Committee	Fernando Medina: Director, Support Services [JA]	6/17/2024
Policy Owner	Fernando Medina: Director, Support Services [JA]	6/17/2024

Status **Active** PolicyStat ID **15603565**

Origination	3/1/2010	Owner	Ian McGraw: Manager Facility Operation
Last Approved	6/12/2024	Policy Area	Administrative - Environment of Care
Effective	6/12/2024		
Last Revised	6/12/2024		
Next Review	6/12/2025		

106.046 Medical Equipment Management Plan

POLICY:

The purpose of the Medical Equipment Management Plan is to support a safe patient care and treatment environment at Ventura County Medical System (VCMS) by managing risks associated with the use of clinical equipment technology. The program includes processes for selection and maintenance of equipment designed to ensure safe and appropriate support of patient care services. The selection and management processes are based on the risks associated with the equipment. The risk management strategies include training, education, and competency evaluation of individuals who maintain and use medical equipment and appropriate inspection, testing, maintenance, and repair of that equipment.

The program applies to the Ventura County Medical Center (VCMC), Santa Paula Hospital (SPH), Inpatient Psychiatric Unit (IPU) and Ambulatory Care Clinics

PROCEDURE:

Scope:

The scope of the medical equipment management plan defines the processes which Ventura County Medical System (VCMS) provides for the safe and proper use of medical equipment used in the patient care setting and to ensure effective preparation of staff responsible for the use or maintenance and repair of the equipment. Finally, the program is designed to ensure continual availability of safe, effective equipment through a program of planned maintenance, timely repair, ongoing education and training, and evaluation of all events that could have an adverse impact on the safety of patients or staff.

Objective:

The objective of Ventura County Medical System (VCMS) Medical Equipment Management Plan includes

the following:

- To minimize the clinical and physical risks of equipment through inspection, testing and regular maintenance
- To establish criteria for identifying, evaluating and inventorying equipment which is included in the program
- To provide education to personnel on the capabilities, limitations and special applications of equipment; operating, safety and emergency procedures of equipment; the procedures to follow when reporting equipment management problems, failures and user errors; and the skills and/or information to perform maintenance activities

To achieve this, the Medical Equipment Management Program includes the following objectives:

Provide the facility with assurance that:

A. It has equipment available which is appropriate for the clinical services that it provides.
B. Items of equipment that could create hazards for patients or staff are working properly and safely, and are maintained in this condition at all times that they are in use.
C. The services related to this equipment remain in full compliance with basic regulatory requirements, manufacturer's recommendations and any authorities having jurisdiction.
D. This program of vital support is provided to the facility as cost-effectively as possible.

RESPONSIBILITY:

- The Biomedical Equipment Technician is responsible for maintaining the Medical Equipment Management Program. Each department manager is responsible for orienting new staff members to the capabilities, limitations, special applications of equipment, basic operating and safety procedures, emergency procedures if failure occurs, maintenance responsibilities, if applicable, and the reporting procedures for equipment problems, failures and user errors.
- All information and data collected is aggregated by the Biomedical Equipment Technician. Conclusions, recommendations, actions and evaluations will be reported along with the aggregated data to the Environment of Care (EOC) Committee.

ELEMENTS OF PERFORMANCE

ACQUISITION OF MEDICAL EQUIPMENT:

The facility has a formal process for acquiring new capital equipment (defined as items at $5,000 or more). This process requires that a formal requisition is generated and evaluated and considered for approval by the Fixed Assets Committee which makes a judgment on the appropriateness of the equipment with respect to the clinical services provided by the institution. The Committee requests support from experts in specialized areas when deemed this additional support is necessary.

SELECTION OF MEDICAL EQUIPMENT:

Once it is determined that a new piece of equipment is to be acquired, the facility utilizes a routine

selection procedure which involves a formal or informal analysis of responses from alternate vendors before the purchase decision is made. This process requires assurance from the vendors that the equipment meets appropriate minimum safety and performance standards. Consideration is also given to the equipment's ease of operation and to the ready availability of assistance with on-going user training.

ESTABLISHING RISK CRITERIA FOR IDENTIFYING, EVALUATING AND TAKING INVENTORY OF MEDICAL EQUIPMENT TO BE INCLUDED IN THE MEDICAL EQUIPMENT MANAGEMENT PROGRAM:

The Risk Criteria used represents the aggregate of function, application, maintenance requirements and the history of the medical equipment.

EQUIPMENT MAINTENANCE STRATEGIES:

The procedures for the periodic performance assurance/safety testing have been developed by the Biomedical Engineering Department (Biomed) and are based on the manufacturer's published performance specifications and current nationally recognized safety standards. All new service reports are kept in Biomed's paperless filing system. Computerized summaries of the maintenance work are also available and are used to provide quarterly status reports to EOC committee.

EQUIPMENT TESTING, INSPECTION AND MAINTENANCE INTERVALS:

All of the critical equipment listed in the facility's medical equipment inventory is subjected to a carefully controlled regimen of performance assurance and safety testing and manufacturer-specified scheduled maintenance. The procedures and intervals for the scheduled maintenance are determined by the manufacturer's specifications.

INVESTIGATION AND REPORTING OF EQUIPMENT MANAGEMENT PROBLEMS AND FAILURES:

Events within the facility in which someone is injured, or could have been injured, are reported to the facility's Safety Officer. In situations where an item of equipment is directly involved, or is thought to have been directly involved, the facility has a policy that the equipment be removed from service and impounded with as little disturbance as possible to the settings and other evidence that might aid the investigation until Risk Management/Safety Officer releases the equipment back to service. Biomed, on request, can assist with investigating the circumstances of the incident, or arranging for others to investigate the incident. Determination of whether or not the incident is reportable pursuant to the Safe Medical Devices Act of 1990 remains with the Administration.

DOCUMENTING USER ERRORS:

A incident report is completed and submitted if user error is identified, if it can be confirmed that the user is unfamiliar with how to operate the equipment properly, the service technician provides the user(s) with an appropriate informal in-service, which is usually limited to addressing the immediate problem. Suspected user-related problems (when the service technician can find no evidence of equipment malfunction) which cannot be confirmed at the time of the service call are reported to the EOC

Committee.

HAZARD NOTICES AND RECALLS:

When an official recall notice from the equipment manufacturer is received by the facility, the recall committee will schedule an emergency meeting to determine the magnitude of the recall. Biomed locates the cited equipment and ensures that the specified corrective action(s) are completed. In addition to this, Biomed monitors the ECRI publication "Hazard Alerts" for information on reported or suspected hazards associated with specific medical equipment or devices. Copies of Hazard Alerts are sent to the appropriate department supervisor for review. The copies are signed off and returned to Biomed. If action needs to be taken, Biomed is available for assistance.

MONITORING AND REPORTING OF MEDICAL DEVICE INCIDENTS RESULTING IN DEATH, SERIOUS INJURY OR SERIOUS ILLNESS OF ANY INDIVIDUAL AS PER SAFE MEDICAL DEVICE ACT OF 1990:

- See attached SAFE MEDICAL DEVICES ACT OF 1990

MEDICAL EQUIPMENT INVENTORY:

All the facility's critical equipment, i.e., those items of medical equipment which could conceivably create a hazard to the health and safety of either patients or staff are listed on the facility's Medical equipment Inventory and are covered by the program. Risk Criteria is used to determine which equipment items are included. All medical equipment items used within the facility are considered for inclusion whether they are owned by the facility or not. Rented equipment, loaned equipment, including that provided for demonstrations, staff-owned equipment and patient-owned equipment are all considered for inclusion in the program.

NON-FACILITY OWNED EQUIPMENT:

Rented equipment, loaned equipment, including that provided for demonstrations, and patient-owned equipment are all considered for inclusion in the program.

INCOMING INSPECTIONS:

All patient care equipment, whether owned, leased or rented is tested for compliance with these previously specified minimum safety and performance standards before being used for the first time for patient care. The results of this testing are documented and the records are filed by Biomed. Similarly, equipment which has been withdrawn from use and placed in storage is also tested to these standards before being returned to service.

PERFORMANCE TESTING OF ALL STERILIZERS USED:

Departments that use sterilizers must document performance testing and biological cultures on all systems used and report results to the Infection Control Committee. Any variations outside standards need to be immediately reported to the Sterile Processing Department Director, the Perioperative Clinical

Nurse Manager, and the Chief Operating Officer.

CHEMICAL AND BIOLOGICAL TESTING OF WATER USED IN RENAL DIALYSIS:

Chemical and biological testing of dialysis product water is performed by an outside vendor. Each machine has biological testing performed by an outside vendor. Results and documentation are kept by Nursing Administration and Biomed.

EMERGENCY PROCEDURES THAT ADDRESS:

1. Specific procedures in the event of equipment disruption or failure
2. When and how to perform emergency clinical interventions when medical equipment fails
3. Availability of backup equipment
4. How to obtain repair services

Emergency clinical interventions that are necessary if a piece of medical equipment fails is established by the equipment-using departments. With few exceptions, Biomed is the first responder for all repair calls involving equipment listed in the biomedical equipment inventory. The exceptions would include sterilizers and specific pieces of equipment in the Laboratory and Imaging Services Biomed is staffed from 8:00 AM – 4:30 PM, Monday through Friday. Emergency coverage is provided on a 24-hour, seven-day-a-week basis through on-call cell phone. Users of medical equipment have several different methods of obtaining repair services. Users may notify Biomed of the need for assistance during regular rounds performed by the Biomed by calling the leading shop at phone number 1-805-652-6676 during normal operating hours or by calling the paging/nursing supervisor for after hours services. Should a piece of equipment malfunction or fail, hospital staff should first ensure the patient's safety, remove the piece of equipment from service, label it using the purple Broken Equipment Form, and notify Biomed through one of the methods listed above. Backup equipment is available for many types of equipment within the user department and loaners or spares maintained by Biomed.

THE MEDICAL EQUIPMENT MANAGEMENT PROGRAM INCLUDES AN ORIENTATION AND EDUCATION PROGRAM FOR EQUIPMENT MAINTAINERS:

Biomed technicians are subjected to technical competency assessments during their pre-employment interview and at annual intervals thereafter. The education and training needs identified through these assessments are met through a continuing education program supplemented by appropriate manufacturer/service vendor training. Technicians are also familiarized with their responsibilities to comply with certain other facility procedures, including those relating to handling emergencies, disaster drills, infection control, handling hazardous materials and wastes, and incident reporting.

THE MEDICAL EQUIPMENT MANAGEMENT PLAN INCLUDES A MEDICAL EQUIPMENT ORIENTATION AND EDUCATION PROGRAM FOR MEDICAL EQUIPMENT USERS:

Responsibility for coordinating and implementing the education and training of the equipment users is

held jointly by Biomed and department managers. The most common training sources on specific equipment are the manufacturer's initial in-services, the manufacturer's refresher in-services, the equipment user instruction manual or other audio/visual equivalents, and other staff trained on the proper use of the equipment. Biomed staff often will assist in this process on an as-requested basis. Where a specific problem is identified as a result of a service call, Biomed shall provide an incidental in-service, usually limited to correcting the user-related problem identified at the service call. Incident report training, which outlines the processes for reporting medical equipment management problems, failures, and user errors, is provided at new employee orientation and, as needed, to all employees and contracted service providers.

THE ORGANIZATION DOCUMENTS MAINTENANCE OF EQUIPMENT, BOTH LIFE SUPPORT AND NON-LIFE SUPPORT, THAT IS CONSISTENT WITH MAINTENANCE STRATEGIES TO MINIMIZE CLINICAL AND PHYSICAL RISKS IDENTIFIED IN THE EQUIPMENT MANAGEMENT PLAN:

Biomed documents all work performed on equipment included in the medical equipment management plan. Information included on the work order includes at a minimum: the asset ID (Biomed Control #), description of the problem, department, technician performing the work, a description of the repair or maintenance action, and time spent on the action.

The heart of the program's maintenance documentation system is the collection of equipment maintenance history files kept by the Biomedical Department. All biomedical equipment and required documentation is currently entered into our CMMS system or kept on file. The paperless system, contain copies of service reports documenting each service event for each piece of equipment since it was first put into service. The basic information on these service reports is also entered into the Biomedical Database computer system enabling the production of a variety of management and summary reports. Available computer generated reports include:

- Biomedical Equipment Inventory by Department and in several other forms.
- Maintenance History Reports in several forms.
- Scheduled maintenance status reports.

PERFORMANCE STANDARDS

- Biomed monitors completion of preventive maintenance actions on equipment included in the medical equipment management plan. The threshold for completion is set at 100% completion for all priority one preventive maintenance (PM) equipment. Incomplete actions include those items that Biomed could not locate. When a piece of equipment cannot be located, Biomed notifies the user department and asks for assistance in locating the device. After the third cycle of trying to locate the device, that piece of equipment is deactivated and a notice is sent to the user department.
- Operator Errors, Could not Duplicate and Operator Abuse are reported monthly and analyzed by equipment type, reported problem, floor, etc. to identify any trends or needs for additional operator training.
- Medical Device Incidents are reported by month to EOC Committee. Incidents are reported by

device type and by department.

- Product recalls/device hazard alerts pertaining to medical equipment are reported by month (or sooner if necessary) to EOC Committee.

PERFORMANCE IMPROVEMENT

The following performance monitors have been established as follows:

1. Measure all priority one and two PMs with 100% compliance with priority one PMs.
2. Reported recalls to EOC committee.

ANNUAL EVALUATION

The annual evaluation will include the review of the Medical Equipment Management Plan by EOC committee and hospital administration, including the plan's scope, objectives, performance effectiveness and goals to evaluate the degree in which the program meets accreditation standards and the current risk assessment of the hospital. A comparison of the expectations and actual results of the program will be evaluated to determine if the goals and objectives of the program were met.

All Revision Dates

6/12/2024, 4/24/2023, 10/22/2022, 2/13/2019, 4/1/2013, 3/1/2012, 4/1/2011, 7/1/2010

Attachments

Annual Eval of Medical Management Plan 2023.pdf

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH [JA]	6/12/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/10/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/10/2024
Environment of Care Committee	Ian McGraw: Manager Facility Operation	6/10/2024

Policy Owner	Ian McGraw: Manager Facility Operation	6/10/2024

Status **Active** PolicyStat ID **16010092**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	6/17/2024
Last Approved	6/17/2024
Effective	6/17/2024
Last Revised	6/17/2024
Next Review	6/17/2026
Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services

L.58 iCASSETTE Fentanyl Urine Test Cassette

Intended Use:

A. The **iCASSETTE *Fentanyl Urine Test Cassette*** is a CLIA Waived immunoassay intended for the qualitative detection of fentanyl in human urine at a cutoff concentration of 1.0 ng/ml.

B. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gaschromatography-mass spectrometry or Liquid Chromatography with Mass Spectrometry is the preferred confirmatory method.

C. For in vitro diagnostic use only.

Summary and Explanation of the Test:

A. Fentanyl is a rapid-acting synthetic opioid that has historically been used to to treat severe pain, especially after surgery and for advanced-stage cancer. Fentanyl is estimated to be 80 times as potent as morphine and hundreds of times more potent than heroin. It is a drug of abuse and is a major contributor to fatal and nonfatal overdoses in the U.S.

B. The **iCASSETTE *Fentanyl Urine Test Cassette*** is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Fentanyl in urine. The Fentanyl Urine Test Cassette yields a positive result when Fentanyl in urine exceeds 1ng/ml.

Principle:

A. The **iCASSETTE *Fentanyl Urine Test Cassette*** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. Fentanyl, if present in the urine specimen below 1ng/ml, will not

saturate the binding sites of antibody-coated particles in the test device. The antibody-coated particles will then be captured by immobilized FTY conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the FTY level exceeds 1ng/ml because it will saturate all the binding sites of anti-FTY antibodies.

B. A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Precautions:

A. For medical and other professional *in vitro* diagnostic use only.

B. Do not use after the expiration date.

C. The test should remain in the sealed pouch until use.

D. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

E. The used test should be discarded according to local regulations.

Storage & Stability:

A. **iCASSETTE Fentanyl Test Kits**

1. Store as packaged in the sealed pouch at 35.6-86°F (2-30°C).
2. The test is stable through the expiration date printed on the sealed pouch.
3. The test cassettes must remain in the sealed pouch until use.
4. DO NOT FREEZE.
5. Do not use beyond the expiration date.

B. **DETECTABUSE Liquid Controls**

1. Unopened: The controls are stable until the expiration date when stored at 2° to 8°C (Oxazepam is stable for only 6 months). Store -10° to -20°C to extend the Oxazepam stability, up to 3 years or until expiration date, whichever comes first.
2. After Opening: The controls are stable for 31 days or until the expiration date, whichever comes first, when stored tightly capped at 2° to 8°C. The controls are stable for six months or until the expiration date, whichever comes first, when stored at -10° to -20°C. Controls can be thawed/frozen up to 5 times.

Materials & Equipment:

A. Materials Provided:

1. iCASSETTE Test Cassettes and Droppers (sealed in foil pouch with a desiccant)
2. User Instructions

3. Procedure Card

B. Materials Required but not Provided:
    1. Specimen Collection Container
    2. Timer
    3. DETECTABUSE Liquid Fentanyl Control Kit (Pos/Neg Controls- 5 ng/mL)

Specimen Collection & Storage:

A. The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used.

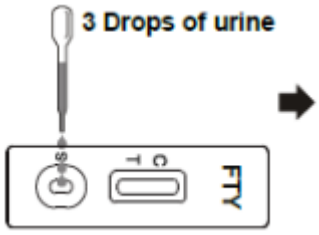
B. Urine specimens may be stored at 35.6-46.4°F (2-8°C) for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -4°F (-20°C). Frozen specimens should be thawed and mixed before testing.

Directions for Use:

A. Allow the test, urine specimen and/or controls to reach room temperature 59-86°F (15-30°C) prior to testing.

B. Remove the test cassette from the sealed pouch and use it within one hour.

C. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120mL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S).



A. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.

B. If preliminary positive results are observed, send the urine sample to the laboratory for confirmation.

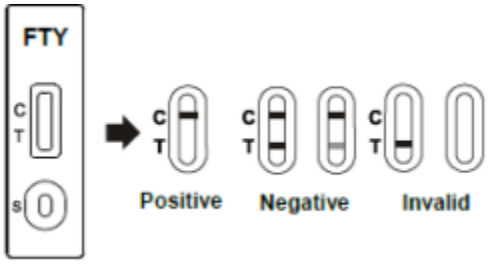
Interpretation of Results:

A. **NEGATIVE**: Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). A negative result indicates that the Fentanyl concentration is below the detectable level (1ng/ml).
"NOTE: The shade of color in the test line region CT) may vary, but it should be considered negative whenever there is even a faint colored line.

B. **POSITIVE:** One colored line appears in the control line region (C). No line appears in the test line region CT). A positive result indicates that the Fentanyl concentration exceeds the

detectable level (1ng/mL).

C. **INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.



Quality Control Test Schedule:

A. **Internal Controls**- A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

B. **External Controls**- It is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance. The recommended quality control material available to users is Fentanyl Cerilliant F-013 at 1.0 mg/ml, which is the same QC material used for manufacturer performance studies.

Quality Control Test Steps:

A. Remove 2 test cassettes from the sealed foil pouch. Label one cassette “Positive” and the other cassette “Negative”. Use within 1 hour.

B. Allow controls to come to room temperature followed by gentle swirling or inversion before use. DO NOT SHAKE.

C. Transfer 3 full drops of the positive control into the specimen well (S) of the “Positive” test cassette.

D. Transfer 3 full drops of the negative control into the specimen well (S) of the “Negative” test cassette.

E. Read results at 5 minutes. Do not interpret the result after 10minutes.

F. The positive DETECTABUSE control must test positive on the drug of abuse test device. The negative control must test negative.

G. Do NOT proceed to patient samples unless both the Positive and Negative controls yield expected results.

Limitations:

A. The **iCASSETTE *Fentanyl Urine Test Cassette*** provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gaschromatography-

mass spectrometry or Liquid Chromatography with Mass Spectrometry is the preferred confirmatory method.

B. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.

C. A confirmed positive result indicates presence of the drug but does not indicate level of intoxication, administration route or concentration in urine.

D. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.

E. Test does not distinguish between drugs of abuse and certain medications.

Performance Characteristics:

Refer to Manufacturer's Instruction for Use (Attachment)

References:

A. DETECTABUSE Liquid Control Urine Package Insert, January, 2024.

B. "Fentanyl Facts." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, www.cdc.gov/stop-overdose/caring/fentanyl-facts.html. Accessed 4 June 2024.

C. iCASSETTE Fentanyl Urine Test Cassette Instructions, December 23, 2023.

All Revision Dates

6/17/2024

Attachments

Detectabuse Controls_IFU_1.2024.pdf

iCASSETTE_IFU_12.23.2023.pdf

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	6/17/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	6/16/2024

Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	6/13/2024

Status **Active** PolicyStat ID **16027291**

Origination	1/28/2012	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	6/13/2024		
Effective	6/13/2024	Policy Area	Laboratory Services
Last Revised	6/13/2024		
Next Review	6/13/2026		

L.SPH.49 Ketones

INTENDED USE:

Ketone tablets are for th semi-quantitative determination of ketones (acetoacetic acid and acetone) in urine, serum, and plasma.

Urine testing is CLIA Waived.

Serum/Plasma Testing is Moderately Complex for clinical laboratory testing only.

SUMMARY AND EXPLANATION:

The presence of ketone bodies is important in the evaluation of carbohydrate metabolism. The test is based on the nitroprusside reaction with ketone bodies to give a purple color.

PRINCIPLE OF THE TEST:

Acetoacetic acid or acetone in urine or blood will form a colored complex with nitroprusside in the presence of glycine. A buffer provides the optimum pH for this reaction.

SPECIMEN:

Urine: Test fresh urine within ***one hour of collection***. If testing cannot be done within an hour, refrigerate specimen immediately and let it return to room temperature before testing. Urine preservatives may affect test results.

Serum or Plasma: Specimens may be refrigerated at 2° to 8°C for up to 72 hours. For longer storage, samples may be frozen at or below -20°C.

REAGENTS AND SUPPLIES:

1. AimTab™ Ketone Tablets
    a. Each AimTab™ Ketone Tablet contains sodium nitroprusside, aminoacetic acid, disodium phosphate, sodium borate, lactose, and nonreactive binding ingredients.
    b. Store at 15° to 30°C unopened.
    c. Once opened, AimTab™ Ketone Tablets stability is decreased on exposure to moisture.
        i. Recap the bottle promptly after removing the tablet.
        ii. Tablets should be used on a regular basis and not stored for an extended period of time after bottle is opened.
    d. Do not store in direct sunlight.
    e. Do not use when deterioration is noted by a tan-to-brown or darkening color of the tablet.
    f. Do not swallow or eat tablet.
2. Calibrated Timer
3. Plastic pipette
4. Clean white paper
5. Quality Control" positive and negative controls
6. Gloves

PROCEDURE:

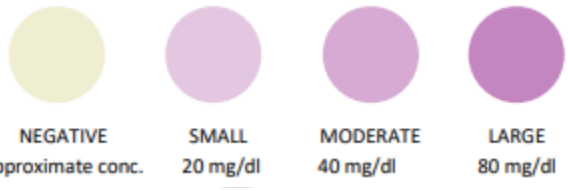
1. Bring samples to room temperature prior to testing.
    - Frozen samples must be completely thawed and mixed well prior to testing.
    - Samples should not be frozen and thawed repeatedly.
2. Carefully remove tablet from bottle and replace cap promptly.
3. Place tablet on a clean, dry, white paper.
4. Using a clean plastic pipette, dispense one drop of urine or serum directly on top of tablet.
5. Urine: Wipe off any excess urine and compare color of tablet to color chart at ***30 seconds*** after application of sample.
6. Serum: Wipe off any excess serum and compare color of tablet to color chart at ***2.5 minutes*** after application of sample.

QUALITY CONTROL:

Serum: Biorex Labs K-Check Controls for Serum Ketones

1. Controls are run each day of use, or at opening of a new bottle of AimTab™ Ketone Tablets.

2. Follow manufacturer's instructions for use. K-CHECK-CONTROLS.pdf (biorexlabs.com)
    a. Do not mix caps from different vials.
    b. Handle as though capable of transmitting disease.
    c. Controls are stable for one year unopened and 30 days after opening the vial
    d. Bring to room temperature. Mix gently by inversion before use.
    e. Do not use if turbid, it may be an indication of contamination.
3. Run levels 0, 1, and 2 controls along with the patient sample. Use in the same manner as patients specimens.
4. Remove a tablet for each test. Securely recap the bottle.
5. Place the tablets on a white paper towel. With a marker/pen label below the tablets accordingly such as “Test”, “Positive” and “Negative” controls.
6. Using a disposable transfer pipette, place a drop of the test specimen directly onto the tablet. Always use a separate pipette for each of the controls.
7. Wait 2.5 minutes.
8. To read results compare the developed color to the color chart. est. Any development of lavender to purple color is a positive test.
9. Wipe off the excess serum and compare to the color chart below for results.



Technical Assistance: Biorex: info@biorexlabs.com.

Urine: Bio-Rad qUAntify Advance Control Level 1(Negative) and Level 2 (Positive)

- Follow manufacturer's instructions for use.
- Bring to room temperature (18° to 25°C) and invert several times to ensure homogeneity.

INTERPRETATION OF RESULTS:

POSITIVE: tablet shows any signs of purple color. Match color to color chart on container and report as SMALL, MEDIUM, or LARGE. No calculations are necessary.

NEGATIVE: No color change will be present at the correct read time. Disregard any pink, tan, or yellow color.

LIMITATIONS:

Improper handling of the product to allow moisture absorption will adversely affect results.

False positive results may occur with urine specimens containing bromsulpthalein, large amounts of phenylketones, levodop metabolites, or other sulfhydryl compounds.

EXPECTED RESULTS:

Ketones ar not found in blood or urine under normal conditions or carbohydrate metabolism.

PERFORMANCE CHARACTERISTICS:

AimTab™ Ketone Tablets will detect as little as 5 mg of acetoacetic acid/dL in urine. AimTab™ Ketone Tablets are specific for the detection of acetoacetic acid and acetone. AimTab™ Ketone Tablets are about 10 times more sensitive to acetoacetic acid than acetone and will not react with betahydroxybutyric acid.

In urine, the small color block corresponds to approximately 20 mg acetoacetic acid/dL, the moderate color block to 20 to 40 mg/dL, and the large color block to approximately 80 to 100 mg/dL.

The lower limit of detection in serum is approximately 10 mg acetoacetic acid per dL.

REFERENCES:

1. Free, H.M., Smeby, R.R., Cook, M.H., and Fern, A.H.: A comparative study of qualitative tests for ketones in urine and serum, *Clin. Chem*. 4:323, 1958.
2. Riekers. H. and Miale, J.B.: Ketonuria: An evaluation of tests and some clinical implications. *Amer. J. Clin. Path*. 30:530, 1958.
3. Levison, S. A., MacFate, J.H., *Clinical Laboratory Diagnostic and Management of Laboratory Methods*. 19th Edition Philadelphia: WB Saunders; pp. 241:374, 454, 1996.
4. Free, A.H., and Free, H.M.: Nature of nitroprusside reactive material in urine in ketosis: *Amer. J. Clin. Path*. 30:7, 1958.
5. Henry, JB. et. al.: *Clinical Diagnostic and Management of Laboratory Methods*, 19th Edition Philadelphia: WB Saunders; pp. 241-374, 454, 1996.
6. Csako, G.: False Positive Results for Ketone with the Drug Mesna and other Free Sulfhydryl Compounds. *Clinical Chemistry*: 33/2:289, 1987.

All Revision Dates

6/13/2024, 5/24/2024, 1/28/2012

Attachments

AimTab Ketone Tablets Rev. 12.18 .pdf

K-CHECK-CONTROLS.pdf

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	6/13/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	6/13/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	6/13/2024

Status Active PolicyStat ID 15308800

Origination	6/10/2024
Last Approved	6/10/2024
Effective	6/10/2024
Last Revised	6/10/2024
Next Review	6/10/2026
Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services

L.SPH.59 ARK Fentanyl II Assay

INTENDED USE

The ARK Fentanyl II Assay is an immunoassay intended for the qualitative detection of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers. This in vitro diagnostic device is for prescription use only. The ARK Fentanyl II Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed positive analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug test result, particularly when the preliminary test result is positive.

SUMMARY AND EXPLANATION OF THE TEST

Fentanyl [N-(1-(2-phenylethyl)-4-piperidinyl)-N-phenylpropanamide] is a synthetic opioid narcotic analgesic similar to morphine.1 Fentanyl is 50-100 times more potent than morphine. It is prescribed for patients with chronic pain and is used to manage pain after surgery or for treatment of breakthrough pain in cancer patients.2 Fentanyl is prescribed in various forms: by injection (intravenous or intramuscular), transdermal patch3 , and orally (transmucosal lozenge or film). Fentanyl such as the transdermal system can be abused in a manner similar to other opioid agonists, legal or illicit. All patients receiving opioids should be routinely monitored for signs of misuse, abuse and addiction. Fentanyl has high potency and short duration of action, and it is abused for its intense euphoric effects. It is very dangerous when substituted illicitly for other opioids because of its potency and overdoses can lead to respiratory depression and death.4,5 It is a Schedule II substance under the U.S. Controlled Substances Act. The ARK Fentanyl II Assay detects fentanyl in human urine. The test is not intended to differentiate between drugs of abuse and prescription use of fentanyl. There are no uniformly recognized drug levels for fentanyl in urine. The primary metabolism of fentanyl leads to the time-dependent urinary excretion of fentanyl and norfentanyl.6-8 The half-life of fentanyl may range 3 - 12 hours. Fentanyl is exclusively metabolized by N-dealkylation and hydroxylation. More than 90% of the dose is eliminated as norfentanyl and hydroxylated metabolites. Less than 7% of the dose is excreted unchanged in the urine.

PRINCIPLES OF THE PROCEDURE

The ARK Fentanyl II Assay is a homogeneous enzyme immunoassay technique used for the analysis of a specific compound in human urine. The assay is based on competition between drug in the specimen and drug labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH) for antibody binding sites. As the latter binds antibody, enzyme activity decreases. In the presence of drug from the specimen, enzyme activity increases and is directly related to the drug concentration. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH in the presence of glucose-6-phosphate (G6P), resulting in an absorbance change that is measured spectrophotometrically. Endogenous G6PDH does not interfere because the coenzyme NAD functions only with the bacterial enzyme used in the assay.

REAGENTS

A. Reagent Kit 5069-0001-00

1. Reagent 1 – Antibody/Substrate (1 X 28 mL): Rabbit monoclonal antibodies to fentanyl, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, sodium azide, and stabilizers
2. Reagent 2– Enzyme (1 X 28 mL): Fentanyl derivative labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH), bovine serum albumin, buffer, sodium azide and stabilizers

B. Reagent Kit 5069-0001-01

1. Reagent 1– Antibody/Substrate (1 X 115 mL): Rabbit monoclonal antibodies to fentanyl, glucose-6-phosphate, nicotinamide adenine dinucleotie, bovine serum albumin, sodium azide, and stabilizers
2. Reagent 2 - Enzyme (1 X 115 mL): Fentanyl derivative labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH), bovine serum albumin, buffer, sodium azide and stabilizers

C. Reagent Kit 5069-0001-02

1. Reagent 1 – Antibody/Substrate (1 X 500 mL): Rabbit monoclonal antibodies to fentanyl, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, sodium azide, and stabilizers
2. Reagent 2 – Enzyme (1 X 500 mL): Fentanyl derivative labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH), bovine serum albumin, buffer, sodium azide and stabilizers

Ordering Information

For orders and technical support, contact Siemens Healthcare Diagnostics. Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591 Siemens.com/healthineers 1-800-227-8994 in the USA 1-800-264-0083 in Canada In other countries, please contact your local representative.

Product Name	Quantity/Kit	ARK Product Number	Siemens Material Number (SMN)
ARK™ Fentanyl II Assay	R1 28mL, R2 28mL	5069-0001-00	11554027
ARK™ Fentanyl II Assay	R1 115mL, R2 115mL	5069-0001-01	11554028
ARK™ Fentanyl II Assay	R1 500mL, R2 500mL	5069-0001-02	11554029
ARK™ Fentanyl Calibrator	2 x 10mL; Negative	5031-0002-01	11354475
ARK™ Fentanyl Calibrator	2 x 10mL; Cutoff	5031-0002-02	11354476
ARK™ Fentanyl Control	2 x 10mL; Low 2 x 10mL; High	5031-0003-00	11354477
Siemens EMPTY Flex® Reagent Cartridge	N/A	N/A	10445039

Reagent Handling and Storage

ARK Fentanyl II Assay reagents are provided liquid, ready to use and may be used directly from the refrigerator. When not in use, reagents must be stored at 2–8°C (36–46°F), upright and with screw caps tightly closed. If stored as directed, reagents are stable until the expiration date printed on the label. Do not freeze reagents. Avoid prolonged exposure to temperatures above 32°C (90°F). Improper storage of reagents can affect assay performance. ARK Fentanyl II products contain ≤0.09% sodium azide. As a precaution, affected plumbing including instrumentation should be flushed adequately with water to mitigate the potential accumulation of explosive metal azides. No special handling is required regarding other assay components.

Important Information

ARK Diagnostics, Inc. manufactures the ARK Fentanyl II Assay, ARK Fentanyl Calibrators and ARK Fentanyl Controls and is solely responsible for the quality of the data obtained which is caused by performance of the reagents, any variation between lots of ARK reagents, ARK calibrators or ARK controls. ARK Diagnostics, Inc. is not responsible for user-defined changes. It is the responsibility of the user to validate any modifications to the parameters defined in this application sheet and their impact on all assay results

Manufacturer Information

ARK Fentanyl II reagents, ARK Fentanyl calibrators, and ARK Fentanyl controls are manufactured by ARK Diagnostics, Inc. and sold/distributed by Siemens Healthcare Diagnostics for application on the Siemens Dimension Systems.

ARK Diagnostics, Inc. 48089 Fremont Boulevard Fremont, CA 94538
www.ark-tdm.com

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use. For prescription use only.

Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

• Reagents and are provided as a matched set and should not be interchanged with reagents from different lot numbers.

• Do not use reagents after the expiration date.

• Reagents contain ≤0.09% sodium azide.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Human urine is required. Treat as potentially infectious material.

• Collect urine using standard sampling cups and procedures. Care should be taken to preserve the chemical and physical integrity of the urine sample from the time it is collected until the time it is assayed, including during transport. Fresh urine specimens are suggested.

• Cap the urine sample immediately after collection, store refrigerated at 2-8°C (36–46°F) and assay within 7 days after collection. If the assay cannot be performed within 7 days, store the urine sample frozen at -20°C for up to 6 months prior to analysis.9,10,11,12

To protect the integrity of the sample, do not induce foaming and avoid repeated freezing and thawing.

• Frozen specimens must be thawed and mixed thoroughly prior to analysis.

• Centrifuge specimens with high turbidity or visible particulate matter before testing.

• The presence of bubbles or foam on specimens may lead to short samples and erroneous results.

• The recommended pH range for urine specimens is 4.0 – 11.013.

• Obtain another sample for testing if adulteration of the sample is suspected. Adulteration of urine specimens can affect the test result.

PROCEDURE

Materials Provided

Materials Provided ARK Fentanyl II Assay – 5069-0001-00, 5069-0001-01 or 5069-0001-02

Materials Required

Provided Separately ARK Fentanyl Calibrator A (Negative) – 5031-0002-01 ARK Fentanyl Calibrator B (Cutoff) – 5031-0002-02 Quality Controls – ARK Fentanyl Control – 5031-0003-00

Instruments

Reagents and may need to be transferred to analyzer-specific reagent containers prior to use. Avoid cross-contamination of and . Refer to the instrument-specific operator's manual for daily maintenance. Consult the analyzer-specific application sheet for programming the fentanyl assay or contact Customer Support.

Assay Sequence

To run or calibrate the assay, see the instrument-specific operator's manual.

Preparation of Assay Components

The following assay components are ready-to-use liquids as supplied. When not in use, store upright at 2-8°C. Components are stable until the expiration date printed on the label if stored as directed.

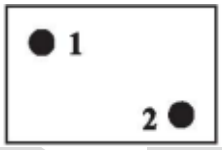
Reagent R1: Antibody/Substrate and Reagent R2: Enzyme.

Precaution: Avoid cross-contamination of R1 and R2. Calibrators and Controls:

Supplied separately. Perform assay-specific calibration and quality control as recommended in the package insert.

Preparation of the Flex® Reagent Cartridge: Venting the Flex® The Flex® well must be vented before filling with a reagent.

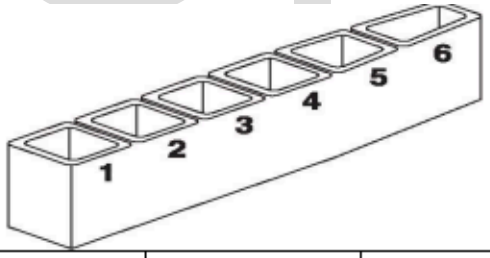
To vent a Flex® well, puncture the film at a corner of the well (1) and then fill the well from the opposite corner (2). Care must be taken to minimize the size of the vent and fill holes without tearing the film



Filling the Flex®

Transfer reagent into an empty, vented Flex® according to the table below.

Well fill volumes shown below have demonstrated 48 hours on-board stability. Use of lower volumes may result in shorter on-board stability.



Reagent	Wells	Volume per Well	Tests per Well	# of Tests Per Flex
Reagent B (R2)	1 and 2	1.85 mL	10	10 x 2 = 20
Reagent A (R1)	5 and 6	1.85 mL	10	10 x 2 = 20

Flex Cartridge Configuration

Well	1	2	3	4	5	6
Component	B	B			A	A
Number of tests	10	10	0	0	10	10
Well Life (hours)	48	48	48	48	48	48
On Board Life	48 hrs		Calibration Time		336 hrs	

Flex Cartridge Configuration

Well	1	2	3	4	5	6
Component	B	B			A	A
Number of tests	10	10	0	0	10	10
Well Life (hours)	48	48	48	48	48	48
On Board Life	48 hrs		Calibration Time		336 hrs	

A pre-filled Flex® must be stored at 2–8°C with the vent and fill holes covered. When taped, the pre-filled cartridge is stable at 2-8°C for 7 days. Remove this covering before loading the Flex® on the analyzer.

The following are parameters for use when performing the ARK Fentanyl II Assay on the Siemens Dimension Systems. Instrument operating instructions are contained in the Siemens Dimension System Operator's Guide.

For customers whose software is at 10.5.1 or greater, we recommend turning on the continuous cuvette option.

INSTRUMENT SETTINGS (QUALITATIVE)

From the Main Menu press: [F7] Diagnostics [F8] Open Channels Channel: Choose a channel from 1 to 15 METHOD: X*** (User Defined)

MODE MEASURE: ABSORBANCE TYPE:

LINEAR

	Time	Volume	Component 1	Component 2	Component 3	Chase	Mix
1st Reagent	– 57.6 sec for RxL®/EXLTM		(A) 155 µL	( ) 0 µL	( ) 0 µL	0 µL	NONE
Sample	0.0 sec	20.0 µL				10.0 µL	GENTLE
2nd Reagent	220.0 sec		(B) 155 µL	( ) 0 µL	( ) 0 µL	20 µL	MODERATE
3rd Reagent	***		( ) 0 µL	( ) 0 µL	( ) 0 µL	0 µL	NONE
Photometry	P1: 270.0 sec P2: 360.0 sec P3: *** P4: *** Press [F7] Calculate: [F5] Template						

Enter the following information:

Mode	Rate	Measuring Filter	340	Blanking Filter	600
P1 Time	270	Dilution 0.0000		IOD 50	BELOW
P2 Time	360	Dilution 0.0000		FOD 1800	ABOVE

Press: [F4] Accept
[Exit] multipoint mau calculations screen
Press: [F2] Set-up
See Continuous cuvette option: Press drop down ON
[Exit]
[F4] Store
[F8] Print
Return to the Main Menu.

Press: [F6] System Config
[F1] Methods Parameters
[Assigned Assay Key]
Verify that the screen appears as shown below:

Test Name: User Defined
Decimals: 0 Units: Qual Calculation: LINEAR
Std vol: Auto Dilute Vols: serum/plasma: urine:

	Serum/Plasma	CSF/Blood	Urine
REFERENCE	** – **	** – **	1000-1000
ASSAY	** – **	** – **	0-2000
PANIC	Reflex if < 0.0 or > 0.0		RUN

LOT	C0	C1
(Lot nb)	0.00	1.00
	0.00	1.00

Press [F4] Store Param

1. Calibrate each new reagent kit and when quality controls are out of their expected ranges.

Press: [F5] Process CTRL
[F1] Calibration
[Enter]
[F2] Set up and Run
[Assigned Assay key]
[F1] Select reagent lot (if necessary)

To calibrate:
Fill 3 sample cups with appropriate calibrators.
Enter the normalized values as shown in table below.

Cup	Level	Normalized Value
1	Cal A (0.0 ng/mL)	0
2	Cal B (1.0 ng/mL)	1000
3	Cal B (1.0 ng/mL)	1000

2. After calibration, review the data.

Validation

Return to Main Menu
Press: [F5] Process CTRL
[F1] Calibration
[Enter]
[F3] Review Data
[Assigned Assay key]
[F1] Select reagent lot (if necessary)
[F7] Calculate
[F2] Accept data

QUALITATIVE RESULTS

Use the 1.0 ng/mL Calibrator B as a Cutoff Calibrator to distinguish negative and positive samples. Run the Low and High Controls as Negative and Positive respectively. Report test results less than the rate (mA/min) value for the Cutoff Calibrator as Negative. Report results equal to or greater than the rate (mA/min) value for the Cutoff Calibrator as Positive.

When to Re-Calibrate

- Whenever a new lot number of reagents is used
- Whenever indicated by quality control results

• Whenever required by standard laboratory protocols

Quality Control (QC) and Calibration

All quality control requirements and testing should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

Each laboratory should establish its own ranges for each new lot of controls.

Control results should fall within established ranges as determined by laboratory procedures and guidelines.

The ARK Fentanyl Control is intended for use in quality control of the ARK Fentanyl II Assay.
The Low Control should be Negative.
The High Control should be Positive relative to the 1.0 ng/mL Cutoff Calibrator.

RESULTS AND EXPECTED VALUES

The actual fentanyl concentration cannot be determined. A confirmatory method is required.

Qualitative Analysis - Negative Results

A specimen that gives a rate (mA/min) value less than the ARK Fentanyl Calibrator B Cutoff rate (mA/min) value is interpreted as negative; either the specimen does not contain fentanyl or fentanyl is present in a concentration below the cutoff level of this assay.

A factor is calculated to adjust the calibrator to 1000. Negative samples are <1000

Qualitative Analysis - Positive Results

A specimen that gives a rate (mA/min) value equal to or greater than the ARK Fentanyl Calibrator B Cutoff rate (mA/min) value is interpreted as positive, indicating that fentanyl is present. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

A factor is calculated to adjust the calibrator to 1000. Positive samples are ≥1000.

LIMITATIONS

• The assay is designated for use with human urine only.
• ARK Fentanyl II Assay reagents, and ARK Fentanyl calibrators and controls were developed as companion products. Performance with substituted products cannot be assured.
• A positive result using the ARK Fentanyl II Assay indicates only the presence of fentanyl and does not necessarily correlate with the extent of physiological and psychological effects.
• Do not use Boric Acid as a preservative.

• Interpretation of results must take into account that urine concentrations can vary extensively with fluid intake and other biological variables.

• It is possible that substances other than those tested in the specificity study may interfere with the test and cause false results.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance characteristics were collected on the Beckman Coulter AU680® automated clinical chemistry analyzer using the ARK Fentanyl II Assay.

Precision

Drug-free, negative human urine was supplemented with fentanyl (0.00 to 2.00 ng/mL). Each level was assayed in quadruplicate twice a day for 20 days (N=160). Results are summarized in the table below.

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Results
0.00	-100	160	160 Negative
0.25	-75	160	160 Negative
0.50	-50	160	160 Negative
0.75	-25	160	160 Negative
1.00	Cutoff	160	84 Negative; 76 Positive
1.25	+25	160	160 Positive
1.50	+50	160	160 Positive
1.75	+75	160	160 Positive
2.00	+100	160	160 Positive

Analytical Specificity

All compounds tested were added to drug-free, negative human urine. The cross-reactivity of the following metabolites and structural analogs of fentanyl was evaluated by spiking these compounds into drug-free, negative human urine and evaluated by dose-response to determine the approximate equivalence to the 1.0 ng/mL fentanyl cutoff. These concentrations were used to determine the percent cross-reactivity according to the formula: % Cross-reactivity = (Cutoff concentration / Concentration approximately equivalent to the 1.0 ng/mL cutoff) X 100 For the compounds Alfentanil and Remifentanil that did not produce a positive result, the highest concentration tested was used to calculate percent cross-reactivity. Cross-reactivity For the major metabolite, norfentanyl, the lowest concentration capable of producing a positive result is shown below.

Norfentanyl (Major Metabolite)

Compound	Concentration Approximately Equivalent to the Cutoff (ng/mL)	Percent Cross-reactivity (%)
Norfentanyl	15	7

Other Metabolites and Structural Analogs of Fentanyl

Compound	Concentration Approximately Equivalent to the Cutoff (ng/mL)	Percent Cross-reactivity (%)
Acetyl fentanyl	1.1	90.91
Isobutyryl fentanyl	1.1	90.91
ω-1-Hydroxyfentanyl	1.2	83.33
Acrylfentanyl	1.3	76.92
Butyryl fentanyl	1.4	71.43
Furanyl fentanyl	1.5	66.67
Para-fluoro fentanyl	1.5	66.67
Ocfentanil	1.6	62.50
4-Fluoro-isobutyryl fentanyl	1.9	52.63
Para-fluorobutyryl fentanyl (p-FBF)	1.9	52.63
Valeryl fentanyl	2.3	43.48
β-hydroxyfentanyl	9.5	10.53
Acetyl norfentanyl	12.1	8.26
(±) β-hydroxythiofentanyl	32.7	3.06
(±)-3-cis-methyl fentanyl	144.1	0.69
Carfentanil	448.2	0.22
Despropionyl fentanyl (4-ANPP)	471.8	0.21
Sufentanil	2,362	0.04
Remifentanil	10,000	<0.01
Norcarfentanil	38,196	0.003
Alfentanil	100,000	<0.001

The following opioids, structurally similar compounds, and functional analogs were negative at the concentrations tested with the ARK Fentanyl II Assay.

Compound	Concentration Tested (µg/mL)	Compound	Concentration Tested (µg/mL)
6-Acetyl morphine	100	Naltrexone	100
Buprenorphine	100	Norbuprenorphine	100
Buprenorphine glucuronide	100	Norcodeine	100
Codeine	100	Normeperidine	100
Dextromethorphan	100	Normorphine	100
Dihydrocodeine	100	Noroxycodone	100
EDDP	100	Oxycodone	100
EMDP	100	Oxymorphone	100
Heroin	100	Pentazocine (Talwin)	100
Hydrocodone	100	Pipamperone	90
Hydromorphone	100	Quinine	100
9-Hydroxyrisperidone	100	Quinidine	100
Labetalol	100	Risperidone	100
Levorphanol	100	Tapentadol	100
m-Chlorophenylpiperazine (m-CPP)	100	Thioridazine	100
Meperidine	100	Tilidine	100
Methadone	100	Tramadol	100
Morphine	100	Tramadol-O-Desmethyl	100
Morphine-3-glucuronide	100	Tramadol-N-Desmethyl	100
Naloxone	100	Trazodone	100

Interference – Structurally Unrelated Compounds

High concentrations of the following structurally unrelated compounds were added into fentanyl-spiked urine (± 50% of the cutoff concentration). The substances listed below did not yield a false result relative to the cutoff.

Compound	Concentration Tested (µg/mL)	0.5 ng/mL (-50% Cutoff)	1.5 ng/mL (+50% Cutoff)
Acetaminophen	500	Negative	Positive
Acetylsalicylic acid	1000	Negative	Positive
Albuterol	100	Negative	Positive
Amitriptyline	100	Negative	Positive
Amobarbital	100	Negative	Positive
Amphetamine	100	Negative	Positive
Benzoylecgonine	100	Negative	Positive
Bupropion	100	Negative	Positive
Caffeine	100	Negative	Positive
Carbamazepine	100	Negative	Positive
Chlorpromazine	100	Negative	Positive
Clomipramine	100	Negative	Positive
Cyclobenzaprine	100	Negative	Positive
Desipramine	100	Negative	Positive
Doxepin	100	Negative	Positive
Ecgonine	100	Negative	Positive
Ephedrine	100	Negative	Positive
Fluoxetine	100	Negative	Positive
Fluphenazine	100	Negative	Positive
Ibuprofen	500	Negative	Positive
Imipramine	100	Negative	Positive
Ketamine	100	Negative	Positive
Lidocaine	100	Negative	Positive
Maprotiline	100	Negative	Positive
Methapyrilene	100	Negative	Positive
Methaqualone	100	Negative	Positive
Metronidazole	300	Negative	Positive
Nicotine	100	Negative	Positive
Norketamine	100	Negative	Positive
Nortriptyline	60	Negative	Positive
Oxazepam	100	Negative	Positive
Phencyclidine	100	Negative	Positive
Phenobarbital	100	Negative	Positive
Propoxyphene	100	Negative	Positive
Ranitidine	100	Negative	Positive
Secobarbital	100	Negative	Positive
Valproic acid	250	Negative	Positive
Venlafaxine	100	Negative	Positive

Interference – Endogenous Substances

High concentrations of the following endogenous substances were added into fentanyl-spiked urine (± 50% of the cutoff concentration). No interference was observed when tested with the ARK Fentanyl II Assay.

Compound	Concentration Tested (mg/dL)	0.5 ng/mL (-50% Cutoff)	1.5 ng/mL (+50% Cutoff)
Acetone	1000	Negative	Positive
Ascorbic Acid	560	Negative	Positive
Bilirubin	2	Negative	Positive
Creatinine	500	Negative	Positive
Ethanol	1000	Negative	Positive
Galactose	10	Negative	Positive
Gamma Globulin	500	Negative	Positive
Glucose	3000	Negative	Positive
Hemoglobin	500	Negative	Positive
Human Albumin	500	Negative	Positive
Oxalic Acid	100	Negative	Positive
Riboflavin	7.5	Negative	Positive
Sodium Chloride	4000	Negative	Positive
Urea	2000	Negative	Positive

Interference – Boric Acid

One percent (1%) w/v of boric acid was added into fentanyl-spiked urine (± 50% of the cutoff concentration). Results are provided in the table below.

Compound	Concentration Tested	0.5 ng/mL (-50% Cutoff)	1.5 ng/mL (+50% Cutoff)
Boric Acid	1% w/v	Negative	Negative

Interference – Specific Gravity and pH

Urine samples with specific gravity values from 1.002 to 1.030 and pH values ranging from 3.0 to 11.0 were tested in the presence of the two levels of fentanyl at ± 50% of the cutoff concentration. No interference was observed when tested with the ARK Fentanyl II Assay.

Method Comparison

A total of one hundred forty seven (147) unaltered clinical urine specimens that are not individually identifiable were analyzed for fentanyl with the ARK Fentanyl II Assay and by LC-MS/MS. The LC-MS/MS

confirmatory method was performed by a licensed reference laboratory and used a fentanyl cutoff of 0.2 ng/mL. Specimens were tested with the ARK Fentanyl II Assay in singleton on a Beckman Coulter AU680 analyzer and compared to results obtained by LC-MS/MS. Groups of up to 31 specimens were assayed per run. Each run was verified by assaying the bi-level ARK Fentanyl Controls (0.5 ng/mL and 1.5 ng/mL) as quality control samples.

Results are summarized as follows:

ARK Immunoassay Result	Low Negative Less than 50% below the Cutoff (< 0.5 ng/mL by LC-MS/MS)	Near Cutoff Negative Between 50% below the Cutoff and the Cutoff (0.5 – 0.9 ng/mL by LC-MS/MS)	Near Cutoff Positive Between the Cutoff and 50% above the Cutoff (1.0 – 1.5 ng/mL by LC-MS/MS)	High Positive Greater than 50% above the Cutoff (> 1.5 ng/mL by LC-MS/MS)
Positive	1*	21	11	62
Negative	50	2	0	0

Discordant Results

*Norfentanyl was detected in this discordant sample (Sample ID #052) and contributed to the positive result obtained with the ARK Fentanyl II Assay for this sample

Sample ID Number	ARK Immunoassay Result	Fentanyl (ng/mL by LC-MS/MS)	Norfentanyl (ng/mL by LC-MS/MS)
052*	Positive	0.4	7.6
065	Positive	0.5	5.2
058	Positive	0.5	7.9
069	Positive	0.5	31.2
060	Positive	0.5	425.4
056	Positive	0.6	3.7
072	Positive	0.6	13.8
062	Positive	0.6	14.5
074	Positive	0.6	14.6
055	Positive	0.6	16.9
071	Positive	0.6	19.0
070	Positive	0.6	161.7
051	Positive	0.7	2.1
066	Positive	0.7	3.1
064	Positive	0.8	15.9
073	Positive	0.8	45.8
063	Positive	0.9	2.2
061	Positive	0.9	6.5
057	Positive	0.9	12.3
053	Positive	0.9	14.0
059	Positive	0.9	62.6
054	Positive	0.9	63.4

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TRADEMARKS

March 2020 1600-1032-00 Rev 01

All Revision Dates

6/10/2024

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	6/10/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	6/10/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	6/10/2024

Status **Active** PolicyStat ID **15076582**

Origination	11/1/1985	Owner	Jessica Rodriguez: Manager, Cardiopulmonary Services
Last Approved	7/12/2024		
Effective	7/12/2024		
Last Revised	7/12/2024	Policy Area	Respiratory Care
Next Review	7/12/2026		

R.50 Responsibilities of the Respiratory Therapist

POLICY:

To outline the responsibilities of Respiratory Therapists working at Ventura County Medical Center/Santa Paula Hospital.

PROCEDURE:

I. Each Respiratory Therapist (RT) is responsible for the following:
   - A. Education of patients and family
   - B. Basic and advanced respiratory therapy modalities
   - C. Completion of Task List in assigned areas
   - D. Complete Respiratory Therapy note for cares provided to a patient that does not have a task available for charting or when a RT needs to provide further detail.
   - E. PRN therapies will be documented at a minimum of once per shift
   - F. All equipment is to be stocked and cleaned in the area assigned
   - G. All equipment shall be labeled with patient identifier
     1. Visibly soiled equipment will be changed
     2. Discontinued equipment will be removed, cleaned, and returned to service before the end of shift
   - H. Respond to any Rapid Response and/or Code Blue in assigned area
   - I. Writing the work phone they can be reached at for the duration of the shift on the unit communication board they are assigned to.

II. Duties to be performed prior to or at the change of shift:

A. The Manager will assign someone to divide the workloads and be lead
    a. Therapist designated to be lead will complete staff assignment and assign phones
    b. Turn phone assignments to operator
    c. Report any internal issues to Manager or Supervisor on call immediately
B. RT will update their workload to designated lead therapist by 1600 or 0400
C. Billing will occur as therapist uses equipment in Cerner
D. Shift report will be given at 0600 and 1800.
    1. Hand off report will be provided on each patient before RT's leave the hospital
    2. Hand off of ventilated patients shall occur at the bedside
    3. RT's will hand off their assigned work phone to appropriate person
    4. Therapist not assigned to ventilator patients will receive report in the RT report room
    5. Any concerns/issues regarding assignments the RT Manager should be called

III. Specific Duties for Intensive Care Units and Emergency Department
A. Maintenance of the Blood Gas Laboratory as specified by Laboratory policies
B. Attendance of rounds
C. AM Blood gas testing will be performed before Resident change shift
D. Completion of Spontaneous Breathing Trials (SBT) will be performed and documented per policy
E. RT will ensure manual resuscitation device is at bedside of all patients on mechanical ventilation
F. Unplanned extubation, notify physician, complete notification form, complete form in department to notify Department Manager
G. Attend and sign in for all Code Yellow Tier 1 and Tier 2
H. Respiratory Emergency airway box will be checked to assure supplies are available

IV. Respiratory Therapist
A. Will provide Department Manager a copy of renewed California Respiratory Care License
B. Will at all times maintain a current
    a. Basic Life Support Training (BLS)
    b. Advance Cardiovascular Life Support (ACLS)
    c. Pediatric Advance Life Support (PALS)
    d. Neonatal Resuscitation Program (NRP) only for NICU therapist and Santa

Paula therapist

C. Education
    1. Will attend yearly skills fair in services
    2. Will use Policy Stat and Lippincott as resource for procedures
    3. Will complete competency check off before the use of new equipment
    4. Will attend training and complete competencies as instructed

All Revision Dates

7/12/2024, 3/15/2022, 2/1/2012, 10/1/2008, 1/1/2006, 12/1/2001, 10/1/1998, 12/1/1995, 6/1/1992, 10/1/1989

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/12/2024
Respiratory Care	Jessica Rodriguez: Manager, Cardiopulmonary Services	7/8/2024

Status **Active** PolicyStat ID **15037309**

Origination	5/1/1983
Last Approved	6/28/2024
Effective	6/28/2024
Last Revised	6/28/2024
Next Review	6/28/2027
Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices
Policy Area	Administrative - Employee

101.017 Verification of Current Licensure

POLICY:

Ventura County Medical Center and Santa Paula Hospital employees who require licensure as a job qualification for their position shall maintain a current license.

All individuals, utilized in a licensed capacity at Ventura County Medical Center and Santa Paula Hospital shall be fully licensed by the State of California or have a temporary license with a stated expiration date.

PROCEDURE:

Department Directors and Managers in the following departments are required to keep documentation of current licenses and perform primary source license verification.

- Ambulatory Care
- Clinical Laboratory
- Dietary
- Imaging Services
- Nuclear Medicine
- Pharmacy
- Rehabilitation Services
- Respiratory Therapy
- Nursing

It shall be the responsibility of the licensed practitioner to comply with licensure requirements, maintain current licensure, and submit evidence regarding current licensure to their Department Director or Manager. The Human Resources (HR) Department, in concert with the Department Director or Manager

is responsible for ensuring proof of current licensure. The HR Department will send pending licensure expirations to the Department Directors and Managers on a regular basis.

If an employee fails to maintain licensure, they will not be permitted to work until licensure is obtained. Failure to maintain licensure may lead to disciplinary action up to and including termination.

All Revision Dates

6/28/2024, 2/23/2021, 1/1/2014

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	6/28/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/12/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/12/2024
Policy Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices	6/12/2024

Status **Active** PolicyStat ID **15037310**

Origination	11/1/1983
Last Approved	6/12/2024
Effective	6/12/2024
Last Revised	6/12/2024
Next Review	6/12/2027
Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices
Policy Area	Administrative - Employee

101.023 Request for Vacation, Leave of Absence, Administrative Leave

POLICY:

It is the policy of Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) and Ambulatory Care (AC) to provide for the needs of its employees for vacations and for leaves of absence. For this reason, use of accrued vacation time shall be encouraged and shall be scheduled by each department manager.

PROCEDURE:

Each manager must schedule leaves within the following parameters: operation of the department must continue without placing undue delays in patient service and without increasing planned operational costs of the department; leaves must be granted in a manner that is fair and internally consistent, as well as in compliance with all Ventura County and VCMC/SPH/AC policies. Requests for leave of absence which meet the criteria of policies established in the County of Ventura Personnel Rules and Regulations and the current Memorandum of Agreement (MOA), and are properly documented may be granted.

In order to maintain an orderly process for review and approval of requests for vacation and leave of absence, it is important that such requests and approval be documented. Because of its size and complexity, the VCMC/SPH Nursing Department maintains a separate leave policy and a special request form which are in compliance with the overall intent of this Administrative Policy.

Any VCMC/SPH and AC department which has special needs may formulate an internal policy and procedure so long as it is within the scope of this policy and is approved by Hospital and/or Ambulatory Care (whichever department is applicable) Administration and reviewed by Labor Relations.

VACATION

The County does not currently utilize a form for vacation request and approval. However, in the interest of improved documentation, it is appropriate for VCMC/SPH and AC to require a documented request and approval for vacation time. Therefore, request forms should be completed by staff and retained by the department manager. It will be useful for those occasions in which a question may arise at a later date.

MOA - Service Employees International Union (SEIU) Employees:
Managers/supervisors shall respond within five (5) calendar days to vacation requests submitted in writing and at least 14 calendar days prior to the first date requested off. The vacation request shall be deemed approved if the manager/supervisor does not respond within the five (5) days, provided the employee has the accrued vacation time to cover the requested time off.

If the manager/supervisor is out of the office (sick, vacation, etc.), they should notify staff who will be handling vacation request in their absence.

LEAVE OF ABSENCE

The County of Ventura does request a specific form, **Leave of Absence-Request** (*PAOF - 882 - SUB*), for the request and approval of leaves of absence. This form should be used for leave of absence requests for sick leave, maternity leave, bereavement leave, and other authorized leave according to the County of Ventura Personnel Rules and Regulations and the current MOA. An absence unrelated to approved vacation and consisting of more than three (3) consecutive workdays requires the completion of form mentioned above. Leaves of absence may be approved by an approving authority if they meet the policy conditions established in the County of Ventura Personnel Rules and Regulations and the current MOAs.

For more information on Leave of Absence please refer to: *Absence Management Program Handbook*. The Absence Management Program Handbook provides information on types of leaves, eligibility, employee responsibilities, employer responsibilities, and returning from leave.

LEAVE WITHOUT PAY FOR PURPOSE OF EXTENDING VACATION

It is the general policy of the Health Care Agency and VCMC/SPH/AC to not grant Leave Without Pay (LWOP) in order to extend vacations or to add to an employee's vacation balance.

The Personnel Rules and Regulations and MOAs are very clear on the allowable circumstances for requesting a leave of absence. It is very important that this information be transmitted clearly to employees in order to reduce the potential for abuses in leave without pay, sick leave and vacation.

ADMINISTRATIVE LEAVE

Administrative Leave is a negotiated benefit which is intended to provide time off with pay for exempt employees (those who are not eligible to be compensated for overtime). The provisions covering

eligibility and utilization of administrative leave are covered in detail in the MOA.

It is the general policy of the Health Care Agency and of VCMC/SPH/AC not to grant administrative leave in order to extend vacations. In addition, the MOA clearly states that Administrative Leave is **not accrued or earned** according to overtime hours accumulated or any other indicator. Its purpose is to allow eligible employees to tend to personal business in addition to vacation, sick leave and holidays.

Administrative Leave must be approved in advance by Hospital and/or Ambulatory Care (whichever department is applicable) Administration.

All hours not worked and not shown as other leave or holiday must be documented and reported to Administration as administrative leave.

No employee is entitled to any specific minimum of hours of administrative leave. Determination of such hours given is at the discretion of the designated Administration. However, as a general rule, Administrative Leave should not exceed 40 hours per year per exempt employee.

All Revision Dates

6/12/2024, 5/1/2006, 7/1/2001, 10/1/1986, 2/1/1984

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH [JA]	6/12/2024
Ambulatory Care Administration	Lizeth Barretto: Chief Operating Officer, Ambulatory Care	6/12/2024
Ambulatory Care Administration	Cynthia Fenton: AC Director of Nursing	6/4/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	5/29/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	5/29/2024
Policy Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices	5/29/2024

Status **Active** PolicyStat ID **9950378**

Origination	11/1/1984
Last Approved	7/11/2024
Effective	7/11/2024
Last Revised	7/11/2024
Next Review	7/11/2027
Owner	Ian McGraw: Manager Facility Operation
Policy Area	Administrative - Environment of Care

106.012 Locking Hospital Entrances

POLICY:

For the purpose of internal security and proper routing of after-hours admissions, it shall be the policy of Ventura County Medical Center and Santa Paula Hospital to lock all entrances at 9:00 p.m. and reopen them at 5:00 a.m. each morning.

PROCEDURE:

The locking and unlocking of doors will be handled by the Security Supervisor.

The only public entrance to Ventura County Medical Center and Santa Paula Hospital after 9:00 p.m. will be through the unlocked Emergency Room entrance.

At the time of locking, a sign shall be hung from the door with the following message:

ENTRANCE LOCKED BETWEEN
THE HOURS OF 9:00 P.M. to 5:00 A.M.

PLEASE USE EMERGENCY ENTRANCE

All Revision Dates

7/11/2024, 12/1/2017, 5/1/2006, 4/1/1994

Approval Signatures

Step Description	Approver	Date

Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	7/11/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/9/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/9/2024
Safety Committee	Fernando Medina: Director, Support Services	7/9/2024
Policy Owner	Ian McGraw: Manager Facility Operation	12/14/2023

Status **Active** PolicyStat ID **13517888**

Origination	4/11/2023
Last Approved	6/12/2024
Effective	6/12/2024
Last Revised	6/12/2024
Next Review	6/12/2027
Owner	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH
Policy Area	Administrative - Environment of Care

106.086 Suicidal Environmental Risk Assessment

PURPOSE:

Our goal is to provide a safe environment for patient care. This policy provides guidance on the process for assessing potential environmental risks for suicide, self-harm, or harm to others. The goal of the assessment is to identify potential environmental hazards to individuals served and take action to safeguard those individuals from the environmental risks.

POLICY:

Patient care areas where care is provided to patients assessed as at risk for self-harm (suicide) and/or harm to others will be assessed to identify potential environmental hazards and action will be taken to safeguard patients from identified hazards/risks.

DEFINITION(S):

1. **Ligature** is an item which can be tied, wrapped, or twisted tightly around one's neck to restrict or prevent breathing. It does not necessarily need to be attached to a ligature point to be effective. Examples include belts, shoe laces, sheets, curtains, and clothing.
2. **Ligature Point** is any fixture or fitting which could be load bearing and used to tie or secure a cord, sheet, or other tether as a means of hanging or suffocation. Examples of ligature points are tops of doors, door knobs/handles, bed railings, wall hooks, towel bars, and plumbing fixtures.
3. Continuous (**1:1 Observation)** iis a level of observation in which an assigned staff member (Patient Safety Attendant) stays within close proximity of the patient and provides direct observation at all times. One to One Observation – Patient has one assigned staff to maintain constant visual observation. This is from the new policy we are adding for IPU.

PROCEDURE(S):

A. EMERGENCY, PERIOPERATIVE AND IN-PATIENT UNITS

1. Annual Environmental Assessment
    a. An annual environmental assessment of potential suicide-ligature risks will be organized by the Safety Manager. Due to the scope of this assessment, Nursing Directors and appropriate Ancillary & Support Managers will also be involved in the assessment process. The scope of the assessment is to evaluate each affected unit with various types of spaces in which patients at risk for suicide may be present. These spaces include patient rooms, patient common areas, and patient bathrooms.
    b. The Suicide/Self-Harm Environmental Risk Assessment is intended to be completed to assess risks in all areas where care for patients at risk for suicide is provided. This assessment aids in the identification of potential environmental risks such as anchor points, ligature, and other items that might otherwise be used to harm patients, staff or visitors should be utilized (The American Society for Healthcare Engineering (ASHE) of the American Hospital Association is one such organization that publishes assessment forms).
    c. The Inpatient Psychiatric Unit (IPU) and the Crisis Stabilization Unit (CSU) are areas of potential high risk for suicide by ligature due to the frequency and numbers of high-risk patients present in these locations. In spaces intended specifically for high-risk patients, it is our goal to identify and permanently eliminate ligature points, ligature, and other harmful items.
    d. Most patient care areas are not routinely used for the care of patients at risk for suicide, and these areas are designed and primarily used with other patients in mind. However, there may be occasions where patients at risk for suicide receive diagnosis or treatment for acute conditions outside the Inpatient Psychiatric Unit. When at-risk patients are cared for in these departments, 1:1 observation will be provided We will also temporarily take out of such areas easily removable items that may cause potential harm to at-risk patients, staff or visitors. Items that cannot be easily removed will be identified and mitigated with the 1:1 observation.
    e. Data collected from the Suicide/Self-Harm Environmental Risk Assessment(s) will be presented to the Environment of Care Committee and used as guidance for environmental and clinical safety improvements.

B. SHIFT ASSESSMENTS

1. Patients who present and/or brought to Ventura County Medical Center/Santa Paula Hospital after a suicide attempt or with active suicidal ideation with/without a psychiatric hold and who are being cared for in areas other than the Crisis Stabilization Unit (CSU) or Inpatient Psychiatric Unit (IPU), will be provided care in a space where suicide risks within the care environment need to be temporarily mitigated. Examples of such areas are the Emergency Department (ED) and the Medical-Surgical Units.
2. A checklist, 'Creating a Safe Environment (C.A.S.E.)," has been established for use by staff who

will be caring for at-risk patients in these locations to temporarily mitigate environmental suicide risks C.A.S.E. will be completed by the Safety Attendant each shift.

C. INPATIENT PSYCHIATRIC UNIT/CRISIS STABILIZATION UNIT

1. Yearly Environmental Assessment
    a. A Yearly or as needed environmental assessment of potential suicide/self- harm risks within these units will be organized by the Safety Manager. Due to the scope of this assessment, the Nursing Director of the Inpatient Psychiatric Unit/Crisis Stabilization Unit and certain Ancillary & Support Services Managers will also be involved in the assessment process. The scope of the assessment is to evaluate each affected area with various types of spaces in which patients at risk for suicide/ self-harm may be present. These spaces include patient common areas, patient bathrooms and patio/ outdoor spaces.
    b. The comprehensive Mental Health Environment of Care Checklist (MHEOCC) is utilized to review the inpatient psychiatric settings for environmental hazards. The checklist was developed by a multidisciplinary team comprising members from the Veterans Affairs National Center for Patient Safety, Nursing, Safety, Environmental Management, and Interior Design. Members of the team developed criteria and shared information with industry leaders. The purpose of the checklist is to identify and abate environmental hazards that could increase the chance of patient suicide or self-harm. Implementation of the MHEOCC was associated with a substantial reduction in the rate of completed inpatient suicide in Veterans Health Administration (VHA) hospitals nationally.
    c. It is our goal to eliminate items that are easily removed that may cause potential harm to at-risk patients. Items that cannot be easily removed will be identified and mitigated.
    d. Data collected from the Mental Health Environment of Care Checklist (MHEOCC) will be presented to the Environment of Care Committee and used as guidance for environmental and clinical safety improvements.

REFERENCE(S):

- Policy *108.050 Patient Safety Attendant Care*
- Policy *100.269 Suicide Prevention Policy*
- The American Society for Health Care Engineering (ASHE) of the American Hospital Association--ASHE Patient Safety and LIgature Identification Checklist(s)/2018.
- Veterans Health Administration (VHA) Mental Health Environment of Care Checklist (MHEOCC). /PATIENTSAFETY/docs.VA-NCPS-Mental-Health-Environment-of-Care-Checklist-20220307.xlsx

All Revision Dates

6/12/2024, 4/19/2023, 4/11/2023

Attachments

C.A.S.E. Safety Checklist.pdf

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH [JA]	6/12/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/10/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/10/2024
Environment of Care Committee	Ian McGraw: Manager Facility Operation	6/10/2024
Policy Owner	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/4/2024

Status **Active** PolicyStat ID **13490179**

Origination	2/12/2019	Owner	Ian McGraw: Manager Facility Operation
Last Approved	7/11/2024	Policy Area	Administrative - Operating Policies
Effective	7/11/2024		
Last Revised	7/11/2024		
Next Review	7/11/2027		

107.065 Security Screening of Patients and Visitors

POLICY:

Ventura County Medical Center (VCMC), Santa Paula Hospital (SPH), Inpatient Psychiatric Unit (IPU) and Crisis Stabilization Unit (CSU) prohibit contraband items or any item that a patient could cause harm to anyone. Patients and visitors entering VCMC, SPH Emergency Department, IPU and CSU will be subject to a safety screening. The screening may consist of a walk through metal detector and/or a screening via a hand-held metal detection wand. The safety screening process is performed 24 hours a day, 7 days a week by trained security personnel.

DEFINITIONS:

Entry Points: Emergency Department, Main Entrance, Ambulance Bay Entrance, IPU & CSU Main Entrance.

Wanding: the process of manually scanning a person with a wand that alarms when in proximity to electromagnetically reflective or metallic objects.

Metal Detector: an instrument that detects the presence of metal**.**

Contraband: any device or item likely to cause death or injury or pose a safety or legal concern to patients, visitors or staff. See Attachment A: List of Contraband Items.

PROCEDURE:

Patients and visitors entering VCMC, SPH ED or IPU will walk through a metal detector and/or be screened by a hand-held metal detection wand. Patients and visitors will be asked to remove all metal objects or contraband items in their possession prior to walking through the metal detector.

A sign will be posted advising patients and visitors in any area that they are required to undergo safety

screening. Patients and visitors with contraband or weapons will either be asked to surrender their belongs or, when appropriate, store items in vehicle.

Patients and visitors who access the Emergency Department entrances, including ambulance bay entry, shall be required to be wanded and have their bags and possessions searched prior to facility entry. Personal belongings may need to be submitted for storage in accordance with policy *100.256 Patient Belongings*.

Emergent Situations

In the event that a person presents to the Emergency Department in extremis and requires emergent medical intervention and is unable to walk through the metal detector or be wanded by the hand-held metal detection wand, the Security Team will communicate to the medical staff member that this person was not screened. While the medical team assesses the patient, the belongings will be removed from the patient and security safety screening will be completed by security personnel utilizing the metal detecting wand.

Inpatient Psychiatric Unit/Crisis Stabilization Unit Procedure

The IPU front lobby doors are to remained locked at all times. Staff members may utilize their designated access cards for entry. Storage lockers are available for visitor belongings if needed. Individuals will complete metal detection and/or wanding. Anyone with contraband will not be permitted to access the facility. Individuals who refuse to store their personal items in the storage lockers or who refuse screening will not be allowed to enter the facility.

A. If a dangerous article is lost and cannot be accounted for, search the entire patient occupied areas.
    1. For example, if a razor is given to a patient and is not returned or if scissors are missing, a search of the entire unit may be necessary.

B. Should a patient decline to turn over their belongings, allow staff to perform the skin assessment/contraband check. The patient will be placed on a 1:1 observation immediately in the admission hallway. The 1:1 observation will continue until the patient cooperates with the skin assessment/contraband check. Use of the portable metal detector/wand may assist in this search.

C. Patients refusing a skin assessment/contraband check will be placed on 1:1 observation.

Wanding

When utilizing the hand-held metal detector, wand will first be passed over a known metallic object to ensure it is alarming properly. To screen the individual, the screener will pass the hand-held metal detector wand over all parts of the individual from their feet to their head without touching the person or allowing the detector to touch the person.

In the event the metal detection wand is activated or alarms:

1. The screener will scan the area of activation a second time, or have them walk back through the threshold for a second walk through.
2. If activation continues, the screener shall ask the person being scanned to remove any items that may be activating the detector, then screen the person again. This step will be repeated until the source of activation is identified. The screener shall NOT conduct a pat-down search.
3. If the individual being screened is a visitor and does not turn over found contraband or refuses to cooperate, entrance into the facility shall be denied.
4. If the individual being screened is a patient and does not turn over found contraband or refuses to cooperate, the local law enforcement may be called for further investigation.

In the event the metal detection wand touches the person, a general purpose disinfection wipe approved by the Infection Control Committee shall be used to disinfect the metal detection wand. The metal detection wand shall be disinfected regularly and when visibly contaminated.

Confiscated Items

Any confiscated items unable to be stored in lockers or vehicles will be placed with the individual's personal belongings, excluding confiscated weapons. Any weapons must be turned over to local law enforcement. All confiscated items will be placed in a sealed, numbered, dated envelope and kept with the person's belongings and stored in accordance with policy *100.256 Patient Belongings*. A receipt with the corresponding number will be given to the owner to present upon departure when claiming items.

Any potentially illegal items should be brought to the Security Watch Commander. The individual with the confiscated item may leave the campus without question or delay. A person in possession of the weapon cannot be detained by Security. Once local law enforcement comes to evaluate a weapon, the weapon must be removed by law enforcement from campus. If the owner of that item wants to retrieve, he or she must contact the local law enforcement agency directly.

Illegal drugs and related paraphernalia will be confiscated and given to local law enforcement. Any medications, including controlled substances, shall be handled in accordance with policy *PH.68 Medications Brought in from Home.*

Pacemakers and Implanted Metallic Objects

Per the American Heart Association, interactions with metal detectors are unlikely to cause symptoms in most pacemakers patients. However, before screening anyone, staff must ask if the patient or visitor has a pacemaker or any other metallic object on his/her person. If the patient reports a pacemaker or other implanted metal, staff will use a wand instead of a walk through metal detector and avoid prolonged screening of the area around the pacemaker or implanted object.

All Revision Dates

7/11/2024, 10/20/2022, 6/8/2022, 8/27/2021, 2/23/2021, 2/12/2019

Attachments

Attachment A: List of Contraband Items

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	7/11/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/9/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/9/2024
Safety Committee	Fernando Medina: Director, Support Services	7/9/2024
Policy Owner	Ian McGraw: Manager Facility Operation	6/12/2023

Status Active PolicyStat ID 13742168

VENTURA COUNTY HEALTH CARE AGENCY

Origination	1/7/2007
Last Approved	6/12/2024
Effective	6/12/2024
Last Revised	6/12/2024
Next Review	6/12/2027
Owner	Ian McGraw: Manager Facility Operation
Policy Area	Facilities

F.23 Facilities Maintenance Eyewash Station Inspection

POLICY:

To state the Facilities Maintenance process for inspecting eyewash stations at Ventura County Medical Center and Santa Paula Hospital.

PROCEDURE:

1. ☐ Eyewash stations must be tested and inspected weekly.
2. ☐ Run the eye wash for 2-3 minutes.
3. ☐ Ensure the water has sufficient water flow.

   Note whether the hands-free mechanism is functioning.
4. ☐ Outlet heads (lids covering where water flows from) should be kept closed when not in use. These lids should pop off upon activation of the water.
5. ☐ Check all plumbing for leaks.
6. ☐ Check all eyewash spray heads.
7. ☐ Ensure unit is numbered.
8. ☐ Ensure unit is identified with emergency eyewash/shower station sign.
9. ☐ Ensure eyewash spray heads operate properly without excessive pressure.
10. ☐ Ensure valves seat properly when units are deactivated.
11. ☐ Clean spray heads and eyewash bowl.
12. ☐ Ensure there are no obstructions limiting access or visibility. If there is, contact the area supervisor and advise staff to clear the area. Note the discrepancies on Preventive Maintenance Inspection in findings area.

13. ☐ Sign and date inspection tag and initial the appropriate box to document a passing inspection.

    If inspection fails, notify all users and call Facilities Maintenance immediately at 1-805-652-6683.

NOTE: IT IS IMPERATIVE THAT ALL SPRAY HEADS & SPRAY HEAD COVERS ARE THROUGHLY RINSED AND/OR FLUSHED WITH CLEAN WATER.

Note: For information pertaining to inspection records, contact Facilities Maintenance. Inspection tags on eyewash stations are not utilized for this purpose on the equipment itself.

- Should an exposure occur, flush the affected eye(s) for 15 minutes.
- To ensure adequate flushing, hold eyelid(s) open and roll the eyeball.

Annual Preventative Maintenance:

SHOWER

1. ☐ Make sure the water supply delivers the required flow when shower and eyewash are operated simultaneously.
2. ☐ Make sure any hands-free stay-open valve activates in one second or less.
3. ☐ Height of water column is between 82” and 96” above floor for shower.
4. ☐ Shower delivers 20 GPM of water at required pattern.
5. ☐ Easily located, accessible actuator is no more than 69” above the floor.
6. ☐ Center of the water pattern is at least 16” from any obstruction.
7. ☐ At 60” above the floor the water pattern is at least 20” in diameter.
8. ☐ Spray heads are protected from airborne contaminants. Covers are removed by water flow.

EYEWASH

1. ☐ Eyewash unit delivers at least 3.0 GPM (eyewash/face wash) or .4 GPM for (eyewash) or 15 minutes.
2. ☐ Hands-free stay-open valves activates in 1 second or less.
3. ☐ Valve actuator is easy to locate and readily accessible to user.
4. ☐ Water flow pattern is positioned between 33” and 53” from the floor and at least 6” form the wall or nearest obstruction.
5. ☐ Water temperatures shall be tepid (60 to 100 degrees)
6. ☐ Eyewash or shower will have visible sign.
7. ☐ Combination units shall be capable of operating simultaneously and shall be positioned so that components may be used simultaneously by the same user.
8. ☐ Unit shall remain on so that the flushing remains on without the use of the operators’

hands. The valve shall be simple to operate and go from off to on in 1second or less

Drench Hose

1. ☐ Water flow is sufficiently high to allow user to hold eyes open while rinsing.
2. ☐ Protective spray heads from airborne contaminants. Covers are removed by water flow.
3. ☐ Drench hoses must deliver a controlled flow of flushing water at a velocity low enough to be non-injurious
4. ☐ Unit delivers at least 0.4 GPM of water for 15 minutes.
5. ☐ Hands-free stay -open valves activates in 1 second or less.
6. ☐ Valve actuator is easy to locate and readily accessible to user.
7. ☐ Water flow patter is positioned between 33” and 53” from the floor and at least 6” from the wall or nearest obstruction.

If inspection fails, notify all users and call and create work order with Facilities Maintenance immediately at 1-805-652-6683.

All Revision Dates

6/12/2024, 3/13/2023, 3/10/2020, 2/1/2017, 7/1/2016, 12/9/2013, 1/7/2008

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH [JA]	6/12/2024
Facilities Department	Ian McGraw: Manager Facility Operation	6/10/2024

Status **Active** PolicyStat ID **15969307**

Origination	1/26/2023	Owner	Matt McGill: Director, Imaging Services
Last Approved	6/5/2024	Policy Area	Imaging Services
Effective	6/5/2024		
Last Revised	6/5/2024		
Next Review	6/5/2027		

IS.01 Radiation Safety & Protection Program

POLICY:

In California, all radiation sources, either radiation (X-ray) machines or radioactive material, are subject to State laws and regulations. The statutes are found in the Health and Safety Code, Division 104-Environmental Health. The regulations are found in the California Code of Regulations (CCR), Title 17, Div. 1, Chapter 5, Subchapters 4, 4.5, and 4.7. Title 17 CCR 30253 incorporates by reference the federal regulations specified in Title 10, Code of Federal Regulations (CFR), Part 20. Requirements in 10 CFR 20 apply to all registrants.

This medical imaging facility is required to develop, document, and implement a radiation protection program commensurate with the scope and extent of use of X-ray machines and sufficient to ensure compliance with the above regulations. Additionally, the medical imaging facility shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are **a**s **l**ow **a**s **r**easonably **a**chievable (ALARA). The Radiation Safety Officer will audit the radiation protection program on an annual basis to ensure it remains within the scope and extent of activities required to ensure compliance with the said regulations.

All components of the Radiation Safety and Protection Program do not have to be contained in one consolidated document. However, all components do have to be documented and identified as being part of the Radiation Protection Program and will be duly listed and described. Records of the Radiation Safety and Protection Program content, implementation and audits must be maintained for inspection by the Department.

The regulatory agency for radiation safety is the Radiologic Health Branch of the Department of Public Health and can be contacted at the following addresses and phone number:

Department of Public Health

Radiologic Health Branch
P.O. Box 997414, MS-7610
Sacramento, CA 95899-7414
Email: RHBInfo@cdph.ca.gov
(916) 327-5106
www.cdph.ca.gov

Access to Title 17 is available for all staff through PolicyStat and can be found within the Imaging Services policy section or directly as policy *IS.17 Title 17 California Code of Regulations*.

PROCEDURE:

Organization and Administration

The delegation and responsibility for each aspect of the radiation program and provisions for ensuring enforcement of radiation safety policies and procedures are as follows:

A. **Facility Radiation Safety Officer, qualifications and responsibilities.**

1. VCMC/SPH's designated Radiation Safety Officer is Miguel Jimenez in partnership with our medical physicist, Therapy Physics Inc.
2. The primary responsibility of the Radiation Safety Officer's (RSO) is implementing the Radiation Safety Program. The RSO shall ensure that radiation safety activities are performed with approved procedures, meeting all regulatory requirements in the daily operation of the licensee's radioactive materials program.
3. The Radiation Safety Officer shall promptly investigate and implement corrective actions as necessary regarding:
    a. Overexposures
    b. Use of ionizing radiation as defined by State and Federal guidelines
    c. Accidents
    d. Spills
    e. Losses
    f. Thefts
    g. Unauthorized receipts, uses, transfers, and disposals; and
    h. Other deviations from approved radiation safety practice. A written report of these investigations and the corrective actions taken shall be given to management.
4. The Radiation Safety Officer shall implement written policies and procedures to:
    a. Authorize the purchase of radioactive material
    b. Use of ionizing radiation as defined by State and Federal guidelines
    c. Receive and open packages of radioactive material
    d. Store radioactive material

e. Keep an inventory record of radioactive material
f. Use radioactive material safely
g. Take emergency action if control of radioactive material is lost
h. Perform periodic radiation surveys
i. Perform checks of survey instruments and other safety equipment
j. Dispose of radioactive material
k. Train personnel who work in or frequent areas where radioactive material is used or stored; and
l. Keep a copy of all records and reports required by department regulations, a copy of these regulations, a copy of each licensing request and license including amendments, and the written policies and procedures required by the regulations.

5. The Radiation Safety Officer shall:
    a. Approve radiation safety program changes for medical use not at a medical institution with the consent of management prior to sending to the department for licensing action. assist the radiation safety committee for medical use at a medical institution.
    b. review, sign and date, at least every 3 months the occupational radiation exposure records of all personnel working with radioactive material.

ALARA Program

VCMC/SPH uses, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA) and documents procedures addressing this requirement. Staff resources and educational materials are available within PolicyStat and through annual education.

Dosimetry Program

All registrants are responsible for the protection of individuals that enter the registrants' controlled areas. The registrant is also responsible for ensuring that the public is protected and that the public dose does not exceed the limits found in 10 CFR 20.

A. Each facility must evaluate whether or not personnel monitoring for occupational exposures is required. If a facility chooses to or is required to monitor, then those who are occupationally exposed to radiation should be instructed in the following:
    1. Types of individual monitoring devices used and exchange frequency.
        - Landauer Film badges (and TLD finger rings for Nuclear Medicine): Monthly
    2. Use of control badges.
        - The use of the control badge is used to maintain a base reading of non-occupational exposure. Control badges are kept in the respective

departments until ready to be sent back with appropriate dosimetry badges for reading.

3. Instructions to employees on proper use of individual monitoring devices, including consequences of deceptive exposure of the device.
    - See Radiation Safety Policy "IS.19 Staff Radiation Safety and Dosimetry Monitoring"

4. Procedures for ensuring that the combined occupational total effective dose equivalent (TEDE) to any employees receiving occupational exposure at this facility and at other facilities does not exceed 5 rem per year.
    - Employee dosimetry reports are monitored at specified intervals (see #1 above) to ensure their combined occupational total effective dose equivalent does not exceed 5 rem per year. An employee's exposure is investigated further if his/her monthly deep dose equivalent is greater than 125 mrem (ALARA Level 1) or quarterly deep dose equivalent is greater than 375 mrem (ALARA Level 2) in a quarter.

5. Procedures for obtaining and maintaining employees' concurrent occupational doses during that year.

    Employees are required to self-disclose any and all concurrent occupational doses received during the previous year in January of the subsequent year or upon being employed. Their doses will be sent to Landauer for inclusion in their dose record. The RSO and designate will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigation Level II and, if warranted, will take action. A notice of exposure and a questionnaire will be sent to the affected staff to determine the source of exposure. An acknowledgement letter will be obtained from the affected staff. A report of the investigation and actions taken will be presented to the Radiation Safety Committee at the first Radiation Safety Committee meeting following completion of the investigation. The details of these reports will be recorded in the Radiation Safety Committee minutes.

6. Procedures for ensuring that if minors are employed, their occupational TEDE does not exceed 500 millirem per year
    - N/A. We don't employ nor have any intentions of employing minors.

7. Procedures for addressing a declaration of pregnancy.
    - See policy *IS.56 Radiation Protection*. Declaration by employees and withdrawal is a voluntary process.

8. Procedures for maintaining documentation of dose to the embryo/fetus and associated documentation for the declared pregnant worker.
    - If an employee declares a pregnancy, she will be required to wear a fetal badge at the waist level and her dosimetry badge at the collar level. The fetal badge will be submitted and processed once a month to ensure fetal readings do not exceed the set dose limits. The employee's occupational dosimetry badges will be submitted monthly or quarterly based on the

department (see item #1). All dosimetry reports are evaluated by the RSO and/or designate to ensure compliance with state/federal regulations concerning dose limits.

Area Monitoring and Control

A. **Radiation Area Monitoring**

The need for area monitoring shall be evaluated and documented.

- Any area regulated through protective measures and safety provisions is considered a "Controlled Area". Access is restricted to controlled areas with warning signs specified in 17 CCR and incorporated sections of 10 CFR 20.
- Any area accessible to personnel in which there exists radiation at such levels that a major portion of the body (whole body, head and trunk, active blood-forming organs, gonads, or lenses of the eye) could receive in any one hour a dose equivalent in excess of 5 mrem or in 5 consecutive days a dose equivalent in excess of 100 mrem is considered a "Radiation Area"

B. **Instrument Calibration and Maintenance**

Instruments used to verify compliance with regulatory requirements must be appropriate for use and calibrated at required frequencies.

Maintenance of the machine should be addressed. This may be addressed in part by the operator's manual from the manufacturer.

All maintenance and calibration is completed by:

- G.E. Healthcare
- Phillips Healthcare
- Konica
- Siemens Medical
- Hologic
- Varian
- In-house Biomedical Engineering: Contracted to the above vendors for all radiation producing and radiation detection instrumentation on campus. All non-PM based services are coordinated with above vendors and completed by qualified field service engineers to meet current regulatory and manufacturer recommendations.

Radiological Controls

A. **Entry and Exit Controls**

Entry and exit from controlled areas must be adequate to ensure radiation safety. Design of emergency escape routes shall comply with applicable building codes. Document procedures

addressing this requirement.

- All applicable building codes were followed in the design of emergency escape routes of our facility.

B. **Posting**

1. Areas that are required to be posted should be identified in the Radiation Protection Program, in addition to procedures for ensuring that such areas are properly posted. Also, include procedures for ensuring that areas or rooms containing as the only source of radiation are posted with a sign or signs that read "CAUTION X-RAY". Identify who is responsible for maintaining those signs and/or labels. In addition, certain documents must be posted. This requirement is found in 17 CCR 30255(b).
    a. Entrances to X-ray suites are posted with signs that read "CAUTION X-RAY".

2. Conspicuously post:
    a. A current copy of the 17 CCR, incorporated sections of 10 CFR 20, and a copy of operating and emergency procedures applicable to work with sources of radiation (If posting of documents specified above is not practicable, the registrant may post a notice which describes the document and states where it may be examined.)
        - A current copy of 17 CCR and incorporated sections of 10 CFR 20 can be found on PolicyStat within policy "IS.17 Title 17 California Code of Regulations"
    b. A current copy of Department Form RH-2364 (Notice to Employees) in a sufficient number of places to permit individuals working in or frequenting any portion of a restricted area to observe a copy on the way to or from such area.
        - A current copy of RH-2364 (Notice to Employees) is posted in each department where ionizing radiation is utilized.
    c. Any notice of violation involving radiological working conditions, or any order issued pursuant to the Radiation Control Law and any required response from the registrant.
        - Notice of violation and any response will be posted in the cited department.

C. **Disposal of Equipment**

Registrants shall report in writing to the Department the sale, transfer, or discontinuance of use of any reportable source of radiation. See the Guidance for Disposal of X-ray Machines available http://www.cdph.ca.gov/programs/Pages/RadiologicHealthBranch.aspx.

D. **Other Controls**

The registrant should evaluate the need for other controls in addition to those mentioned above.

1. The following items should be considered :
    a. Types of controls used to reduce or control exposure to radiation, such as positioning aids, gonadal shielding, protective aprons, protective gloves, mobile shields, etc.
        - Refer to the "Apron Inventory" listing all of the above in each department utilizing radiation or radiation-producing devices.
    b. Procedures for routine inspection/maintenance of such controls.
        - Refer to the policy "IS.24 Lead Apron and Glove Survey" on PolicyStat

Emergency Exposure Situations and Radiation Accident Dosimetry

Identify any possible emergency exposure situations or radiation accidents and document procedures to address such, to include dose assessment.

- An established process to address and manage high radiation dose fluoroscopically guided procedures to ensure proper patient follow-up and follow-ups on suspicious readings has been developed and is followed.
- All exposure situations or radiation accidents that have occurred are reported immediately to the RSO and reviewed quarterly by the Radiation Safety Committee for trends and performance improvement.

Record Keeping and Reporting

All record keeping and reporting requirements are specified in regulations. Document the applicable requirements and commitments to compliance. The facility must also maintain all records of the Radiation Protection Program, including annual program audits and program content review. The following items should also be identified:

The person responsible for maintaining all required records.

- The RSO and/or delegate are responsible for maintaining all required records.

Where the records will be maintained.

- For the most part, all records will be located in Radiology or online.

The format for maintenance of records and documentation.

- Documentation of policies and procedures are online, with a hard copy for specific departments. Film Badge reports are located in their respective departments, and online with Landauer.

Procedures for record keeping regarding additional authorized sites (mobile providers).

- N/A

Reports to Individuals

The Registrant shall provide reports of individual exposure when requested in accordance with 17 CCR 30255. Document procedures addressing this requirement.

- Employees are provided, free of charge, dosimetry badges throughout the duration of their employment. Dosimetry badges must be submitted on a department specific basis. Monthly badges are available on the first of each month, quarterly badges are due on the 15th of each quarter. The dosimetry pick-up/drop-off container is located in each department utilizing badges. The most current dosimetry report is available through the "myLDR.com" web portal.
- User: VCMCDOSEREPORTS
- Pass: Radiation1
- The RSO or delegate reports Level 1 or higher exposure levels to the Radiation Safety Committee. A termination radiation dosimetry summary report is available to each employee once their employment has ended. Annual summary reports are kept indefinitely, available on-line from Landauer Inc.

Radiation Safety Training

A. **Operating and Safety Procedures**

1. All registrants are required to have a written operating and safety procedure manual. This may be the operating manual that comes with a radiation unit which may include safety procedures. However, if safety procedures are not included in the manual they must be developed. These safety procedures must be posted on the machine or where the operator can observe them while using the machine.
2. Document all training your employees, both occupationally exposed and non-occupationally exposed workers, are required to have before using radiation machines including continuing education. Also, document other training you provide to your employees or visitors such as radiation safety and protection program review, safety meetings, formal classroom training, etc.
3. Some of these requirements are found in the 17 CCR 30255(b) (1). Specifically, each registrant shall:
    a. Inform all individuals working in or frequenting any portion of a controlled area of the use of radiation in such portions of the controlled area.
    b. All new employees are required to attend a departmental orientation where he/she is orientated to the various components (policies & procedures) of our radiation protection plan.
    c. Instruct such individuals in the health protection problems associated with exposure to radiation, in precautions or procedures to minimize exposure, instruct such individuals in, and instruct them to observe, to the extent within their control, the applicable provisions of Department regulations for the protection of personnel from exposures to radiation occurring in such areas.

i. This facility has adopted the Radiation Right policies as a guide to effective Radiation Safety.

ii. Annual Radiation Safety review is mandated for all staff dealing with radiation and/or radiation producing devices.

iii. Staff meetings are held routinely, and Radiation Safety incidents are reviewed for best practice.

d. Instruct such individuals of their responsibility to report promptly to the registrant any condition which may lead to or cause a violation of department regulations or unnecessary exposure to radiation, and of the inspection provisions of 17 CCR 30254.

i. Staff are encouraged to report any causes for concern promptly as it relates to department regulation violations or unnecessary radiation exposure. Excessive Fluoroscopy is reported and documented per policy and procedures.

4. Instruct such individuals in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and advise such individuals as to the radiation exposure reports which they may request pursuant to 17 CCR 30255.

5. Any unusual occurrence or malfunction involving exposure to radiation will be promptly reported to the Equipment Service Coordinator who notifies the vendor and administration. Excessive radiation exposure reports will be documented and presented to the Radiation Safety Committee.

Quality Assurance Programs

Quality assurance program testing and frequency will conform with CCR Title 17 and accreditation requirements. Examples include but are not limited to:

Radiographic QC Tests

Factor	Monitoring Frequency	Responsible Party	Limits	Test Tool
AEC	**Annual**		**None**	**Exposure meter**
Collimation	**Annual**		**<2% SID**	**IR + metal markers**
Exposure Linearity	**Annual**		**Greater or less than 10%**	**Exposure meter or ion chamber**
Exposure Reproducibility	**Annual**		**Greater or less than 5%**	**Exposure meter or ion chamber**
Exposure time	**Annual**		**<10 ms, greater or less than 20%**	**Exposure meter**
			>10 ms, greater or less than 5%	
Filtration	**Annual**		**>2.5 mm Al**	**Aluminum sheets**

Focal Spot Size or Spatial Resolution	**Annual**		**± 50% stated FSS - <0.8 mm 40% larger – 0.8 mm – 1.5 mm 30% larger – >1.5mm**	**Slit/pinhole camera or star pattern phantom**
kVp	**Annual**		**Greater or less than 10%kVp**	**kVp meter**

Fluoroscopic QC Tests

Factor	Monitoring Frequency	Responsible Party	Limits	Test Tool
ABC	**Annual**		**None**	**Exposure meter**
Exposure rate	**Annual**		**<10 rad/min**	**Exposure meter**
Protective apparel	**Annual**		**No cracks or gaps**	**Fluoroscope, IR**
Resolution	**Annual**		**None**	**Resolution phantom**

CT Scanner QC Tests

Factor	Monitoring Frequency	Responsible Party	Limits
Contrast resolution	**Semiannual**		**Resolve 5mm objects at 0.5% contrast**
Linearity	**Annually**		**coefficient correlation between the densities & HU should equal or exceed 0.96%**
CT number Accuracy, Noise	**Daily**	**CT Technologist**	**0 +/- 5HU for CT number of water, Noise is dependent on scan parameter (mAs)**
Slice thickness <5mm	**Semiannual**		**0.5 mm**
Slice thickness >5mm	**Semiannual**		**±1.0 mm**
Spatial resolution	**Annual**		**greater or less than 20%**
Table increment accuracy	**Annually**	**Field Service Engineer (PM)**	**Expected table movement should be within ±2 mm**
Uniformity	**Daily**	**CT Technologist**	**<±10 HU across the image**

Nuclear Medicine QC Tests

Factor	Monitoring Frequency	Mfr	Model	Serial Number
Accuracy	Annual	Capintec	CRC-55tW	560257

Factor	Monitoring Frequency	Mfr	Model	Serial Number
ALARA	Quarterly			
Linearity-200	Quarterly	Capintec	CRC-55tW	560257
Chi-Square	Annual	Capintec	CRC-55tW	560257
Eff Co-57	Annual	Capintec	CRC-55tW	560257
Eff Ba-133	Annual	Capintec	CRC-55tW	560257
Eff Cs-137	Annual	Capintec	CRC-55tW	560257
Eff Na-22	Annual	Capintec	CRC-55tW	560257
Geometry	Annual	Capintec	CRC-55tW	560257
Inv of SS	Semi-Annual			
Leak Test	Semi-Annual	NEN	DCRS	S356009-10
Leak Test	Semi-Annual	EZIP	DCRS	1618-60-12
Leak Test	Semi-Annual	EZIP	Flood Disk	2183-047
LLRW Report	Annual			
Waste Monitor x1	Annual		Loading Dock	

Factor	Monitoring Frequency	Responsible Party
Area Survey	Daily	Technologist
Wipe Test	Weekly	Technologist
DOT Receipt	Daily	Technologist

Regulations

Maintenance of all applicable regulations is required.

Acceptance testing performed on all newly acquired equipment prior to usage. Acceptance testing performed by qualified medical physicist. All acceptance testing procedures are to meet ACR, TJC, IAC, CDPH and Federal Requirements (i.e. MQSA).

Internal Audit Procedures

The Registrant must audit the Radiation Protection Program on an annual basis. Documentation of the annual audits may be requested during inspection. The following items should be addressed depending on the scope of the radiologic health protection problems:

A. Identification of inspection types and program audits conducted, to include radiation machines, personnel and procedures.
    1. Each piece of radiation producing and or radiation detecting device shall be inspected by a qualified medical physicist on an annual basis. All annual testing shall be performed within the confines of current state regulations.

2. Notification of failure to pass performance-based testing shall be documented and remedied within the allowable time period as dictated by current state regulations.
3. In certain circumstances equipment must be retested by a qualified medical physicist. Vendor qualified field service engineers shall remedy all deficiencies noted in testing results, and their remedies shall be communicated to the qualified medical physicist.

B. Identification of the individual(s) who are responsible for performing inspections and/or audits.
    1. Only qualified medical physicists shall perform inspections/audits. These individuals must meet requirements as outline by the accreditation body (The Joint Commission diagnostic imaging requirements) and be authorized by the State of CA to provide mammography services.
    2. As a Technologist:
        a. If the test indicates that the x-ray equipment is not functioning within specified standards, I will contact the department Director, equipment vendor, or in-house biomedical engineering to ensure that the equipment is repaired as soon as possible.
        b. If other image quality is not satisfactory, I will contact Therapy Physics, Inc (the medical physicist) to evaluate the system and correct the problem as soon as possible.
        c. All corrective actions will be carried out as soon as possible (within regulatory limits).

C. Identification of where and at what intervals the inspections and/or audits are conducted.
    1. The program is to be valid for VCMC/SPH
    2. Intervals of testing are to be annual. Testing in between annual periods will be dictated by equipment purchases, major component changes in particular systems or the movement of fixed equipment into areas that they do not normally occupy. Acceptance testing will be conducted at purchase and prior to clinical use for newly acquired equipment. All acceptance testing is designed to satisfy current CDPH, Federal, TJC, ACR, IAC standards.

D. Procedures for conducting the inspections and/or audits.
    1. We are contracted with qualified field service engineers as well as qualified medical physicists. Their contractual obligations are such that they are to make certain that all equipment is compliant with current state and OEM standards and specifications.
    2. The compliance is dictated by the frequency of visits and the legal mandate for frequency of testing. Deficiencies or fail items resulting from testing are remedied within the time confines of current state regulations.

E. Instructions on identification of proper use of instrumentation if staff performs machine maintenance or fluoroscopic monitoring.
    1. The quality control (QC) technologist is responsible for all quality assurance duties not assigned to the lead interpreting physician or the medical physicist. Normally, he

or she is expected to perform these duties, but may also assign other qualified personnel or may train and qualify others to do some or all of the tests. When these duties are assigned to others, the QC technologist retains the responsibility to ensure they are performed in accordance with the regulations.

2. "Other personnel qualified" means persons with technical training appropriate for the task(s) assigned to them. Examples include a radiological technologist qualified under state regulations with appropriate training, a technologist who is trained to do the QC test(s) by the QC Technologist, or other persons appropriately trained to do the task(s) and supervised by the QC technologist. A receptionist or a secretary whose sole qualification is to copy documents, type, or answer the phone is not included under "other" qualified personnel.

All Revision Dates

6/5/2024, 3/4/2024, 1/23/2024, 5/12/2023, 1/26/2023

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	6/5/2024
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	6/4/2024
Imaging Services	Matt McGill: Director, Imaging Services	6/4/2024

Status **Active** PolicyStat ID **14255758**

Origination	12/1/2013
Last Approved	6/5/2024
Effective	6/5/2024
Last Revised	6/5/2024
Next Review	6/5/2027
Owner	Matt McGill: Director, Imaging Services
Policy Area	Imaging Services

IS.46 Gamma Cameras Quality Control and Maintenance

POLICY:

The existing gamma cameras used in Nuclear Medicine are checked in accordance with the Imaging Services' quality control program, as written in the Radiation Protection Program.

PROCEDURE:

In case of a breakdown or mechanical problem with the VERTEX or ARGUS cameras, Nuclear Medicine staff shall call for service. Linearity checks are done on a monthly basis.

The Vertex and Argus cameras are the gamma cameras in use in the Nuclear Medicine department..

All Revision Dates

6/5/2024, 10/26/2020, 10/25/2017, 2/1/2016, 10/1/2015

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	6/5/2024
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	6/4/2024

Imaging Services	Matt McGill: Director, Imaging Services	6/4/2024

Status **Active** PolicyStat ID **13798938**

Origination	11/1/1986	Owner	Sul Jung: Associate Director of Pharmacy Services
Last Approved	6/21/2024		
Effective	6/21/2024	Policy Area	Pharmacy Services
Last Revised	6/21/2024		
Next Review	6/21/2027		

PH.14 Procurement of Pharmaceuticals

POLICY:

The Ventura County Medical Center (VCMC) Pharmacy Department will procure pharmaceuticals from approved wholesalers, manufacturers, and vendors. All pharmaceuticals must have pedigree from the manufacturer or manufacturer to wholesaler to VCMC. Drugs, chemicals and biologicals used at VCMC shall meet national standards of quality. These medications will be procured to meet the needs related to the diseases and conditions treated at VCMC.

PROCEDURE:

A. Medications are selected based on patient need and patient safety. Medications are evaluated utilizing the following criteria:
    1. Effectiveness: efficacy, toxicity, pharmacokinetic properties, bioequivalence, generic equivalence, therapeutic equivalence.
    2. Risks: adverse reaction profile, likelihood of medication errors.
    3. Cost-Impact: acquisition costs to the organization.
    4. Pedigree: All medications procured must have a pedigree from their manufacturer or manufacturer to wholesaler to VCMC.
        a. Staff shall confirm receipt of orders in ConsortiEX for applicable products. See policy PH.13 Drug Supply Chain Security Act (DSASA) for full detail.

B. The Pharmacy Department shall establish a blanket purchase order with each of the major suppliers of pharmaceuticals at the beginning of each fiscal year. Other drugs and items not covered by the major suppliers are obtained from individual suppliers. A purchase order shall be established for each of these individual suppliers.

C. 340B Drug Program:

1. VCMC qualifies as a covered entity to purchase drugs for qualified outpatients under the Federal 340B drug program.
2. Pharmaceuticals procured under the 340B program are purchased from an account that is distinct from non-340B pharmaceuticals.
3. All drugs for 340B qualified patients are purchased under the 340B account.
4. Refer to *PH.18 340B Drug Pricing Program: Disproportionate Share Hospitals* for more details.

D. Inventory control records should be maintained to determine usage and to maintain the lowest possible inventory levels.

All Revision Dates

6/21/2024, 7/14/2020, 2/1/2014, 12/1/1989

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	6/21/2024
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	6/20/2024

Status **Active** PolicyStat ID **16197809**

Origination	10/1/1986	Owner	Sul Jung: Associate Director of Pharmacy Services
Last Approved	7/11/2024		
Effective	7/11/2024	Policy Area	Administrative - Operating Policies
Last Revised	7/11/2024		
Next Review	7/11/2027		

PH.45 Monthly Inspections

POLICY:

Pharmacists shall inspect all areas of Ventura County Medical Center (VCMC), Santa Paula Hospital (SPH) and the Ambulatory Care clinics where pharmaceuticals are stored on a monthly basis. Licensed pharmacy staff shall inspect the pharmacy inventory in the pharmacy areas for expired medications on a monthly basis.

PROCEDURE:

Nursing Unit and Clinic Inspections

A. Inspections of units or clinics containing pharmaceuticals shall be conducted every month by an assigned pharmacist.
    1. Physical inspection of the drugs in the automated dispensing cabinet (ADC) shall be part of the monthly inspection performed by the pharmacist.

B. Veriform (https://apps.pharmacvonesource.com/?a=vf) is used to conduct and document completion of the inspections.
    1. Any medication that has expired or will be expiring in the current month or following month shall be removed from inventory. For example, in an inspection performed in February, the pharmacist shall remove any medication expiring in Feburary, the current month, or March, the following month.

C. The inspecting pharmacist shall document all findings on the Veriform inspection form online.

D. Once the Veriform inspection form has been completed and submitted by the pharmacist, the Unit Manager or Clinic Manager of the respective nursing unit or clinic shall be sent the results

of the inspection.

E. The Unit Manager or Clinic Manager shall review and approve the Veriform inspection online.

Pharmacy Inventory

A. Sections of pharmacy inventory shall be assigned to Pharmacy Technicians.

B. Pharmacy Technicians shall inspect their respective section of the pharmacy inventory for expiring or expired medications.

C. Pharmacy Technicians shall also clean and disinfect their respective section of the pharmacy inventory.

D. Any medication, including those in medication boxes and kits, that has expired or will be expiring in the current month or following month shall be removed from pharmacy inventory and quarantined.

1. Exceptions include products purchased from 503b facilities, high-cost medications (>$100/unit) and drugs that are in short supply nationally. These medications may be stored until its final expiration date.

E. Place a "Use Now Short Dated" sticker on any medication (except 503b compounded sterile products) that will be expiring in the next three months and place these medications at the medication's storage area.

F. Veriform (https://apps.pharmacyonesource.com/?a=vf) is used to document completion of the inspections. Any findings shall be documented.

G. Once the Veriform inspection form has been completed and submitted by the Pharmacy Technician, the Pharmacy Supervisor shall review the submitted Veriform document and approve the monthly inspection.

H. The Pharmacy Supervisor or designee shall conduct random checks of the pharmacy inventory for outdated medications and/or IV solutions.

I. The Pharmacy Supervisor or designee shall also inspect medication boxes and kits on a weekly basis to ensure there are no expired medications.

1. Any medication that has expired or will be expiring in the current month or following month shall be removed from the medication box or kit and quarantined. Exceptions include products purchased from 503b facilities, high-cost medications (>$100/unit) and drugs that are in short supply nationally. These medications may be stored until its final expiration date.

All Revision Dates

7/11/2024, 5/15/2019, 11/26/2018, 10/1/2015, 8/1/2011, 5/1/1999, 11/1/1998

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/11/2024
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	7/11/2024

Status **Active** PolicyStat ID **16045376**

Origination	6/17/2024	Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH
Last Approved	6/17/2024		
Effective	6/17/2024	Policy Area	Trauma Services
Last Revised	6/17/2024		
Next Review	6/17/2027		

T.20 Guidelines for Care of the Injured Older Adult

PURPOSE:

Traumatic injury in the older adult is prevalent and is associated with higher morbidity and mortality. Optimization of positive outcomes requires an interdisciplinary approach. The goal of the trauma department with this population is to standardize care for the injured older adult, minimize complications and improve clinical outcomes.

POLICY:

This policy identifies the protocols in place to provide care for the injured older adult, defined as any trauma patient ≥ 65 years of age. Certain patient populations (ie ICU) may initially be managed by the trauma team but will ultimately be transferred to the care of the medical service (see Attachment A).

PROCEDURE(S):

Identification of Vulnerable Older Adults: All trauma patients ≥ 65 years of age will be included in this policy. As this population will also benefit from the input of a health care provider with geriatric expertise, all trauma patients ≥ 65 years old will be seen by medicine service attending physicians (see Attachment A).

A. Prevention, Identification and Management of Dementia, Depression and Delirium- refer to CPG.53 Analgosedation in the Intensive Care Unit
    1. Assess every shift for and as needed for delirium (CAM-ICU) and depression (eg ITSS, CSSRS, etc).
    2. Customize plan of care based on score from validated assessments.
    3. Depression screen positive- consult social work and/or psychiatry.
    4. Delirium screen positive

a. Non-pharmacologic options: early mobilization, promote healthy sleep/ wake cycle. For example, keeping the room lit and blinds open during the day; decreasing interruptions at night and ensuring lights off.

b. Pharmacological interventions as ordered: Dexmedetomidine or antipsychotic agents may be considered.

c. Engage with patient in ways to decrease anxiety and confusion (ie speak softly, re-orient the patient, talk about family and friends, decorate room with reminders of home, etc).

B. Process to capture and document what matters to patients (including preferences and goals of care, code status, advanced directives and identification of a proxy decision maker)

1. All patients admitted to the hospital will have a code status order entered- the licensed practitioner (LP) is responsible for discussions with the patient and next of kin to ensure the patient/family wishes are reflected. The patient will also be asked about preferences and goals of care by the LP.
2. The nursing staff is responsible for completing an admission intake on all patients, including older adults. This intake includes identification of a proxy decision maker, and an assessment of whether the patient has an advanced directive.
3. Palliative care consult as needed. This team is available to function as an expert resource to nursing and ancillary personnel without a physician's order for education, advanced care planning and for help in assessing the need for a referral. For older adults with life limiting injuries secondary to trauma, a consult will be ordered by the LP. The palliative care team will assist with symptom management, patient/family support, determination of code status and advanced directive assistance if needed.
4. Social work assessment and continued consults as needed to provide additional support to patient/family and to assist with post-discharge planning.

C. Medication Reconciliation and avoidance of inappropriate medications

1. Patients ≥ 65 years of age meet criteria for pharmacy tech medication reconciliation Medication Reconciliation Policy. When available, a pharmacy technician shall obtain a best possible medical history (BPMH) for emergency department AND admitted patients and document this into the electronic health record (EHR). Registered nursing or LPs shall assist in obtaining and documenting the medication history in the EHR when the pharmacy technician is not available. The admitting medical team shall be responsible for reconciling the patient's home medication list within 48 hours of admission.
2. Obtaining and documenting the patient's home medication history or list into the EHR is the collaborative responsibility of providers, nurses, pharmacy staff, and licensed health care personnel involved in the patient's medication management. If a history or list cannot be obtained, the healthcare professional will document this in the EHR.
3. The specific decision of whether a patient should continue or discontinue a specific medications and treatments at various stages of their hospitalization (i.e., upon admission, upon transfer, upon discharge) shall be completed by the LP.

4. Medications that can cause fall risk will be reviewed by LP (eg diuretics, sedatives, analgesics, hypnotics and antihypertensives). Medications that can contribute to other untoward side effects in the older adult should also be reviewed and removed as appropriate.

D. Screening for mobility limitations and assurance of early, frequent, and safe mobility- promote early mobilization for all patients, including those ≥ 65 years of age (see policy 100.260 Early Mobility for more details).

1. General Guidelines for Early Mobility: 5he established early mobility protocol is representative of general guidelines for treatment by the early mobility team based on a model indicated for mechanically ventilated and critically ill patients able to tolerate a progression of mobility from edge of bed (EOB) sitting through ambulation with or without assistive equipment. Modification to the protocol may be necessary to accommodate patient populations that include, but not limited to, patients presenting with strokes, polytrauma, varying degrees of spinal cord injury, burns, orthopedic issues and neurological impairments.
2. Forming an Interdisciplinary Culture of Early Mobility- A viable early mobility team should comprise all of the components addressed in this protocol. Interactions will occur between LPs, nurses, respiratory therapists and rehabilitation services personnel to assure appropriateness of functional mobility training and subscribe to a clinically logical and stepwise process to minimize functional decline during hospitalization.
3. Reassessment for Progression/Modification of Services- Physical Therapists/ Occupational Therapists will coordinate with the LP, nurse and respiratory therapist to discuss medical status, modification or initiation of an early mobility program and discharge planning.
4. Evaluation by Physical Therapist/Occupational Therapist will Determine Appropriate Level for Initiation of Activity. Based on the clinical expertise and reasoning of the rehab therapist treating the patient ordered for evaluation, the rehab therapist will provide guidance as to what phase of the early mobility protocol to implement upon skilled intervention. Progression of functional mobility, utilization of the early mobility team staff, use of assistive equipment and treatment goals will be individualized to the patient based on level of acuity, overall medical condition, co-morbidities stability, weight bearing status, cognition and prior level of function.
5. Consider any potential contraindications for mobility and consult LP prior to mobilizing (eg increased intracranial pressure, undersedation, unstable hemodynamics, end of life, active hemorrhage, etc).
6. Mobility assessment will place patient into one of four levels: Level 1 (unconscious), Level 2 (Conscious but non-ambulatory), Level 3 (Conscious with pre-gait activities), Level 4 (Conscious and Ambulatory). The assigned level determines the interventions needed for the patient. (refer to Policy 100.260).

E. Fall Risk Assessment

1. Fall risk is assessed on all patients, including older adults, using a screening tool (ie modified MEDFRAT for ED, Morse for adult inpatient, Humpty Dumpty for pediatrics).

Interventions to prevent falls in the hospital will be customized based on the patient's fall risk.

a. Prevention interventions include: keeping bed in low position, call light in reach, locking wheels, providing appropriate footwear and hourly rounding to include proactive toileting.

b. Medications and symptoms that could contribute to greater fall risk are assessed by the LP, and treatment plan may be adjusted accordingly.

2. When appropriate, the older adult will be referred to the Fall Prevention Program. Goals are to decrease the frequency and severity of fall injuries in the elderly population of Ventura County utilizing prevention strategies. This will be coordinated by the Ventura County Medical Center Department of Trauma Services Injury Prevention Program in conjunction with Ventura County Emergency Medical Services (VCEMS), Ventura County Area Agency on Aging (VCAAA), Ventura County Public Health Department, local hospitals, private physicians, skilled nursing facilities, and ancillary medical professionals in our community by utilizing a screening and intervention process.

F. Implementation of safe transitions to home or other healthcare facility

1. Social work consult or consult to case management as needed for discharge planning.
2. Discharge planning evaluations are completed for all patients. Evaluation for the older adult must include the following:

a. A patient's likely need for appropriate post-hospital services including, but not limited to, care at home, care in a skilled nursing or intermediate care facility, hospice care services, post-hospital extended care services, home health services, and non-health care services and community based care providers and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

b. The patient's capacity for self-care.

c. The ability of the patient to safely return to the environment from which he or she entered the hospital.

d. The hospital shall provide each patient who has been admitted as an inpatient with an opportunity to identify one family caregiver/support person who may assist in post-hospital care and shall record this information in the patient's electronic health record (EHR). In the event the patient is unconscious or otherwise incapacitated upon admission, the hospital shall provide the patient or patient's legal guardian with an opportunity to designate a caregiver within a specified time period, at the discretion of the attending physician, following the patient's recovery of consciousness or capacity. Hospital staff shall promptly document the attempt in the patient's EHR. In the event the patient or legal guardian declines to designate a caregiver/support person, the declination shall be recorded in the EHR.

3. Post Acute Care Services: Case Management/Social Service staff must assist patients, their families, or the patient's representative in selecting the following types of post-acute care providers: Home Health Agencies (HHA), Skilled Nursing Facilities (SNF), Inpatient Rehabilitation Facilities (IRF), and Long Term Acute Care Hospitals (LTCH). Case Management/Social Service staff will share information for these types of post-acute care providers that includes, but is not limited to, data related to quality and resource use measures that are applicable to the patient's goals of care and treatment preferences.
    a. The hospital must include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient.
    b. As part of the discharge planning process, hospital staff must inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post hospital care services and must, when possible, respect the patient's or patient's representative's goals of care and treatment preferences when they are expressed as well as other preferences they express. The hospital will not specify or otherwise limit the qualified providers or suppliers that are available to the patient.
    c. Every patient anticipated to be in need of long-term care at the time of discharge shall be provided with contact information for at least one public or non-profit agency or organization dedicated to providing information or referral services relating to community-based long-term care options in the patient's county of residence and appropriate to the needs and characteristics of the patient. At a minimum this information shall include contact information for the area agency on aging serving the patient's county of residence, local independent living center, or other information appropriate to the needs and characteristics of the patient.

G. Medical needs of the older adult
    1. The trauma team acknowledges that the care of the injured older adult ≥ 65 years old requires additional considerations. Each patient's treatment plan should be individualized to consider potential comorbidities. This may include cardiology, syncope or neurological workup. Additional renal and infectious co-morbidities will also be considered, as well as psychosocial needs.

REFERENCE(S):

- American College of Surgeons Trauma Quality Improvement Program. ACS TQIP Geriatric Trauma Management Guidelines. October 2013. https://www.facs.org/quality-programs/trauma/tqp/center-programs/tqip/best-practice.
- The ABCDEF Bundle: Science and philosophy of how ICU Liberation serves patients and families. Ely, Wesley. 2017, Critical Care Medicine, Vol. 45, pp. 321-330

All Revision Dates

6/17/2024

Attachments

T Med Protocol.pdf

Approval Signatures

Step Description	Approver	Date
Trauma Services	Thomas Duncan: Trauma Director	6/17/2024
Trauma Services	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/17/2024
Trauma Services	Gina Ferrer: Manager, Trauma Services	6/17/2024

VENTURA COUNTY MEDICAL CENTER
SANTA PAULA HOSPITAL
A Division of Ventura County Health Care Agency

Ventura County Health Care System Oversight Committee

Administrative Policies

August 2, 2024

The following administrative policies were reviewed and recommended for approval by appropriate departments and committees.

1. 109.023 Use and Disclosure of Protected Health Information for Marketing or Sale
2. 109.055 HCA Non-Monetary Compensation and Medical Staff Incidental Benefits
3. 109.063 No Information Blocking Policy
4. VC HCA Compliance Program

Status **Draft** PolicyStat ID **15844280**

Origination	4/1/2003	Owner	Charles Flood: HCA Compliance Officer
Last Approved	N/A	Policy Area	Administrative - Compliance
Effective	N/A		
Last Revised	N/A		
Next Review	N/A		

109.023 Use and Disclosure of Protected Health Information for Marketing or Sale

PURPOSE

Under the Health Information Portability Accountability Act of 1996, (HIPAA), the sale of protected health information or the use or disclosure of protected health information for marketing purposes is subject to the individual's written authorization, with some limited exceptions. The purpose of this policy is to ensure that protected health information will not be sold without the individual's authorization and will be used or disclosed for marketing purposes only as permitted under applicable State and Federal laws and regulations.

POLICY

It is Ventura County Health Care Agency (VCHCA) policy that VCHCA and/or its workforce may not sell, or use or disclose for marketing purposes (other than as described below), an individual's protected health information without that individual's authorization. If VCHCA is receiving financial remuneration for the sale for the use or disclosure of protected health information for marketing purposes, the authorization must state that such remuneration is involved.

PROCEDURE

1. **Use and Disclosure of PHI for Marketing Purposes:** VCHCA must obtain an individual's authorization before using or disclosing a patient's protected health information for marketing purposes.
    a. **Marketing includes.** Marketing under HIPAA is any communication about a product or service that encourages the recipient of the communication to purchase or use the product or service. Such communications included in the definition of marketing require prior patient authorization.

b. **Marketing does not include.** Marketing under HIPAA does not include communications for the individual's treatment regarding possible alternative treatments, therapies, or other health care providers or settings of care unless financial remuneration is involved. Because such communications are excluded from the definition of marketing, an authorization is not required.

c. **Authorization required.** If the use or disclosure of confidential information for marketing purposes results in financial remuneration to VCHCA, the authorization must so state.

d. **Authorization not required.** An authorization is not necessary if use or disclosure of protected health information is made to provide refill reminders or otherwise communicate about a patient's current prescription medicines and no financial remuneration (other than the recovery of reasonable costs) is received by VCHCA in exchange for making the communication. An authorization is also not required if the marketing involves a face-to- face communication between VCHCA and the patient or if the marketing is limited to a promotional gift of nominal value provided by VCHCA.

2. **Use and Disclosure for Sale of PHI Purposes: V**CHCA may not sell an individual's protected health information without first obtaining the individual's authorization. The authorization must state that VCHCA is obtaining financial remuneration.

REFERENCES

45 CFR 164.501; 45 CFR 164.508

Approval Signatures

Step Description	Approver	Date
Compliance & Privacy Office	Charles Flood: HCA Compliance Officer	Pending

Status Draft PolicyStat ID 15843465

Origination	9/1/2022
Last Approved	N/A
Effective	9/1/2022
Last Revised	N/A
Next Review	N/A
Owner	Charles Flood: HCA Compliance Officer
Policy Area	Administrative - Compliance

109.055 HCA Non-Monetary Compensation and Medical Staff Incidental Benefits

PURPOSE

The Physician Self-referral Law commonly known as "Stark" prohibits a physician from making referrals for designated health services (DHS) payable by Medicare or Medicaid to an entity with which he or she (or an Immediate Family Member) has a financial relationship (ownership, investment, or compensation), unless an exception applies. The purpose of this Policy is to establish guidelines to comply with the exceptions promulgated under Stark Law and Regulations when providing Non-Monetary Compensation or Incidental Benefits to Physicians or their Immediate Family Members.

SCOPE

This policy applies to Ventura County Health Care Agency (VCHCA), its affiliates and all satellite locations.

DEFINITIONS

A. ***"Immediate Family Member"*** means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

B. ***"Incidental Benefits"*** means compensation in the form of items or services (excluding cash or cash equivalents) from HCA to a Physician when the item or service is used on VCHCA campuses or sites, provided that:

   a. The Incidental Benefit is **offered** to all members of the medical staff practicing in the same specialty without regard to the volume or value of referrals or business

generated between the parties.

b. Except for the identification of medical staff members on VCHCA website or in advertising, the compensation is provided only during periods when the medical staff members are making rounds or engaged in other on-campus activities that benefit HCA or its patients.

c. Examples include lab coats, Internet access to facilitates patient care, pagers,free parking and cafeteria meals on VCHCA campus during times when the Physician is in the hospital.

d. Incidental Benefits are not counted against the annual Non-Monetary Compensation limits unless they exceed the threshold established for each occurrence of a benefit. As of 2024, the limit is less than $44 per occurrence.

C. ***"Non-monetary Compensation"*** is items and benefits provided without charge or for less than fair market value to a physician outside of a specific contractual relationship and unsolicited by the Physician or persons under his or her control (i.e., office staff). Non-monetary Compensation may include items such as non-working hour meals, gift baskets, event giveaways, flowers, appreciation events, parties, golf outings, concerts, or sporting events (excluding cash and cash equivalents). Non-monetary Compensation is limited to an aggregate annual amount $507 per Physician as of 2024.

D. ***"Physician"*** means a Doctor of Medicine or Osteopathy, a Doctor of Dental Surgery or Dental Medicine, a Doctor of Podiatric Medicine, a Doctor of Optometry, or a Chiropractor.

E. ***"Responsible Person"*** means any individual or department of HCA that provides or directs the provision of items or services that qualify as Non-Monetary Compensation or Incidental Benefits.

POLICY

VCHCA monitors non-cash items and services provided to referring Physicians to ensure compliance with Stark Law and Regulations. Non-monetary Compensation and Incidental Benefits shall not, in any manner, be related to the volume or value of referrals or business generated between the parties and cannot be solicited by the referring Physician. This Policy and related procedures provide guidelines for documenting, tracking, and recording Non-Monetary Compensation and Incidental Benefits.

Physicians employed by VCHCA are exempt from this Policy and may receive items or services under the terms and conditions of their employment.

PROCEDURE

The Non-monetary Compensation and Incidental Benefit limits may be adjusted annually for inflation effective January 1st of each calendar year. Annually, VCHCA Compliance Officer will consult the Centers for Medicare and Medicaid (CMS) website for the current annual limitations and communicate them to Responsible Persons.

NON-MONETARY COMPENSATION

A. All Responsible Persons providing Non-Monetary Compensation to Physicians must provide detailed information to the Compliance Officer prior to the provision of such items or services to ensure the applicable annual limits are not exceeded.

B. If the applicable limit will be exceeded by the anticipated cost of an item or service, VCHCA Compliance Officer shall notify the Responsible Person immediately to prevent the provision of such items or services to the Physician.

C. HCA may host one local, annual event for the entire medical staff without the cost subject to the Non-Monetary Compensation annual limit for those in attendance. Giveaways or gifts at such an event will count toward the annual Non-monetary Compensation limit.

D. Continuing Medical Education (CME) provided on-campus which otherwise meets the conditions set forth above in the definition of Incidental Benefits may be offered to Physicians and recorded as an Incidental Benefits unless its value exceeds the annual limits. All other CME or discount related to CME must be counted as Non-Monetary Compensation and toward the annual limit unless provided under a written agreement that satisfies another exception under the Stark Law and Regulations.

E. A single item that exceeds the Non-Monetary Compensation annual limit may not be allocated to several Physicians to fall below the threshold. For example, a gift valued at $750 may not be given to a three-person group practice and allocated to the Physicians at $250 each. The total value of the gift must be allocated to each Physician.

F. The fair market value of items or services provided to Physicians pursuant to this Policy is the full fair market value of the item or service, not VCHCA cost of providing such item or service.

G. The fair market value of all items or services shall be reported to VCHCA Office of Compliance and Privacy along with copies of all receipts or other documentation of expenses using the Non-Monetary Compensation and Incidental Benefit Form attached hereto as Appendix A. Compliance shall maintain a complete calendar year log of all reports received by Physician.

H. Within sixty (60) days of the end of the calendar year, VCHCA Compliance Officer will review all Non-Monetary Compensation and Incidental Benefits provided to Physicians in the preceding calendar year and report on such to VCHCA Compliance and Oversight Committees.

Excessive Amounts

A. Non-monetary Compensation may be provided from multiple sources, therefore Responsible Persons should contact VCHCA Office of Compliance and Privacy to determine the availability of additional Non-monetary Compensation to avoid exceeding the annual limits. In the event an exact amount is unavailable, an estimate may be provided until the amount is determined.

B. In the event VCHCA has inadvertently provided Non-Monetary Compensation to a Physician in excess of the annual limit, such compensation may be deemed to be within the limit if:

    a. the value of the Non-Monetary Compensation is no more than (50%) greater than the annual limit; and,

    b. the Physician returns the excess Non-Monetary Compensation (or an amount equal to its value) by the earlier of the end of the calendar year in which the excess Non-

Monetary Compensation was received; or, within 180 consecutive calendar days following the date that the excess Non-Monetary Compensation was received.

REFERENCES

Stark Law, § 42 U.S.C 1395nn
Non-Monetary Compensation Exception, 42 C.F.R. § 411.357(k)
Medical Staff Incidental Benefits Exception, 42 C.F.R § 411.357(m)

APPENDIX A

Ventura County Health Care Agency (HCA) Reporting Form for Non-Monetary Compensation For the year

Physician	Item/Service	Cost/Fair Market	Responsible Person
Total		**$**	

This form must be completed and sent to the Compliance Office within 5 business days of providing Non-monetary Compensation to a Physician.

Approval Signatures

Step Description	Approver	Date

Status Draft PolicyStat ID 15812716

Origination	N/A
Last Approved	N/A
Effective	N/A
Last Revised	N/A
Next Review	N/A

Owner	Melissa Guevarra: Compliance Office Program Admnistrator
Policy Area	Administrative - Compliance

109.063 No Information Blocking Policy

PURPOSE

The purpose of this policy is to support the commitment of the Ventura County Health Care Agency ("VCHCA") to facilitating the timely Access, Exchange and Use of Electronic Health Information (EHI) in compliance with applicable law. VCHCA will implement this policy in a consistent and non-discriminatory manner.

DEFINITIONS

Access means the ability or means necessary to make electronic health information available for Exchange or Use, or both.

Actor means a health care provider, a health IT developer of certified health IT or a health information network/health information exchange.

Designated Record Set (DRS) means medical records, billing records, or any other group of records maintained by or for a covered health care provider to make decisions about individuals.

Electronic Health Information (EHI) means electronic protected health information contained in a designated record set. It does not include psychotherapy notes or information compiled in anticipation of or for use in a civil, criminal, or administrative action or proceeding.

Electronic Protected Health Information (ePHI) means individually identifiable health information (as defined by HIPAA) that is transmitted by electronic media or maintained in electronic media.

Exchange means the ability for electronic health information to be transmitted between and among different technologies, systems, platforms, or networks; and is inclusive of all forms of transmission such as bidirectional and network-based transmission.

HIPAA collectively refers to the Health Insurance Portability and Accountability Act of 1996, the Health

Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their implementing regulations.

Information Blocking a practice that prevents or materially discourages the access, exchange, or use of electronic health information (EHI) when an actor knows, or should know, that these practices are likely to interfere with access, exchange, or use of EHI.

- If conducted by a health care provider, there must also be knowledge that such practice is unreasonable and likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI.

Use means the ability for electronic health information, once accessed or exchanged, to be understood and acted upon. "Acted upon" includes the ability to read and write and is also bidirectional.

POLICY

VCHCA and its workforce members will comply with VCHCA health information policies and procedures and all applicable law in connection with the access, exchange or use of EHI, including this No Information Blocking Policy and the Information Blocking Rule.

What is the Information Blocking Rule? The information blocking rule prohibits actors - including VCHCA and its workforce members from engaging in practices (such as acts and omissions) that are likely to interfere with the access, exchange or use of EHI, unless the practice is required by law or covered by a regulatory exception. ***(The information blocking rule does not require VCHCA to disclose EHI if doing so would violate other applicable law, such as HIPAA or other state or federal privacy laws applicable to VCHCA.)***

The information blocking rule is intent based therefore actors must have the required knowledge and intent to interfere with access, exchange, or use of EHI for a violation to occur however, facts and circumstances unique to each action will be considered when determining whether a violation has occurred. Workforce members will follow this policy and all relevant procedures when engaging in practices that involve the access, exchange or use of EHI over which VCHCA has control.

If a practice falls within an exception, it will not violate the information blocking rule. **All of the regulatory conditions must be met in order for an exception to apply.**

EXCEPTIONS

VCHCA will comply with the CURES Act provided exceptions in developing and performing internal practices with respect to accessing, exchanging, or using EHI and meet the conditions of one or more exceptions to ensure the practice is not considered information blocking. In general, VCHCA practices will be:

- **Reasonable and necessary:** Reasonable and necessary practices include providing appropriate protections to prevent harm to patients and others and promote the privacy and security of EHI.
- **Address significant risk**: Practices intended to address a "significant risk" and that actors

would otherwise avoid engaging in out of concern that such activities could be interpreted as info blocking.

- **Subject to strict conditions**. Practices are subject to strict conditions to ensure they are limited to those that are reasonable and necessary.
- **Documentation.** When an exception is used, the specific facts and circumstances associated with the decision to use an exception will be documented.

A. Not fulfilling requests to access, exchange, or use of EHI.

1. Preventing Harm Exception

VCHCA seeks to protect its patients therefore, if a request to access, exchange, or use EHI presents an unreasonable risk of harm to a patient or other persons, VCHCA may interfere with or not fulfil the request in order to prevent or substantially reduce a risk of harm to a person.

So long as the conditions of the Preventing Harm Exception are met, conditions being: there is a reasonable belief that the practice will substantially reduce a risk of harm, the practice is no broader than necessary, the practice is related to the type of risk, type of harm, and implementation basis, and satisfies the condition concerning a patients right to request review of an individualized determination of risk of harm.

. The practice may include:

- Declining to share data that is corrupt, inaccurate, or erroneous.
- Declining to share data arising from misidentifying a patient or mismatching a patient's EHI.
- Refraining from a disclosure that would endanger the life or physical safety of a patient or another person. The licensed provider who made the determination must have done so in the context of a current or prior clinician-patient relationship.

VCHCA will implement its practices in a consistent and non-discriminatory manner.

2. Privacy Exception

VCHCA will follow its HIPAA policies and related procedures with respect to granting, delaying or denying an individual's (or personal representative's) request to access the individual's EHI, including those circumstances where the HIPAA right to access denial is not viewable or it is not appropriate to treat a person as an individual's personal representative.

VCHCA will follow its HIPAA use and disclosure policies and related procedures with respect to granting, delaying or denying a third-party's request for access, exchange or use of EHI, including when a legal precondition must be met.

Under the privacy exception VCHCA practices will meet the criteria of at least one of the following sub-exceptions.

a. ***Precondition not satisfied***. Legal preconditions will be satisfied before VCHCA provides access, exchange or use of EHI. Examples of legal preconditions include, but are not limited to authorization, consent, verification of identity and authority.

b. ***Denial of an individual's request for their EHI.*** VCHCA may deny an individual's request for access to his or her EHI if fulfilling the request would violate HIPAA policies or the HIPAA privacy rule.

c. ***Respecting an individual's request not to share information.*** VCHCA may choose not to provide access, exchange or use of an individual's EHI if doing so fulfills the wishes of the individual and would not violate HIPAA policies or the HIPAA privacy rule.

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3. Security Exception

VCHCA will follow its HIPAA security policies, procedures and security risk analyses and risk management plans with respect to granting, delaying, denying or otherwise interfering with the provision of access, exchange or use of EHI.

In the event VCHCA's HIPAA security policies and procedures do not sufficiently address a known security risk, VCHCA will determine on a case-by-case basis and document its security practice based on particularized facts and circumstances surrounding the security risk, including.

- How VCHCA's practice related to safeguarding the confidentiality, integrity, and availability of EHI;
- Why the security practice was necessary to mitigate the security risk to EHI; and
- That there were no reasonable and appropriate alternatives that would address the security risk and would be less likely to interfere with the access, exchange or use of EHI.

VCHCA will not engage in security practices that have the practical effect of disadvantaging competitors or steering referrals.

4. Infeasibility Exception

If VCHCA faces legitimate practical challenges that limit its ability to comply with a request for access, exchange or use of EHI, it will regard the request as infeasible so long as certain conditions are met. It may be infeasible for VCHCA to fulfill a request for access, exchange or use of EHI under one the following circumstances:

- uncontrollable event
- inability to segment data
- third party is seeking modification.
- circumstances exist that prevent the fulfillment of the request.
- the manner exception is exhausted, meaning after offering alternatives the request still cannot be fulfilled.

If VCHCA makes an infeasibility determination due to any of the circumstances listed above, it will notify the requester of the infeasibility determination in writing — including the reason(s) for the infeasibility determination — **within 10 business days** of the EHI request.

5. Health IT Performance Exception

VCHCA regularly and routinely maintains its health information technology systems to improve

performance. These practices may require systems to be taken offline or become temporarily unavailable. In doing so VCHCA will comply with the regulatory conditions of the health IT performance exception. At least one of four conditions will be met.

- Maintenance and improvement of health IT (e.g., an EHR upgrade).
- Existing service level agreements
- Practices that prevent harm and comply with Preventing Harm Exceptions.
- Security-related practices that comply with Security Exception.

B. Procedures for fulfilling requests to access, exchange, or use EHI

1. Content and Manner Exception

VCHCA strives to fulfill requests for Access, Exchange or Use of EHI in the manner it is requested and in compliance with applicable law. However, VCHCA may fulfill the request in an alternative manner and do so, if the conditions of the Content and Manner Exception are met.

- **Alternative Manner Circumstances.** VCHCA may responds to an EHI request in an alternative manner if one of the following limited circumstances apply:
  - VCHCA is technically unable to fulfill the request; or
  - VCHCA is unable to reach agreeable terms with the requestor.

If VCHCA is technically unable to fulfill the request in the manner requested or cannot reach agreeable terms with the requestor, VCHCA will fulfill the request in an alternative manner and without unnecessary delay, unless it is infeasible to do so (see the Infeasibility Exception). The requestor will be notified within **10 business days** of the request if fulfilling the EHI request in the manner requested or in an alternative.

If responding in an alternative manner is feasible, VCHCA will technically fulfill the request using the technical standards listed below in the following order of priority, only proceeding to the next technical standard if technically unable to fulfill the request using the higher priority standard:

- Using technology certified to standard(s) adopted by ONC under the Health IT Certification Program (e.g., via application programming interface (API), direct protocol);
- Using content and transport standards specified by requestor and published by the federal government or a standards development organization accredited by the American National Standards Institute (ANSI); or
- Using an alternative machine-readable format agreed upon with the requestor (e.g., Portable Document Format (PDF), comma-separated value (CSV) files.

VCHCA may also require the requestor to first agree to licensing terms for the interoperability elements and/or fees in accordance with the Licensing Exception and Fees Exception. If applicable, VCHCA will begin negotiating any licensing terms within **10 business days** of the request and ***offer a negotiated license within*** **30 business days** of the request.

2. Fees Exception

Any fees that VCHCA charges for the access, exchange or use of EHI including those that result in a reasonable profit margin will be established in compliance with regulatory conditions of the Fees Exception. The practice of charging fees will meet the basis for fees condition, such as that they are based on the following.

- objective and verifiable criteria uniformly applied;
- are reasonably related to costs of providing access, exchange or use of EHI, and;
- are not based on a practice that facilitates competition.

VCHCA will not charge any fees that are prohibited by HIPAA or based in any part on the electronic access of an individual's EHI by the individual, their personal representative, or another person or entity designated by the individual. For example, VCHCA will not charge fees for electronic access if an individual directs it to disclose the individual's EHI to a biomedical research program, a personal health application or a personal health record of the individual's choosing. This exception does not permit or support the sale of EHI.

3. Licensing Exception

VCHCA may protect the value of its innovations and charge reasonable royalties in order to earn returns on investments, it made to develop, maintain and update innovations. VCHCA's licensing practices will meet the conditions of the Licensing Exception.

- Negotiating a license conditions to be complied with include.
- Begin license negotiations with a requestor within **10 business days** of the request; and
- Negotiate in good faith a license within **30 business days** of the request.

The license will meet all of the following requirements (*as applicable*):

- **Scope of License.** Will provide all rights necessary to enable the access, exchange or use of EHI achieve the intended access, exchange or use of EHI via the interoperability elements.
- **Royalty.** If a royalty is charged, the royalty will be reasonable, non-discriminatory and based solely on the independent value of VCHCA's technology to the licensee's products. A royalty will not be based on any strategic value stemming from VCHCA's control over essential means of accessing, exchanging, or using EHI. VCHCA will not charge a royalty for intellectual property if it recovered any development costs that led to the creation of the intellectual property.
- **Non-Discriminatory.** The licensing terms will be based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons and requests..
- **Collateral Terms.** VCHCA will not require the requestor to do any of the following:
    - Execute a non-compete in any product, service, or market;
    - Deal exclusively with the VCHCA in any product, service, or market;
    - Obtain additional licenses, products, or services that are not related to or can be unbundled from the requested interoperability elements;
    - License, grant, assign, or transfer to the VCHCA any intellectual property of the licensee; or

- Pay a fee of any kind unless the Fees Exception is met.

INFORMATION BLOCKING REPORTING

1. Information Blocking Reporting and No Retaliation

Workforce members that reasonably believe VCHCA or one of its workforce members (including any affiliate, agent or vendor) is violating this No Information Blocking Policy or the information blocking rule must promptly notify VCHCA Office of Compliance and Privacy or anonymously through the Helpline.

VCHCA will not retaliate against any workforce member for reporting a suspected or actual violation of this No Information Blocking Policy or the information blocking rule.

2. Investigations

VCHCA Office of Compliance and Privacy will respond to all allegations of information blocking and, where appropriate, investigate such allegations within a reasonable period of time.

3. Sanctions

VCHCA may discipline workforce members who violate this No Information Blocking Policy or the information blocking rule in accordance with its sanctions policies and procedures.

REFERENCES

Related Policies

109.054 Compliance Helpline Reporting

Non-Compliance Report Internal Investigation Policy

109.045 Privacy Incident Internal Investigation Policy

109.006 Employee Sanctions for Privacy and Security Violations

109.048 Patient Rights to Access, Inspect and Copy Protected Health Information (Patient Access to Medical Records)

VCHCA's HIPAA Use and Disclosure Policies and related procedures – working to edit this policy/policies

Legal References

42 U.S.C. § 300jj-52

45 C.F.R. Part 171

ONC Cures Act Final Rule (85 Fed. Reg. 25462)

United States Core Data for Interoperability, Version 1 (Feb. 2020)

Approval Signatures

Step Description	Approver	Date

Status **Draft** PolicyStat ID **15968145**

Origination	N/A
Last Approved	N/A
Effective	N/A
Last Revised	N/A
Next Review	N/A

Owner	Melissa Guevarra: Compliance Office Program Admnistrator
Policy Area	Administrative - Compliance

VC HCA Compliance Program

HEALTH CARE AGENCY COMPLIANCE PROGRAM

Purpose and Overview

Ventura County, its Oversight Committee, and its Health Care Agency (HCA) are committed to quality and efficient patient care; high standards of ethical, professional, and business conduct; and full compliance with all applicable federal and state laws in the delivery or payment of health care. The purpose of this Compliance Program and its component policies and procedures is to establish a structure to facilitate and maintain this commitment through the prevention, detection and resolution of conduct that does not conform to HCA's standards and policies, applicable law, and health care program or payor requirements.

The Compliance Program applies to all personnel, including but not limited to its Oversight Committee, administration, physicians and other practitioners, employees, volunteers, and other entities providing services on behalf of HCA.

The Compliance Program includes the following elements:

1. Written standards, policies and procedures which promote HCA's commitment to compliance with applicable laws and regulations.
2. The designation of a Compliance Officer and Compliance Committee charged with the responsibility of implementing and monitoring the Compliance Program.
3. Regular, effective education and training programs for all affected personnel as appropriate to their functions.

4. A process to receive complaints concerning possible Compliance Program violations, procedures to protect the anonymity of complainants to the extent possible, and policies that protect complainants from retaliation.
5. A process to respond to allegations of improper activities and the enforcement of appropriate disciplinary action against personnel who have violated policies, laws, regulations, or health care program requirements.
6. Periodic audits or other methods to monitor compliance and assist in the reduction of problems in any identified areas.
7. A process for investigating and resolving any identified problems.

As demonstrated by the signatures below, the Compliance Program is enacted at the direction and with the support of the Oversight Committee.

APPROVED BY:

Chairman, Oversight Committee
Date

HCA Director
Date

Compliance Officer
Date

Introduction

Ventura County Health Care Agency (HCA), its affiliates and all satellite locations are committed to conducting business in accordance with its Mission, Vision, and Values. In compliance with its established Code of Conduct and other policies, HCA requires the exercise of high ethical standards in its business and clinical decision making. In addition, as a non-profit tax-exempt county entity, HCA is fully committed to serving and promoting the health of its community.

As a healthcare provider accepting Federal and State health care program funds, HCA is required to establish a compliance program to prevent, detect and correct any instances of fraud, waste, and abuse. Ventura County's Board of Supervisors, therefore, has directed that HCA undertake an integrity program to demonstrate its commitment to high standards of conduct, honesty, and reliability. This integrity program is referred to as the HCA Compliance Program (Program). The Program is largely based on Health and Human Services Office of Inspector General's compliance guidance, United States Sentencing Guidelines, applicable California laws, and continuing guidance received from regulatory agencies.

The Program undertakes a significant and coordinated effort to create system-wide awareness of the

importance of preventing, detecting, and correcting fraud, waste, or abuse at HCA. As such, the Program develops appropriate processes, policies, and procedures to help ensure operations are in conformance with Federal and State laws and regulations. In addition, the Program, through regular education and training, promotes an understanding of and adherence to these regulations.

The Program's intent is to create a comprehensive framework to prevent, detect and correct violations of the law by its employees, medical staff, clinical affiliates, volunteers, and other individuals who are representatives or agents of HCA. The Program is intended to support both individual and service specific compliance efforts and applies to all personnel and functions related to the acceptance of Federal and State health care funding. Detailed training, manuals or other materials covering compliance in specific areas will be separately developed and will fit within this framework.

Accountability

Accountability begins with the County Board of Supervisors (Board). The Board has designated an Oversight Committee that is responsible for the review and oversight of matters related to compliance with Federal health care program requirements. The Oversight Committee (Committee) includes independent members as well as HCA executives that serve as staff to the Committee. The Committee is responsible for review and oversight of HCA Compliance Program including the performance of its Compliance Officer and Compliance Committee.

While the workforce has a duty to ensure that the integrity and accountability of HCA is preserved, higher expectations are placed on leaders. The Ventura County Board of Supervisors maintains the ultimate responsibility and accountability for HCA's Compliance Program. Administration, both at the Health Care Agency level and at the County level, are charged with supporting the Board of Supervisors in carrying out its oversight for HCA's Compliance Program. The Administrations will ensure that financial and other operational transactions are open for review and fully transparent. They, along with the Compliance Office, will ensure that best practices are put into place and monitored for compliance to ensure that they continually confront the issues of privacy, fraud, waste, and abuse.

I. Structure - Compliance Officer and Compliance Committee

Compliance Officer

HCA has a Compliance Officer who serves as the leader for day-to-day activities of this Compliance Program. The Compliance Officer occupies a high-level position within HCA and has the authority to carry out the compliance responsibilities described in this Compliance Program.

The Compliance Officer is responsible for fully implementing the Compliance Program to maintain HCA's conformance to the Code of Conduct and all Federal and State health care requirements. Any noncompliance job responsibilities of the Compliance Officer are limited and will not interfere with the ability to perform the duties required under the Compliance Program.

The Compliance Officer will provide periodic reports to the Compliance and Oversight Committees about the functioning of the Compliance Program.

Responsibilities of the Compliance Officer

The Compliance Officer's responsibilities include the following:

- Overseeing and monitoring the implementation and maintenance of the Compliance Program.
- Reporting to the Oversight Committee (no less than annually) on the progress of implementation and operation of the Compliance Program and assisting the Oversight Committee in establishing methods to reduce the HCA's risk of fraud, abuse, and waste.
- Periodically revising the Compliance Program considering changes in the needs of HCA's operations and changes in applicable statutes, regulations, and government policies.
- Reviewing at least annually the implementation and execution of the elements of this Compliance Program. The review includes an assessment of each of the basic elements individually and the overall success of the program. This will include review of the Compliance Department against its established goals and objectives as well as industry standards.
- Developing, coordinating, and participating in educational and training programs that focus on elements of the Compliance Program with the goal of ensuring that personnel are knowledgeable about, and act in accordance with the Compliance Program and all pertinent federal and state requirements.
- Ensuring that independent contractors and agents are aware of the requirements of the HCA Compliance Program.
- Ensuring that HCA does not contract with any individual who has been convicted of a criminal offense related to health care within the previous five years, or who is listed by a federal or state agency as debarred, excluded, or otherwise ineligible for participation in Medicare, Medicaid (Medi-Cal), or any other Federal or State health care program.
- Coordinating internal compliance review and monitoring activities.
- Investigating and acting on matters related to compliance, including design and coordination of internal investigations and implementation of any corrective action.
- Maintaining a good working relationship with other key operational areas, such as human resources, revenue cycle and clinical departments.
- Designating those individuals that are needed to carry out specific assignments, such as investigating or evaluating a proposed enhancement to the Compliance Program.

The Compliance Officer has the authority to review all documents and other information relevant to compliance activities, including, but not limited to, patient records, billing records, and arrangements with third parties, including independent contractors, suppliers, agents, and physicians.

The Compliance Officer reports to Ventura County's Chief Executive. The Compliance Officer has direct access to the Oversight Committee, Executive Officer, and other senior management, and to legal counsel, when necessary.

Compliance Committee

HCA has established a Compliance Committee to advise the Compliance Officer and assist in monitoring this Compliance Program. The Compliance Committee provides the perspectives of individuals with diverse knowledge and responsibilities within the HCA. The Compliance Committee consists of representatives including those from the areas designated below and other members, including representatives of senior management, chosen by the Health Care Agency Director in consultation with the Compliance Officer.

The Compliance Officer serves as the chairperson of the Compliance Committee. The Compliance Committee will meet at least quarterly. The Compliance Officer will also consult with members of the Compliance Committee on an interim basis, as necessary. The Compliance Committee serves in an advisory role and its functions include the following:

- Assessing existing and proposed compliance policies for modification or incorporation into the Compliance Program.
- Working with the Compliance Officer to develop further standards of conduct and policies to promote compliance.
- Recommending and monitoring, in conjunction with the Compliance Officer, the development of internal systems and controls to carry out the standards and policies of this Compliance Program.
- Reviewing and proposing strategies to promote compliance and detection of potential violations.
- Assisting the Compliance Officer in the development and ongoing monitoring of systems to solicit, evaluate and respond to complaints and problems related to compliance.
- Assisting the Compliance Officer in coordinating compliance training, education and other compliance related activities in the departments and business units in which the members of the Compliance Committee work.
- Consulting with vendors on a periodic basis to promote adherence to this Compliance Program as it applies to those vendors and to promote their development of formal Compliance Programs.

II. Structure - Written Standards

All of HCA's business affairs must be conducted in accordance with Federal, State, and local laws, professional standards, and with honesty, fairness, and integrity. It is expected that the workforce will perform their duties in good faith, in a manner that he/she reasonably believes to be in the best interest of HCA and its patients, and with the same care that a reasonably prudent person in the same position would use. To further these overall goals, policies and standards have been adopted by HCA. These standards include, but are not limited to, the HCA's Code of Conduct, Ventura County's Employee Handbook, Ventura County Medical Center's Medical Staff Rules, and Regulations as well as other compliance policies and procedures.

These standards are not intended to cover every situation that may be encountered, and individuals

should comply with all applicable laws and regulations regardless of whether they are specifically addressed. Questions about the existence, interpretation or application of any law, regulation, policy, or standard should be directed to an employee's chain of command or directly to the Compliance Officer. Policies, procedures, and standards are reviewed, revised, and updated as needed, but no less than annually to reflect changes in the regulatory environment. Any revisions communicated in a timely manner through administrative notification.

III. Structure - Education and Training

HCA acknowledges that this Compliance Program will be effective only if it is communicated on a routine basis and in a manner that clearly details its requirements. As a result, HCA requires all personnel to attend training programs. Training programs include, as appropriate, training in Federal and State statutes, regulations, guidelines, and HCA's Code of Conduct.

Training programs include sessions that highlight this Program, summaries of fraud and abuse laws, claims development and submission processes, and related business practices upon which regulatory standards are imposed. This training will be developed and conducted by qualified personnel and formal training, undertaken as part of the Compliance Program, is documented. Documentation includes the identification of the personnel participating in the training, the subject matter of the training, the length of the training, the time and date of the training, the training materials used, and any other relevant information. New employees are trained upon hire.

The Compliance Officer evaluates the content of the training program at least annually to ensure that the subject content is appropriate and sufficient to cover the range of issues confronting HCA. The training program is modified as necessary to keep up to date with any changes in federal and state health care program requirements, and to address results of the HCA's audits and investigations; trends in compliance matter reports; and guidance from applicable Federal and State agencies. The appropriateness of the training format is evaluated by reviewing the length of the training sessions; whether training is delivered via live instructors or via computer-based training programs; the frequency of training sessions; and the need for general and specific training sessions. Post-training tests, as appropriate, are used to ensure attendees understand and retain the subject matter.

Targeted training and education is provided to individuals whose work may affect the accuracy of claims submitted to payers. This targeted training includes not only the billing and coding workforce, but also physicians and providers whose documentation of services are used as a basis for payment from Federal and State health care programs. This may include training on ordering of services, medical necessity, coding, documentation, Diagnostic Related Groups (DRGs) and such other information as might be reasonable and useful to enable HCA to comply with applicable laws and claim regulations.

Adherence with the provisions of this Compliance Program, including training requirements, is a factor in the annual evaluation of each employee. Where feasible, outside contractors will be afforded the opportunity to participate in, or be encouraged to develop their own, compliance training and educational programs, to complement the HCA's standards of conduct and compliance policies.

The Compliance Officer will ensure that records of compliance training, including attendance logs and

copies of materials distributed at training sessions, are maintained according to HCA's retention policy. Attendance and participation in compliance training programs is a condition of continued employment. Failure to comply with training requirements will result in disciplinary action, including possible termination.

The members of the HCA's Oversight Committee will be provided with periodic training, not less than annually, on governance responsibilities and specifically with respect to their responsibility to review and provide oversight of the compliance program. The training shall address the unique responsibilities of health care including the risks, oversight areas, and strategic approaches to conducting oversight of health care entities. This training may be conducted by an outside compliance expert and will include a discussion of the OIG's guidance on the Oversight Committee's member responsibilities.

IV. Structure - Auditing and Monitoring

HCA complies with all relevant Federal and State rules and regulations to self-assess and to self-identify any matters that, in HCA's reasonable assessment could potentially violate Federal and State criminal, civil or administrative laws and/or indicate internal billing patterns or operational issues that might affect HCA's right to Medicare or Medi-Cal reimbursement.

The Compliance Officer develops and implements an audit work plan. The work plan specifies the number, service areas and functions to be audited. The plan will be reviewed and updated no less than annually to confirm that it addresses the proper areas of concern. Areas of emphasis from regulators, findings from previous years' audits, areas previously identified as part of the annual risk assessment, and high-volume or new services are considered in the development of the work plan. These periodic audits are used to confirm compliance and address, at a minimum, regulations governing kickback arrangements, physician self-referrals, claims development and submission and reimbursement. HCA will report and refund any overpayments to Medicare and Medi-Cal within the statutory required mandates determined through the audit process.

HCA, under the direction of the Compliance Office, conducts periodic tests of claims submitted to Medicare, Medi-Cal and other federal health care plans, and reviews the claims development and submission process. These procedures may include reviewing the work of coders, billers; admitting and registration representatives, patient care providers, ancillary departments such as laboratory and diagnostic imaging, and other risk areas identified by the OIG or Medicare Administrative Contractors. Audits also cover HCA's relationship with third party contractors, including physicians, NP's, and PA's that are on the staff of HCA or who provide services for HCA patients and whose services are billed by HCA.

HCA will devote such resources as are reasonably necessary to ensure that audits are adequately funded and performed by persons with appropriate knowledge and experience. These audits are performed by internal or external auditors who have the appropriate qualifications and expertise in federal and state health care health care program requirements. All personnel are expected to cooperate fully with auditors during this process. If any employee has concerns regarding the scope or manner of an audit, the employee should discuss this with his or her immediate supervisor. The

Compliance Office may request that the Director or Manager of each affected area prepare and submit testing and monitoring plans for his or her service area.

Auditors shall have access to all necessary documents including those related to claim development and submission, patient records, e-mail, and the contents of computers. Auditors and reviewers will, always, be held to the strictest standards of confidentiality.

V. Structure - Lines of Communication

HCA recognizes that clear and open lines of communication between the Compliance Officer and the workforce are important to the success of this Compliance Program. HCA maintains an open-door policy for Compliance Program related matters. The workforce is encouraged to seek clarification from the Compliance Officer in the event of questions about a statute, regulation, or policy discussed in this Compliance Program.

HCA has established a telephone helpline to report concerns or possible wrongdoing regarding compliance issues referred to as the Compliance Line. The Compliance Line and the Compliance Officer's phone contacts are posted in conspicuous locations throughout the HCA's facilities.

Calls to the Compliance Helpline are answered by a third-party. All calls are treated confidentially and are not traced. The caller need not provide his or her name. HCA's Compliance Officer or designee investigates all contacts and initiates follow-up actions as appropriate.

Personnel may also submit compliance-related questions or complaints in writing. Letters may be sent anonymously. All such letters should be sent to the Compliance Officer at the following address:

5851 Thille Drive, Suite 102

Ventura, California 93003

Communications via the Compliance Line and other contacts directed to the Compliance Officer are treated as confidential however, it is possible that the identity of a person making a report may become known, or that governmental authorities or a court may compel disclosure of the name of the reporting person.

Matters reported through the Compliance Helpline, or in writing, that suggest violations of compliance policies, statutes, or regulations are documented and investigated promptly. A disclosure log is maintained by the Compliance Officer of calls or communications, including the details of the investigation and subsequent results. A summary of this information is included in reports by the Compliance Officer to the Compliance Committee, Oversight Committee and Executive Director.

It is the HCA's policy to prohibit retaliatory action against any person for making a report, anonymous or otherwise, regarding a potential compliance. However, the HCA workforce cannot use complaints to the Compliance Officer to insulate themselves from the consequences of their own wrongdoing or misconduct. False or deceptive reports may be grounds for termination. It will be considered a mitigating factor if a person makes a forthright disclosure of an error or violation of this Compliance Program, or the governing statutes and regulations.

VI. Structure - Detecting Offenses and Corrective Actions

Violations of HCA's Compliance Program, failure to comply with applicable Federal or State laws, and other types of misconduct can threaten the HCA's status as a reliable and honest provider of health care services. Detected but uncorrected misconduct can seriously endanger its business, reputation and can lead to serious sanctions against HCA.

Upon reports of a potential compliance matter involving non-compliance, prompt steps will be taken to investigate the conduct under the direction of the Compliance Officer. The investigation will focus on determining whether a material violation of applicable law or the requirements of the Compliance Program has occurred. Depending upon the nature of the alleged violations, the Compliance Officer's internal investigation might include interviews with relevant persons and review of documents. Legal counsel, auditors or health care experts may be engaged to assist in an investigation where the Compliance Officer deems such assistance is appropriate.

Complete records of all investigations will be maintained which detail the alleged violation, a description of the investigative process. copies of interview notes and key documents, witness log, results of the investigation (e.g., any disciplinary action taken), and corrective actions. If, during the investigation, the Compliance Officer believes its integrity may be at stake because of the employees under investigation, those employees will be removed from their current work activity until the investigation is completed. Where necessary, the Compliance Officer will take appropriate steps to secure or prevent the destruction of documents or other evidence relevant to the investigation.

If such a violation has occurred, prompt steps will be taken to correct the problem, with consideration of the root cause of the problem. As appropriate, such steps may include corrective action plan, a report to the Office of Inspector General (OIG) or any other appropriate government organization, and/or return of any overpayments.

VII. Structure - Enforcement and Discipline

It is the policy of HCA to discipline appropriately and equitably those who fail to comply with the Code of Conduct, or the policies set forth in, or adopted pursuant to, the Compliance Program or any Federal or State statutes or regulations.

HCA may impose sanctions on any member of the workforce who intentionally or unintentionally violates established policies or procedures. Confirmed acts of non-compliance may result in corrective action including the removal of privileges, discharge from employment and, if appropriate, referral for civil and/or criminal prosecution.

Disciplinary action may also be prompted by failure to perform any duty required by the Compliance Program, failure to supervise or manage personnel in a manner to detect non-compliance, and failure to report violations of the Compliance Program. Any instance involving disciplinary action shall be thoroughly documented by the employee's supervisor, Human Resources, and the Compliance Officer.

Approval Signatures

Step Description	Approver	Date

VENTURA COUNTY
HEALTH CARE AGENCY

COMPLIANCE PRESENTATION TO OVERSIGHT COMMITTEE

Friday, August 2, 2024

Proposed Compliance Work Plan 2024-2025

	Compliance Coding Audit Categories	Quarter
1	Professional Fee*	Q1-4
2	Facility – Inpatient and Outpatient**	Q1-4
3	Investigative Coding Audits	As needed
4	Corrective Action Plans Required under the CIA	TBD
	Non-Coding Audit Compliance Initiatives	
1	Revenue Cycle Billing Process***	Q1-4
2	Physician Service Arrangements	Q2
3	Information Security Impact Assessment	Q2
4	Privacy Reporting	Q2-4
5	Physician Conflicts of Interest/Arrangements with Vendors	Q3-4
6	Annual Compliance Policy Review	Q1-4
7	Clinical Research	Q3
8	Gifts and Gratuities	Q4

*Professional Fee audits include; routine/annual physician service audits for targeted groups; physician documentation practices (copy/paste); Modifier 25 follow-up audits; excessive units of hospital services
**Facility – Inpatient and Outpatient audits include; behavioral health; high dollar, low length of stay claims; clinical research
***Revenue Cycle Billing Process includes; charge description master; credit balances; utilization management; uninsured patients

Proposed Training Plan 2024-2025

Proposed HCA Compliance Training Plan Changes		
Seeking one time oversight committee delegation of authority to approve alterations of the formal HCA Compliance Training Plan required by CIA. (to avoid necessity to call another oversight committee meeting)		
Compliance Training Cycle		
	Current Due Date Schedule	**Proposed Due Date Schedule**
Med Staff	Annual defined period	No change (May - June)
Employees (Non-Med Staff)	Annual defined period	*Anniversary date*
Contracted Work Force	Annual defined period	*Anniversary date*
Training Content		
Med Staff	Includes covers topics required by CIA	*Review and update content to include proactive and remedial training topics based of reports to OCP.*
Employees (Non-Med Staff)		
Contracted Work Force		

VENTURA COUNTY HEALTH CARE AGENCY

VENTURA COUNTY
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THANK YOU!

VENTURA COUNTY
AMBULATORY CARE

VENTURA COUNTY
BEHAVIORAL HEALTH

VENTURA COUNTY
HEALTH CARE PLAN

VENTURA COUNTY
MEDICAL CENTER

VENTURA COUNTY
PUBLIC HEALTH