

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

March 31, 2025

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

- 1. IS.16 Code Red in the MRI Department
- 2. IS.51 Imaging Services Employee Unscheduled Time Off/ Sick Calls
- 3. IS.53 MRI Preventive Maintenance and Repairs
- 4. PH.100 KitCheck for Pharmacy Boxes, Kits and Anesthesia Medication Trays
- 5. PH.18.01 340B Drug Pricing Program: Disproportionate Share Hospital
- 6. PH.28 Sick Leave and Vacation Requests
- 7. 109.069 Patient Billing And Collections Policy*
- 8. 109.070 Bad Debt Assignment Policy*
- 9. 109.071 No Surprises Act Compliance Policy*
- 10. 110.030 Charity Care Policy*
- 11. 110.032 Discount Payment Program Policy*

*Policy approved by Board of Supervisors on December 17, 2024. Presenting to Ventura County Health Care System Oversight Committee for acknowledgement.



Ventura County Health Care System Oversight Committee Administrative Policies - March 31, 2025 Summary of Changes

#	Title	Review Period	Summary of Changes
1	IS.16 Code Red in the MRI Department	Triennial	Removed reference to MR Trailer
2	IS.51 Imaging Services Employee Unscheduled Time Off/ Sick Calls	Triennial	Updated to address issues identified with prior process
3	IS.53 MRI Preventive Maintenance and Repairs	Triennial	Removed reference to MRI trailer
4	PH.100 KitCheck for Pharmacy Boxes, Kits and Anesthesia Medication Trays	Triennial	Update workflow to include technician preparing tray. Pharmacist will continue to complete final check.
5	PH.18.01 340B Drug Pricing Program: Disproportionate Share Hospital	Annual	After a recommendation from Apexus, Attachment A was added. Attachment A: List of Non-Covered Outpatient Drugs applies only to mixed-use areas and does not extend to clean sites, such as clinics and contract pharmacies.
6	PH.28 Sick Leave and Vacation Requests	Triennial	Clarified lanuage and added excerpts from SEIU regarding sick and vacation hour use.
7	109.069 Patient Billing And Collections Policy*	Triennial	New Policy
8	109.070 Bad Debt Assignment Policy*	Triennial	New Policy
9	109.071 No Surprises Act Compliance Policy*	Triennial	New Policy
10	110.030 Charity Care Policy*	Triennial	Revised policy to incorporate updates required by State law
11	110.032 Discount Payment Program Policy*	Triennial	Revised policy to incorporate updates required by State law

*Policy approved by Board of Supervisors on December 17, 2024. Presenting to Ventura County Health Care System Oversight Committee for acknowledgement.

Origination Last	12/1/2013 3/14/2025	Owner	Matt McGill: Director, Imaging
Approved	3/ 14/ 2023		Services
VENTURACOUNTY Effective	3/14/2025	Policy Area	Imaging Services
HEALTH CARE AGENCY Last Revised	3/14/2025		
Next Review	3/13/2028		

IS.16 Code Red in the MRI Department

POLICY:

Magnetic Resonance Imaging (MRI) personnel will work in conjunction with other hospital staff to ensure safe procedures are followed throughout the Code Red process. Safe procedures include the evacuation of any patients from the Magnetic Resonance (MR) Scan room (zone IV), assessment of the need to disable electrical power or magnetic field, and proper screening of all responders.

PROCEDURE:

Status (Active) PolicyStat ID (17791301

FIRE EMERGENCY (CODE RED)

This procedure includes all fire emergencies in the MR scan room and may also involve patient emergency (code blue). For small fires, local MR-safe extinguishers can be used if the operator is confident and competent of its use. There is no responsibility to fight fires. In addition to patientemergency rescue procedures, the MR operator is responsible for following these general procedures for Code Red:

A. Rescue the patient

- 1. Remove patient from scan room. For medical emergencies, Code Blue procedures should be followed.
 - a. For power failures, manual table movement is required.
- 2. Move patient to a safe area.
- B. Pull the nearest fire alarm.
- C. Call the emergency line at x76666.
 - 1. State the code and appropriate location.

- D. Press the "Emergency Power OFF" button.
 - 1. This will cut all power to MR room and system. Note: MR MAGNET IS STILL ON.
 - 2. These buttons are located inside and outside the MR scan room. They are distinguished from the MR Quench button.
 - 3. Note: for large fires that will need professional intervention, magnetic quench will be necessary.
- E. Evacuate the MR control room.
- F. Prevent emergency fire personnel from entering the MR room with external fire equipment. Local MR-safe fire extinguishers should be used to control confined fires.
 - 1. For large fires in the gantry, MR quench will be necessary. (See MR Quench procedures)

Fire Containing Procedures

Following patient removal and emergency calls, procedures can be followed to extinguish small, controlled fires. However, there is no responsibility to do so. This will require an MR-Safe fire extinguisher. Please note the location of this device in the MR control room. The use of the extinguisher is generalized to the PASS procedures: P – Pull the pin from the MR safe extinguisher; A – Aim at the base of the fire; S – Squeeze the handle; S – Sweep from side to side.

MRI EMERGENCY QUENCH and STOP BUTTONS:

A magnet emergency power off is specific to each scanner and should be known by the MR scanner operator prior to assuming any scanning duties. Use of the magnet emergency stop button should be restricted to extremely emergent conditions, which include:

- Forces attributed to the magnetic field that are causing patient or personnel injury.
- Fire and/or other unexpected occurrences that demand immediate action.

MR personnel should be familiar with the location and difference between the MR quench button and MR emergency power off button.

- A. MR Quench button located inside and outside MR room. Usually protected by plastic shield.
 - May be used to disable the magnetic field if there is a fire in the scan room (Zone IV) that cannot be contained and/or if first responders must enter the room to contain the fire.



- B. MR Emergency Power Off generally a red button with the label "EPO" or "Power OFF".
 - 1. Should be used to disable electrical power to equipment in the MRI room. It will NOT disable the magnetic field.

QUENCH

An MR "quench" is a release of the helium needed to cool the superconducting magnet. It can be triggered manually or can occur spontaneously. The process of a quench cannot be stopped. There are usually loud noises and the magnet gets very hot. Typically the rapid boil off of helium escapes through a vent, but can be very dangerous if the vent fails, does not function, or bursts. If this occurs, white chilled gas will escape into the room. It is essential that the room be evacuated before this occurs. With the gas present, oxygen will be depleted, and there is a high risk of asphyxiation and frostbite. There also will be an increase in pressure in the room, enough to destroy walls or equipment. All helium may not be dissipated during a quench, so no ferrous material should be allowed in the magnet room, including rescue equipment, until proper clearance is given.

A spontaneous quench can occur due to: fire, large projectiles, natural disasters or weather events, or no particular reasons at all.

A quench results in several days of downtime, and significant financial burden. It should only be activated in true emergencies.

- A. When to Quench:
 - 1. Quench only if there is a personal or patient injury risk.
 - 2. A subject is "pinned" within or against magnet.
 - 3. A fire within gantry that cannot be extinguished.
- B. Quench is NOT necessary
 - 1. For an isolated projectile in magnet, without patient risk; the service engineer should be called.
 - 2. In an emergency event (i.e. ER code, fire), if the patient can be removed safely.
- C. MRI Staff Workflow for Quench
 - 1. Remain calm, and assess the situation. Determine if an emergency event warrants activation of a quench (see criteria above).
 - a. If warranted, push quench button.
 - b. If spontaneous quench occurs, inform the patient to stay calm, and to remain on the table. Follow the procedures below.
 - c. If spontaneous quench occurs due to fire, follow MRI fire procedures.
 - 2. Notify nearby colleagues/staff of the emergency.
 - a. If available, other MR staff can initiate notification of appropriate emergency personnel
 - 3. Keep MR door propped open in case of sudden cryogen gas release in the room.
 - 4. Proceed to vacate patient:
 - a. Move table out of magnet automatically (if power is still on) or manually with table release (if power is out)
 - b. Transport patient out of MR room with dockable table, or magnet-safe stretcher (if table and/or patient is immobile).
 - c. For "trapped" patients, a quench will last approximately 2-3 minutes, at which time the ferromagnetic object may become dislodged. Proceed to vacate patient after this time.
 - 5. Transport patient to a safe area, which will be determined by the extent of the quench event, and the nature of patient injury.
 - 6. Notify appropriate emergency personnel, if not already done so.
 - a. Determine which codes need to be activated (i.e. fire, ER, etc).
 - Despite a quench event, no ferrous material should be allowed in the MR room (zone 4) until zero magnetic field is confirmed.
 - a. If available, other MRI staff members should remain near the entrance of

zone 4 to prevent premature entry of emergency personnel.

- b. If available, other MRI staff members should remain near the entrance of zone 3 to direct and inform emergency personnel of the event.
- 8. Notify manufacturer service engineer and Director of Imaging Services.
- 9. Document as much of the event as possible.
- D. Quench Vent Failure

In some cases, there may be a failure of the vent, and cryogen may leak into the room (cloud of smoke). It is important to remain calm in this situation.

- 1. Prop the MR door and the hallway door open (to relieve pressure build-up).
 - a. If the door does not open after several attempts, it may be necessary to break glass. Some installations also have a small trap door underneath the scanner console to relieve pressure.
- 2. Proceed to remove the patient as quickly and calmly as possible using the methods described above.
 - a. Oxygen is dissipating with a cryogen/helium leak. Oxygen will be highest near the floor, so lowering table may be appropriate.
 - b. There is also frostbite risk.
- 3. Transport patient to a safe place outside of the MR room and MR control room, and ensure emergency personnel is notified if patient requires attention.
 - a. The open doors will allow gas/pressure to be released into control room.
- 4. Evacuate all other patients and personnel from the MR control room (zone 3 and 4) until normal air is restored.
- 5. Notify external emergency personnel, depending on the emergency event (i.e. fire, spontaneous quench).
- 6. Notify manufacturer service engineer, MRI director, and MR Physicist.
- 7. Document as much of the event as possible.

All Revision Dates

3/14/2025, 5/23/2023, 12/1/2015, 10/1/2015

Attachments

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/14/2025
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	3/14/2025
Imaging Services	Matt McGill: Director, Imaging Services	3/14/2025



Status Active PolicyStat ID 9582541			
Origination	11/20/2015	Owner	Matt McGill:
Last Approved	2/25/2025		Director, Imaging Services
VENTURACOUNTY Effective	2/25/2025	Policy Area	Imaging Services
HEALTH CARE AGENCY Last Revised	2/25/2025		
Next Review	2/25/2028		

IS.51 Imaging Services Employee Unscheduled Time Off/ Sick Calls

POLICY

The purpose of the "Employee Unscheduled Time Off/Sick Call" policy is that through advance planning and flexible scheduling, our departments will be able to deliver quality patient care while meeting the operational needs of this department. See also policy <u>101.023 Request for Vacation, Leave of Absence,</u> <u>Administrative Leave</u>.

PROCEDURE

- 1. Utilize your modality specific pathway to notify leadership (Lead Tech and/or Supervisor, or Supervisor on call) at least 4 hours prior to your shift if you are unable to report to work or will be reporting to work later than scheduled and give an estimated time of when you will arrive.
- 2. If contacting the Supervisor on call by text you must receive a text back confirming receipt or visualize "read" for the message you sent. If there is no reply or notice of "read", a call must be placed. When contacting the Supervisor on call after 8pm a phone call is required.
- 3. When leaving a voicemail or sending a text, state your name, reason for not reporting to work, if you had on-call responsibilities during the time you are calling out, and a number that you can be reached at during the day.
- 4. Contact leadership every day that you are unable to report to work. The exception to this is approved vacation or medical leave.
- 5. If you become ill during the day and need to leave your work site, you **must** contact the manager or supervisor. If one is not available, you must leave a voice mail at either of the above numbers stating the time and reason for leaving.
- 6. It is the **employee's** responsibility to contact the manager or supervisor in the event you are placed on a medical leave. It is also the **employee's** responsibility to submit the appropriate

paperwork in order to be placed on a medical leave.

- 7. Failure to follow these steps may result in the employee being considered absent without leave and will result in leave without pay and disciplinary action.
- 8. If you receive a **jury duty summons**, please notify the manager or supervisor of the date **PRIOR** to returning the form. The manager or supervisor may request a date change based on staffing needs.

CONTACT PHONE NUMBERS

Matt McGill, Manager	652-6564 / CELL # 805-585-7750
Lena Jasso, Clerical Supervisor	652-6789 / CELL # 805-421-6557
Dan Hallack, Imaging Supervisor	Cell# 805-390-7683
Joyce Stimac, Imaging Supervisor	Cell# 805-901-2292
Renee Ayala, Imaging Supervisor	Cell# 805-616-6364

TIME OFF REQUEST FORM

- 1. Per the new MOA agreement between the SEIU and Ventura County, 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.
- 2. Time off requests shall be given to department leadership directly.
- Requests submitted more than THREE (3) MONTHS ahead of or less than THREE (3) WEEKS before requested vacations/doctor's appointments will be approved based on operational ability, unless it is an emergency.
- 4. Requests for time off that overlap previously approved requests from other staff will be approved based on operational ability.
- 5. Request that exceed a regular 80 hour pay period or 10 regularly scheduled working days will be evaluated for approval based on operational ability.
- 6. Requests during peak holiday weeks or for the same holiday two years in a row will be reviewed based on operational ability and to allow others to make a first time request.

All Revision Dates

2/25/2025, 7/5/2018, 11/20/2015

Approval Signatures

Step Description

Approver

Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/25/2025
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	2/24/2025
Imaging Services	Matt McGill: Director, Imaging Services	2/18/2025



Status	Active	PolicyStat ID	17791339)
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Origination	12/1/2015	Owner	Matt McGill:
Last Approved	3/14/2025		Director, Imaging Services
VENTURACOUNTY Effective	3/14/2025	Policy Area	Imaging Services
HEALTH CARE AGENCY Last Revised	3/14/2025		
Next Review	3/13/2028		

IS.53 MRI Preventive Maintenance and Repairs

POLICY:

The 3.0T MRI magnet located in the VCMC Imaging department will be covered for repairs and regular scheduled maintenance by a service contract provided by Philips Healthcare.

PROCEDURE:

- A. The 3.0T MRI magnet purchased from Philips Healthcare will be maintained by Philips Healthcare Service Engineers.
 - 1. Philips service personnel will be responsible for performing all scheduled preventive maintenance on the magnet.
 - 2. Philips service personnel will be responsible for all repairs needed on the magnet.
 - 3. Philips will coordinate with the MRI staff at VCMC when scheduling a preventive maintenance service of the magnet. This is so patients will not be delayed or exams cancelled.

All Revision Dates 3/14/2025, 11/22/2024, 2/13/2019, 1/1/2016

Approval Signatures

Step Description

Approver

Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/14/2025
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	3/14/2025
Imaging Services	Matt McGill: Director, Imaging Services	3/14/2025



Origination	9/2/2020	Owner	Sul Jung:
Last Approved	3/3/2025		Associate Director of Pharmacy
VENTURACOUNTY Effective	3/3/2025		Services
HEALTH CARE AGENCY Last Revised	3/3/2025	Policy Area	Pharmacy
Next Review	3/2/2028		Services

PH.100 KitCheck for Pharmacy Boxes, Kits and Anesthesia Medication Trays

POLICY:

Radio-frequency identification (RFID) technology may be utilized by pharmacy staff to improve the medication box/kit replenishment process and for inventory management including management of expiration dates, lot numbers, and recalled medications. The KitCheck system utilized RFID technology and is available at both Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) inpatient pharmacy.

PROCEDURE:

- A. Assigning of user name and password
 - 1. Each staff member will have his/her own unique user name and password.
 - 2. Security level will be based on job category, pharmacy technician or pharmacist, assigned by a pharmacy supervisor.
 - 3. Users are to change their password as prompted by the Kit Check system.
- B. Education and training
 - 1. All personnel with access will receive training prior to use of KitCheck.
 - 2. Training consists of the following:
 - a. Online training and competency assessment provided by KitCheck (pharmacist).
 - b. Live training of KitCheck with a KitCheck certified trainer/super user for both pharmacist and pharmacy technician.
- C. Responsibility

- 1. Pharmacy technician
 - a. Affix the RFID labels to the medications and maintain adequate inventory levels.
 - b. Scan and refill KitCheck tagged medications for all medication trays, boxes, and kits.

2. Pharmacist

- a. Ensure accuracy of the national drug code (NDC), lot number, and expiration date associated to the medication.
- b. Confirm the Kit Masters medication list is correct and updated in the system.
 - i. Contact pharmacy supervisor if medication list needs to be revised.
- c. Perform final inspection of the trays, kits, and boxes and place a lock if applicable.
 - i. Ensure alternate expiration beyond use date sticker is applied on the individual medication if applicable (e.g. rocuronium)
- d. Assign the location of the boxes, kits, and trays when it leaves the pharmacy.

D. KitCheck medication storage

1. Medications with the RFID labels attached are kept separately in a designated area to be used exclusively with KitCheck technology.

E. List of KitCheck boxes, kits and trays

- 1. Adults crash cart tray
- 2. Anaphylaxis kit
- 3. Anesthesia emergency kit
- 4. Anesthesia Pyxis tray
- 5. Anesthesiologist medication box
- 6. Cardiac drawer medication box
- 7. Code Blue medication box (VCMC only)
- 8. Malignant Hyperthermia Cart
- 9. Neonatal crash cart tray
- 10. NICU transport box (VCMC only)
- 11. Pediatric crash cart tray
- F. Restocking procedure
 - 1. Used, opened, or expired boxes, kits, or trays must be returned to the pharmacy for replenishment of the content with RFID labeled medications.

- a. Boxes and kits including anesthesiologist medication box: See policy PH.115 Medication Boxes and Kits.
- b. Crash cart: See policy <u>100.113</u> Crash Cart Checks and Restocking <u>Process</u>.
- c. Anesthesia Pyxis tray and Anesthesia emergency kit exchange process will be performed by a pharmacy technician.
- 2. The pharmacist shall use the Kit Check technology as outlined in Attachment A to replenish the medications associated with each box, kit, or tray.
- 3. The pharmacist shall assign a specific location to each box, kit, or tray for tracking purposes (if applicable) and secure it with appropriate locks.
- 4. The expiration date and name of the earliest expiring medication shall be readily available/visual on the box, kit, or tray.
- G. System Management and Maintenance
 - 1. KitCheck inventory
 - a. The pharmacy department shall be responsible for maintaining inventory including restocking, modifying medication inventory due to shortage, and removing outdates.
 - b. Outdates shall be tracked by KitCheck and will be routinely checked at least once monthly.
 - 2. KitCheck support shall be called when KitCheck technology complications/problems cannot be resolved by staff or KitCheck superuser.
 - a. Website: http://app.kitcheck.com
 - b. Email: help@kitcheck.com
 - c. Phone number: 786-548-2432 ext 2

All Revision Dates

3/3/2025, 10/22/2024, 2/20/2024, 3/24/2023, 9/13/2022, 9/2/2020

Attachments

S Attachment A: Kit Check Procedure Manual

Approval Signatures

Step Description

Approver

Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2025
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	3/3/2025



Origination	1/1/2014	Owner	Beatriz Cachu:
Last Approved	2/28/2025		340B Program Administrator
VENTURACOUNTY Effective	2/28/2025	Policy Area	Pharmacy Services
HEALTH CARE AGENCY Last Revised	2/28/2025		Germees
Next Review	2/28/2026		

PH.18.01 340B Drug Pricing Program: Disproportionate Share Hospital

I. Purpose

This policy serves as the basis for the covered entity (CE) Ventura County Medical Center's (VCMC, DSH050159) policy and procedures for the 340B Drug Pricing Program (340B Program), which requires drug manufacturers to provide outpatient drugs to eligible health care organizations, including the covered entity (CE) Ventura County Medical Center [DSH050159], at significantly reduced prices. The CE uses savings from the 340B Program following its intent to reach "more eligible patients and provide more comprehensive services."

II. Background

- A. Section 340B of the Public Health Service Act (1992), (<u>See Reference I</u>), requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of the Department of Health and Human Services (DHHS).
 - 1. This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs.
- B. The 340B Program is administered by the federal Health Resources and Services Administration (HRSA) in the Department of Health and Human Services (DHHS).
- C. Upon registration on 340B Office of Pharmacy Affairs Information System (OPAIS), the CE:
 - 1. Agrees to abide by specific statutory requirements and prohibitions.
 - 2. May access 340B drugs.

III. 340B Policy Statements

- A. The CE shall comply with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than an eligible patient of the entity.
- B. The CEs have systems and internal controls in place to ensure ongoing compliance with all 340B requirements:
 - 1. Audit Process (See Section "340B Program Compliance, Monitoring and Reporting")
 - 2. Purchasing process (See Section "Inventory Management")
 - 3. Shipping and receiving process (See Section "Inventory Management")
- C. Registration & Recertification (See Section "340B Program Enrollment Recertification")
- D. The CEs maintain auditable records demonstrating compliance with the 340B Program.
 - 1. These records are reviewed by the CE monthly as part of its 340B oversight and program compliance. (See Section <u>"340B Program Compliance, Monitoring and Reporting"</u>)
- E. Policy review, updates, and approval shall be updated and approved by the CEs' Compliance Committee whenever there is a rules clarification, regulations change, or change in guidelines to the 340B Program requirements. Otherwise, the policy shall be reviewed and approved annually by key stakeholders.

IV. Definitions

- A. <u>Child Site:</u> An offsite location that is eligible to participate in the 340B Program because it is part of the Covered Entity but is separately registered with the Office of Pharmacy Affairs (OPA) because it has a different street address than the Covered Entity's main facility. A Covered Entity does not need to register outpatient clinics and departments located within the four walls of the entity's main facility. OPA guidance establishes a Medicare cost report test to determine whether an offsite clinic is part of the Covered Entity and, therefore, eligible to use 340B drugs. Under this test, an offsite clinic's costs must be reimbursable on the hospital's Medicare cost report. In implementing this guidance, OPA has taken the position that, to be 340B eligible, an offsite clinic's costs must appear on a reimbursable line of a hospital's most recently filed cost report. A Covered Entity pharmacy is not a Child Site.
- B. <u>Covered Entity</u>: The statutory name for facilities and programs eligible to purchase discounted drugs through the 340B Program. Covered entities include federally qualified health center look-alike programs; certain disproportionate share hospitals owned by, or under contract with, State or local governments; and several categories of facilities or programs funded by Federal grant dollars, including federally qualified health centers, AIDS drug assistance programs, hemophilia treatment centers, STD and TB grant recipients, and family planning clinics.
- C. <u>Covered Outpatient Drug</u>: The category of drugs for which manufacturers must give 340B discounts to covered entities under the 340B Program. In order for a product to qualify as a Covered Outpatient Drug, it must be FDA-approved, prepared and dispensed pursuant to a

prescription, and used on an outpatient basis. In order for a Covered Outpatient Drug to be paid for by Medicaid or Medicare Part B, a manufacturer must enter into both a Medicaid Drug Rebate Agreement and a Pharmaceutical Pricing Agreement (PPA) that covers the Covered Outpatient Drug. The Medicaid statute includes a limiting provision that excludes from the definition of "Covered Outpatient Drug" any drug, biological product, or insulin that is "provided as part of, or incident to and in the same setting as" certain specified services and paid for by Medicaid as part of payment for those services and not as direct reimbursement for the drug.

- D. <u>Disproportionate Share Hospital (DSH)</u>: A type of 340B covered entity that receives adjustment payments to provide additional help to those hospitals that serve a significantly disproportionate number of low-income patients. The primary method of qualification is based on the sum of the percentage of Medicare inpatient days and the percentage of total patient days attributable to patients eligible for Medicaid but not eligible for Medicare Part A. Among other requirements, DSHs must have a DSH Adjustment Percent >11.75% in order to be 340B eligible. VCMC qualified for the 340B Drug Pricing Program as a DSH covered entity.
- E. <u>Duplicate Discount</u>: When a manufacturer gives both an up-front 340B discount to a Covered Entity at the time of purchase and a post-purchase discount to a state Medicaid agency after Medicaid pays the Covered Entity for the drug and submits a rebate request to the manufacturer under the Medicaid rebate program. Both the 340B and Medicaid rebate laws protect manufacturers from duplicate discounts. A Covered Entity must comply with the prohibition against duplicate discounts by: (1) billing Medicaid at no more than actual acquisition cost plus a dispensing fee; OR (2) "carving out" Medicaid drugs from its 340B program.
- F. <u>Eligible Patient Definition</u>: An individual is a "patient" of a covered entity only if:
 - 1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
 - 2. The individual receives health care services from a health care professional who is either employed by the covered entity or under contractual or other arrangement such that responsibility for the care provided remains with the covered entity.
- G. <u>Parent Site:</u> The main facility of the Covered Entity that becomes eligible to use 340B drugs by virtue of the entity's enrollment in the 340B Program. In contrast, outpatient clinics that have a different street address than the entity's main facility, which are commonly called "child sites," must be separately registered with OPA before they can begin using 340B drugs.
- H. <u>Mixed-use setting</u>: A hospital area that serves a mixed patient type of both inpatients and outpatients. Often these are facilities such as surgery centers, cardiac catheter labs, infusion centers, and emergency departments.
 - 1. Inpatient Status: VCMC determines that patients have an inpatient status if the patient's admit type is one of the following in the electronic health record:
 - a. Inpatient
 - b. Inpatient Psych
 - c. Trauma Inpatient
 - 2. Outpatient Status: VCMC determines that patients have an outpatient status if the patient's admit type is one of the following in the electronic health record:

- a. Clinic
- b. Day Surgery
- c. ED Telehealth
- d. Emergency
- e. Observation
- f. Outpatient
- g. Outpatient Multiday
- h. Outpatient in Bed
- i. Recurring
- j. Telehealth
- k. Trauma Emergency
- I. Trauma Observation

V. Covered Entity Eligibility

A. Policy

1. The CE must meet the requirements of 42 USC §256b(a)(4)(L), (See Reference II), to be eligible for enrollment in, and the purchase of drugs through, the 340B Program.

B. Purpose

1. To ensure the CE's eligibility to participate in the 340B Program.

C. Covered Entity

- 1. The CE has locations where it would be appropriate to dispense, administer or prescribe 340B drugs to eligible patients. (*See Reference III*).
- 2. These locations include the following:
 - a. Within the four walls of the parent site; and
 - b. Within off-site outpatient locations that are fully integrated in the hospital, reimbursable on the most recently filed Medicare cost report, and registered on 340B OPAIS.

D. Eligibility Requirements

- 1. The CE is owned or operated by a unit of state or local government.
- 2. The CE has a disproportionate share adjustment percentage greater than 11.75%.
- 3. The CE does not obtain covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement for eligible locations, in accordance with GPO Policy Release. (*See Reference IV*)
 - a. The CE may define non-covered outpatient drugs: Non-covered outpatient drugs may be purchased on GPO or non-340B contracts.
 - b. The CE will maintain a list of all non-covered outpatient drugs. See

Attachment A: List of Non-Covered Outpatient Drugs.

- c. CE does not dispense or administer covered outpatient drugs to individuals not meeting the 340B patient definition.
- d. If a pharmaceutical manufacturer refuses to sell enough of a 340B priced drug to serve all of the CE's 340B eligible patients, the rest of the quantity needed will be purchased on a non-GPO account. The CE will notify OPA in writing that the manufacturer will not sell the drug at a 340B price. (See <u>Reference V</u>)
- e. The GPO exclusion does not preclude CE from purchasing covered outpatient drugs through the Prime Vendor Program (PVP). OPA does not consider purchases made through PVP to be a violation of the GPO exclusion
- 4. The CE maintains a complete roster of 340B, GPO, and non-340B/non-GPO vendor accounts, including segregated GPO accounts for the primary care network.
- 5. The CE has tracking systems and safeguards in place to prevent GPO violations. (See Section "340B Program Compliance, Monitoring and Reporting")
- The CE ensures that OPAIS is complete, accurate, and correct for all 340B eligible locations including the parent entity, off-site locations, and contract pharmacies. (See Reference III)
 - a. All off-site locations that use 340B drugs are registered on 340B OPAIS.
 - b. All main addresses, billing and shipping addresses, the authorizing official, and the primary contact information are correct and up to date.
 - c. The CE regularly reviews its 340B OPAIS records quarterly.
 - d. The CE will inform HRSA immediately of any changes to its information by updating the 340B OPAIS and or Medicaid Exclusion File.
 - e. The CE will notify HRSA immediately of any changes to The CE's Medicare disproportionate share adjustment percentage resulting in a disproportionate share percentage less than 11.75%.
- 7. The CE annually recertifies information on 340B OPAIS.

E. GPO Prohibition Exclusion

- 1. The CE has identified exclusions to the covered outpatient drug definition.
 - a. Drugs that are part of or incident to the service, these drugs are given in the same setting as the service provided, and they are paid (bundled) as part of the service rendered.
 - b. Items that do not meet the covered outpatient drug definition are listed in *Attachment A: List of Non-Covered Outpatient Drugs*.
 - c. Attachment A: List of Non-Covered Outpatient Drugs only applies to mixeduse areas and does not extend to clean sites, such as clinics and contract pharmacies.

2. An offsite outpatient clinic that is not registered as a child site may purchase drugs using a GPO account as long as the purchase is made on a wholesaler account that is separate from the 340B Program accounts.

VI. 340B Program Enrollment Recertification

A. Policy

1. The CE shall maintain the accuracy of 340B OPAIS and be actively registered to participate in the 340B Program.

B. Purpose

- 1. To ensure the CE is appropriately registered and maintains accurate records on 340B OPAIS.
 - a. Registration dates:
 - i. January 1–January 15 for an effective start date of April 1
 - ii. April 1-April 15 for an effective start date of July 1
 - iii. July 1–July 15 for an effective start date of October 1
 - iv. October 1-October 15 for an effective start date of January 1
 - b. 340B Contract Pharmacy Guidelines (https://www.gpo.gov/fdsys/pkg/ FR-2010-03-05/pdf/2010-4755.pdf).

C. Enrollment

- The CE is eligible to participate in the 340B Program (See Section "Covered Entity Eligibility")
- 2. The CE identifies upcoming registration dates and deadlines.
- 3. The CE identifies authorizing official and primary contact.
- 4. The CE has available the required documents:
 - a. Medicare cost report:
 - i. Worksheet S, S-2, S-3
 - ii. Worksheet E, part A, and
 - iii. For outpatient facilities: Worksheet C, Worksheet A, and Working trial balance
 - b. Certification of ownership status
- 5. The CE completes registration on 340B OPAIS (https://340bopais.hrsa.gov/).

D. Recertification Procedure

- 1. The CE shall recertify information listed on 340B OPAIS annually.
- 2. The CE shall verify and confirm cost centers listed on 340B a crosswalk and assure that it matches with the most recently filed Medicare Cost Report.
- 3. 340B Crosswalk is compared to the OPAIS database to ensure all contact and

address information is listed accurately.

- 4. Any changes or corrections to clinic / contract pharmacy information can be completed during recertification period. However, new clinics cannot be registered at this time.
- 5. Ensure there are no clinic termination(s) to be completed.
- 6. NPI numbers, Primary Contact and Authorizing Official's (AO) contact information is verified and confirmed.
- 7. Review and verify contract pharmacy name, store #, address listed on the OPA database match the covered entity's contract pharmacy agreement.
- 8. Ensure all contract pharmacy agreements are current and match the copy of the Third Party Administrators.
 - a. Authorizing official completes the annual recertification by following the directions in the recertification email sent from HRSA to the CE prior to the stated deadline.
- 9. The CE submits specific recertification questions to <u>340b.recertification@hrsa.gov</u>.

E. New Outpatient Facilities

1. The CE will determine that a new outpatient service or facility is eligible to participate in the 340B Program.

- a. The criteria used include that the outpatient service must be fully integrated into hospital, appear as a reimbursable service or clinic on the most recently filed cost report, have outpatient drug use, and have patients who meet the 340B patient definition.
- 2. The CE's authorizing official completes the online registration process during the registration window.
 - a. Submit any updated Medicare cost report information, as required by HRSA: <u>http://www.hrsa.gov/opa/eligibilityandregistration/hospitals/</u> disproportionatesharehospitals/index.html

F. New Contract Pharmacies

- 1. The CE has a signed contract pharmacy services agreement.
 - a. The CE's Contracts Division reviews the contract and verifies that all federal, state and local requirements have been met.
- 2. The CE has contract pharmacy oversight and monitoring policy and procedure developed, approved, and implemented.
- 3. The CE's authorizing official or designee completes the online registration during one of four registration windows.
 - a. Within 15 days from the date of the online registration, the authorizing official certifies online that the contract pharmacy registration request was completed.
- 4. The CE begins using the contract pharmacy services arrangement only on or after

the effective date shown on 340B OPAIS.

G. Changes to Information in 340B OPAIS

- 1. Ventura County Medical Center notifies HRSA immediately of any changes to Medicare disproportionate share adjustment percentage resulting in a disproportionate share percentage less than 11.75%.
 - a. Ventura County Medical Center will stop the purchase of 340B drugs as soon as Ventura County Medical Center files its cost report with a disproportionate share percentage is less than 11.75%.
 - b. Authorizing official will complete the online change request as soon as a change in eligibility is identified.
- 2. Ventura County Medical Center's registered and eligible clinics that move to new locations can continue with 340B eligibility if only a 'Change Request Form' is submitted with new address. Once approved by Office of Pharmacy Affairs, clinic can continue to be 340B eligible.
- 3. Clinic expansions and cost centers that are eligible and listed on the current Medicare cost report are registered during the next registration period by the Authorizing Official. 340B drugs shall not be used at the expansion location until clinic is registered and approved by OPA.

VII. 340B Program Roles, Responsibilities and Education

A. Policy

 The CE participating in the 340B Program must ensure program integrity and compliance with 340B Program requirements. 340B key stakeholders will participate in education and training as needed to ensure that these key stakeholders have the knowledge to guarantee compliant 340B operations.

B. Purpose

1. To identify The CE's key stakeholders and determine their roles, responsibilities and education in maintaining 340B Program integrity and compliance.

C. Committee Oversight

- 1. The CE will maintain a roster of all key stakeholder's roles, responsibilities and education within the CE's 340B Program.
- 2. The CE's Compliance Committee is responsible for the oversight of the 340B Program.
- 3. The CE's Compliance Committee:
 - a. Meets on a quarterly basis with all key stake holders.
 - b. The CE maintains readily retrievable meeting agendas and minutes.
 - c. Reviews 340B rules, regulations and guidelines to ensure consistent policies procedures and oversight throughout the entity.

- d. Identifies activities necessary to conduct comprehensive reviews of 340B compliance.
 - i. Ensure that the organization meets compliance requirements of program eligibility, patient definition, 340B drug diversion and duplicate discounts via ongoing multidisciplinary teamwork.
 - ii. Integrate departments such as information technology, legal, pharmacy, compliance, and patient financial services to develop standard processes for contract/data review to ensure program compliance.
- e. Oversees the review process of compliance activities and audits, as well as taking corrective actions based on findings.
- f. The Compliance Committee assesses if the results of audits are indicative of a material breach. (See Section "340B Material Breach and Noncompliance Disclosure")
- g. Reviews and approves work group recommendations (process changes, self-monitoring outcomes and resolutions).
- 4. HRSA Audits:
 - a. Upon notification of a HRSA audit, all key stakeholders (Pharmacy, Compliance, Finance, Purchasing, Contract Pharmacies, etc.) will be informed of the audit.
 - b. The CE will comply with any and all requests for information from HRSA during the pre-audit period.
 - c. During an on-site HRSA audit, all key stakeholders will be involved, and the CE will fully cooperate with the auditor throughout the audit process.
- 5. Manufacturer Audits
 - a. The CE will respond to all manufacturer requests for information related to 340B purchases in a timely manner.
 - b. Upon notification of a manufacturer audit, all key stakeholders will be informed of the audit.
 - c. The CE will respond to all requests for information from a manufacturer in a timely manner
 - d. During the on-site manufacturer audit, all key stakeholders will be involved as necessary, and the CE will fully cooperate with the auditor throughout the audit process.

D. Education and Stakeholder Certification

- 1. Education
 - a. The CE determines any educational requirements for each 340B Program role.
 - b. Education and training may consist of any of the following:

- i. Initial basic training upon hire
- ii. On-demand modules on the Apexus website
- iii. 340B University
- iv. 340B conferences
- v. Complete Advance 340B Operations Certification Exam
- vi. Participate in HRSA and 340B Health webinars
- vii. Participate in statewide 340B workgroup calls
- viii. Other 340B related activities
- 2. The CE provides educational updates and training, as needed.

VIII. Patient Eligibility/Definition

A. Policy

1. Per the Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 340B drugs are to be provided only to individuals eligible to receive 340B drugs from covered entities. (*Reference VI*)

B. Purpose

1. The CE ensures that 340B drugs are dispensed, administered, and prescribed only to eligible patients.

C. Patient Eligibility

- 1. An individual is a patient CE is 340B eligible only if:
 - The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
 - b. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity.
- 2. The CE recognizes observation patients, registered outpatients, hospital discharge patients and/or any status prior to admission from an eligible location may be eligible to receive 340B Covered Outpatient Drugs.
- 3. The CE often provides specialty care subsequent to a referral. The prescriptions written for conditions treated by the CE's specialty providers in the outpatient clinics are eligible for 340B prices at the CE's contracted pharmacies with the patient outcomes and follow-up remaining the responsibility of our contracted providers.
- 4. CE staff are eligible as patients ONLY when they meet all the same criteria required under the patient definition.

IX. 340B Program Compliance, Monitoring and Reporting

A. Policy

1. The CE is required to maintain auditable records demonstrating compliance with the 340B Program requirements.

B. Purpose

1. To provide an internal monitoring program to ensure comprehensive compliance with the 340B Program.

C. Diversion and Duplicate Discounts

- The CE complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulation, public notices, and guidelines including, but not limited to, selling, giving, or otherwise transferring of covered outpatient drugs purchased under the program to anyone other than a "patient of the covered entity." (See Section "Patient Eligibility/Definition".)
- The CE maintains compliance with 42 USC §256b(a)(5)(A)(i) which prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts.
 - a. The CE will append the appropriate modifiers on all claims. Physician Administered Drug claims require a "UD" modifier. The "UD" modifier informs California Department of Health Care Services (DHCS) that a 340B purchased drug was used for the claim. The CE maintains and reviews Medicaid provider numbers and NPI numbers quarterly and assures that they are properly reflected in the Medicaid Exclusion File (MEF).

D. Medicaid Carve-In

- The CE dispenses or administers 340B purchased drugs to Medicaid patients AND subsequently bills Medicaid for those 340B drugs (carve-in) for the mixed-use setting.
- 2. The CE bills Medicaid per state Medicaid reimbursement requirements. This is audited monthly using internal audits.
- 3. The CE reviews its 340B OPAIS Medicaid Exclusion File (MEF) records quarterly. Any changes in our MEF information shall be communicated to HRSA immediately by updating 340B OPAIS before the 15th of the month prior to the quarter when the change would take effect.
- 4. Medicaid reimburses the CE for 340B drugs per state policy and does not seek rebates on drug claims submitted by the CE.
- 5. All Medicaid prescriptions are excluded from the CE's contract pharmacies. This includes both fee-for-service (FFS) and geographic managed care (GMC) plans.
- 6. Covered outpatient drugs are only billed to Medicaid for the state of California.

E. Program Assurance

- 1. The designation of all outpatient clinics (340b-eligible or non-340B) are identified when clinics are first created. These clinics are reviewed thereafter on a monthly basis and audited quarterly.
- 2. The CE voluntarily contracts with an independent consultant to conduct an annual external audit of our program that has been approved by the Compliance Committee.
- 3. The CE ensures compliance with the GPO Prohibition.
 - a. Segregated purchasing accounts are used for non-registered sites
 - b. Orders for mixed use are placed through a split billing platform
 - c. All orders for clean 340B only sites are placed on separate accounts
- 4. To demonstrate the ongoing responsibility for health care, the CE shall provide health care to the individual at a registered site of the CE within 15 months of a written prescription.
- 5. The CE determines outpatient locations and status that meet the following criteria:
 - a. Registered hospital-based clinics that provide care to outpatients.
 - b. Emergency departments that provide outpatient emergency and primary care to the insured, uninsured and underinsured.
 - c. Non-admit patients seen in mixed-use areas (e.g., GI lab, OR, PACU and radiology).
 - d. Discharge patients.
 - e. Authorized Observation non-admit patients carrying the appropriate outpatient classification. or
 - f. Any patient class prior to admission orders being written
- 6. The CE determines provider eligibility as either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the CE.
- 7. At no time are prescriptions rewritten solely for the purpose of patient eligibility for 340B prescriptions.
- 8. Patients treated in the Emergency Department may remain in the Emergency Department for extended periods of time, e.g., awaiting placement to a proper unit or facility, observation status, etc. Once inpatient orders are written for a patient in the Emergency Department, the patient's status shall change to inpatient and they will no longer be eligible to receive 340B drugs.

F. Program Self Audits & Maintenance

- 1. The CE routinely conducts internal monthly reviews of each registered contract pharmacy, mixed use areas and clinics for compliance with 340B Program requirements.
- 2. The following elements will be reviewed when conducting self-audits:
 - a. The prescription shall be written from a site of care that is registered on

340B OPAIS and included as a reimbursed outpatient service cost center on the most recently filed Medicare cost report; and

- b. The patient shall have had an eligible encounter in the last 15 months; and
- c. The patient shall meet the eligibility defined by HRSA and DHHS; and
- d. The provider shall be eligible at the time the prescription is written
- 3. The CE reviews 340B OPAIS quarterly to ensure the accuracy of the information for the parent site, off-site locations, and contract pharmacies.
- 4. The CE reviews the Medicaid Exclusion File (MEF) quarterly to ensure the accuracy of the information for the parent site, off-site locations, and contract pharmacies.
 - a. Twenty randomly selected 340B medications dispensed to Medicaid patients are audited every quarter.
 - i. The CE shall confirm that the Medicaid number and/or National Provider Index numbers used to bill Medicaid on the Medicaid Exclusion File are accurate.
- 5. The CE reconciles purchasing records and dispensing records to ensure that covered outpatient drugs purchased through the 340B Program are dispensed or administered only to patients eligible to receive 340B drugs and that any variances are not the result of diversion.
- 6. The CE shall maintain its split billing software program by conducing the following:
 - a. Weekly review of unknown items.
 - b. Quarterly audit of multipliers.
- 7. The CE reconciles dispensing records to patients' health care records to ensure that all medications dispensed were provided to patients eligible to receive 340B drugs.
 - a. Thirty randomly selected dispensed 340B drugs are audited every quarter to confirm that the patients receiving 340B medications were qualified outpatients.
- 8. The CE will randomly select records from a drug utilization file and perform the audit monthly for all contract pharmacies.
- 9. The CE reconciles dispensing records and Medicaid billing practices on a monthly basis, to demonstrate compliance with Medicaid billing and duplicate discount.
- 10. Provider listing is retrieved from reporting on a monthly basis, reviewed for accuracy and is shared with a third party administrator for outpatient contract pharmacy operations.
- 11. All audit results shall be presented to the Compliance Committee every quarter.

G. Record Keeping and Data Management

- 1. The CE maintains records of 340B-related transactions for a minimum of 7 years in a readily retrievable and auditable format.
 - a. This will be stored in a network location and kept up to date on a monthly basis for internal and external audit purposes

- 2. The CE reviews and maintains data being sent to all third parties as part of its audit and maintenance process
- 3. The CE maintains complete and auditable records of individual's health care.
- 4. The CE has an electronic medical records shared between hospital and clinics. No undocumented care is provided under the CE.

X. Inventory Management

A. Policy

1. The CE must be able to track and account for all 340B drugs to ensure the prevention of diversion.

B. Purpose

1. Ensure the proper procurement and inventory management of 340B drugs.

C. Background

- 1. 340B inventory is procured and managed in the following settings:
 - a. In-house pharmacies
 - b. Clinic site administration
 - c. Contract pharmacies
- 2. The CE uses both of the following inventory methods:
 - a. Physical 340B-only inventory
 - b. Virtual mixed-use inventory

D. Procedure for Purchasing and Logistics

- 1. The CE has registered 340B eligible hospital based clinics.
 - a. Clinics eligible for 340B pricing are listed on the Health Resources and Services Administration website. (*See Reference III*)
 - b. Clinics eligible for 340B pricing shall receive medication using 340B eligible accounts dedicated to 340B-eligible clinics.
 - c. Requisitions for 340B pharmaceuticals are submitted in the electronic health record by clinic staff.
 - d. When the 340B order arrives at the hospital pharmacy, they are received, quantified and separated by clinic and delivered to the 340B eligible clinic or picked up by the 340B eligible clinic.
 - e. Automated dispensing machines located in 340B eligible clinics are refilled with medications that are ordered through 340B accounts dedicated to 340B-eligible clinics.
- 2. The CE has outpatient GPO eligible clinics.
 - a. Outpatient clinics eligible for GPO pricing are located at a different physical address than the parent site and are not registered in 340B

OPAIS.

- b. Outpatient clinics eligible for GPO pricing shall receive medication using GPO accounts dedicated to outpatient clinics eligible for GPO pricing.
- c. Requisitions for outpatient GPO purchases are are submitted in the electronic health record by clinic staff.
- d. When the GPO order arrives at the hospital pharmacy, they are received, quantified and separated by clinic and delivered to the GPO eligible clinic or poicked up by the GPO eligible clinic.
- 3. Mixed use settings
 - For the purposes of this policy, all areas within the four walls of Ventura County Medical Center (300 Hillmont Avenue; Ventura, CA 93003) and Santa Paula Hospital (825 North 10th Street; Santa Paula, CA 93060) are mixed use settings.
 - b. Designated pharmacy purchasers will ensure all orders are placed appropriately through applicable systems.
 - c. Orders for mixed use areas are split to the appropriate account (340B, GPO, non-340B/non-GPO) based on utilization data using an 11-digit NDC match.
 - d. All direct non wholesaler vendor orders will be created using split billing software. *See policy PH.17 Direct Ordering Procedure*.

4. Transfers

- a. Transferring between inventories should only be done in the event of an immediate patient need. (e.g. emergency, delay of therapy, and pending discharge.)
- b. At no time should inventory be transferred for convenience or re-stocking purposes.
- c. All transfers should be documented on a Loan-Borrow form, which can be found as Attachment A of policy <u>PH.16 Pharmaceutical Borrowing and Loaning</u>.
- d. In the event of inventory transfer, a pharmacist shall sign the form to verify it is needed for immediate patient need.
- e. Inventory transferred from the mixed use areas are replenished at WAC.
- f. Inventory transferred from 340B only shall only be approved by the Director of Pharmacy or designee. Transfers from 340B only areas shall be replaced at WAC or adjusted into accumulation by the 340B team to reconcile the transfer.

5. Returns

a. Returns shall be processed by inventory management staff and are returned for credit under their corresponding account in a timely manner.

- 6. Wasted 340B Medication
 - a. The CE's mixed use areas use a virtual inventory system and does not define any inventory as 340b for the purpose of waste.
 - b. Purchases made in clean 340b only areas have their inventory wasted on site in appropriately labeled medication waste bins without credit.

XI. Contract Pharmacy Operations

A. Policy

 Covered entities are required to provide oversight of their contract pharmacy arrangements to ensure ongoing compliance. The covered entity has full accountability for compliance with all requirements to ensure eligibility and to prevent diversion and duplicate discounts. Auditable records shall be maintained to demonstrate compliance with those requirements.

B. Purpose

 To ensure that the CE remains responsible for all 340B drugs used by its contract pharmacies in accordance with HRSA requirements and guidelines. (See Reference VII)

C. Procedure

- 1. The CE maintains regular contact with third party administrators (TPA) to ensure compliance with applicable federal and state policy and legal requirements. This includes at minimum monthly calls with each TPA.
- 2. The CE contracts with TPAs to facilitate both the design and implementation of the 340B contract pharmacy program.
- 3. The CE has a written contract in place for each contract pharmacy location that meets HRSA requirements. These contracts follow the suggested 12 essential elements of contract pharmacy agreements. (*See Reference VII*)
 - a. Copies of the written contracts for each contract pharmacy location shall be maintained in the Pharmacy Department and shall be made available to HRSA or impacted drug manufacturer upon request.
- 4. The CE registers each contract pharmacy location on the CE's 340B OPAIS prior to the use of 340B drugs at that site.
- 5. The CE must notify OPA of any changes to its contract pharmacy program, including when a contract pharmacy relationship has ended.
- 6. The contract pharmacy may provide other services to the CE or its patients.
- 7. The CE may not restrict patients to use a contract pharmacy; all patients may use the pharmacy of their choice.
- 8. Both parties will adhere to all applicable federal, state and local laws.
- 9. The CE uses a virtual replenishment model using an 11-digit-to-11-digit NDC match for its contract pharmacies.

- 10. 340B-eligible prescriptions are presented to contract pharmacies via e-prescribing, hard copy, fax and/or phone.
 - a. Each prescription is verified by the TPA for patient, prescriber, and outpatient clinic eligibility via encounter data file provided daily and provider file provided monthly.
 - b. Updates are may be made to these mechanisms by the CE at minimum monthly intervals or as needed sooner if need be.
- 11. Contract pharmacies may dispense prescriptions to 340B eligible patients using non-340B drugs.
- 12. The CE implements a bill-to, ship-to arrangement with the contract pharmacies.
 - a. Each individual contract pharmacy orders 340B drugs based on 340B eligible use as determined by the TPA, from CE's contracted wholesalers.
 - i. Orders are created by the TPAs or pharmacy and placed using their preferred ordering method.
 - b. Invoices are billed and review on a bi-weekly basis to the CE.
- 13. Contract pharmacy receives shipments directly.
- 14. Contract pharmacy will verify quantity received with quantity ordered.
 - a. Identifies inaccuracies.
 - b. Resolves inaccuracies.
 - c. Documents resolution of inaccuracies.
- 15. The CE receives and reviews the invoice for drugs shipped to its contract pharmacies for accuracy on a bi-weekly basis.
- 16. Contract pharmacies are included in the CE's internal-audit process.
- 17. Prescriptions that are found to be ineligible in the event of monthly audit shall be submitted to the TPA to process a reversal. These reversal requests are to be tracked to ensure approval of the pharmacy and completion. In the event that a prescription cannot be reversed, it will need to be tracked accordingly and directly with the manufacturer during the next accumulator review.

XII. Material Breach and Non-Compliance Disclosure

A. Policy

1. Covered entities are responsible for contacting HRSA as soon as reasonably possible if there is any material breach by the covered entity or any instance of noncompliance with any of the 340B Program requirements. (See Reference VIII)

B. Purpose

1. To define the CE's material breach of 340B compliance and self-disclosure process.

C. Non-Compliance

- The CE's established threshold of what constitutes a material breach of 340B Program compliance is any error that includes 15% of our total 340B purchases. Any errors less than that shall be reviewed by the Compliance Committee to determine materiality. Any instance of non-compliance that the Compliance Committee decides to consider material shall be reported to HRSA.
 - The CE ensures that identification of any threshold variations occurs among all its 340B settings, including contract pharmacies during monthly audits.
 - b. Such violations require self-disclosure. Violations identified through internal self-audits, independent external audits, or otherwise that exceed this threshold, and that remain non-correctable within a 6 month period from the time of review, shall be immediately reported to HRSA.
- 2. The CE assesses materiality.
 - a. The CE maintains records of materiality assessments.

D. Disclosure

- 1. The CE reports identified material breach immediately to HRSA and applicable manufacturers along with a corrective action plan to address the violation.
 - a. The CE will maintain records of material breach violations, including manufacturer resolution correspondence.

References

- I. Section 340B of the Public Health Service Act (1992) <u>http://www.hrsa.gov/opa/</u> programrequirements/phsactsection340b.pdf
- II. Title 42 USC 256b(a)(5)(A)(i) https://www.govinfo.gov/content/pkg/USCODE-2010-title42/ pdf/USCODE-2010-title42-chap6A-subchapII-partD-subpartvii-sec256b.pdf
- III. HRSA OPAIS Database https://340bopais.hrsa.gov/
- IV. 340B Policy Releases https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/ prohibitionongpoparticipation020713.pdf
- V. GPO prohibition entity purchase via GPO https://www.340bpvp.com/content/contentSearch.html?category=content&Ntt=1242&main-submit.
- VI. Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/ patientandentityeligibility102496.pdf
- VII. Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/contractpharmacyservices082396.pdf
- VIII. HRSA Entity Self-Disclosures https://www.hrsa.gov/opa/self-disclosures/self-disclosure.html

All Revision Dates

2/28/2025, 7/23/2024, 1/30/2024, 10/16/2023, 5/18/2020, 5/31/2017, 4/1/2016, 11/1/2015, 7/1/2015, 4/1/2015, 1/1/2015

Attachments

S Attachment A: List of Non-Covered Outpatient Drugs

Approval Signatures

Step Description	Approver	Date
340B Compliance Committee	Beatriz Cachu: 340B Program Administrator	2/28/2025
Authorizing Official	John Fankhauser, MD: Chief Executive Officer, VCMC & SPH	1/31/2025
Hospital Administration	Jason Arimura: Associate Hospital Administrator- AncillaryServices	12/27/2024
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	12/6/2024
Pharmacy Services	Beatriz Cachu: 340B Program Administrator	12/2/2024

List of Non-Covered Outpatient Drugs

Attachment A of PH.18.01 340B Drug Pricing Program: Disproportionate Share Hospital

The following list of drugs are not considered by Ventura County Medical Center [DSH050159] as covered outpatient drugs as it pertains to the 340B Drug Pricing Program:

- 1. Anesthetic gases
- 2. Contrast agents
- 3. Diluents
- 4. Insulin
- 5. Irrigation fluids
- 6. Local anesthetics
- 7. Non-medicated intravenous fluids
- 8. Large volume IV fluids
- 9. Vaccines

Status Active FolicyStat ID 7304099			
Origination	7/1/1992	Owner	Sul Jung:
Last Approved	1/22/2025		Associate Director of Pharmacy
VENTURACOUNTY Effective	1/22/2025		Services
HEALTH CARE AGENCY Last Revised	1/22/2025	Policy Area	Pharmacy
Next Review	1/22/2028		Services

PH.28 Sick Leave and Vacation Requests

POLICY:

Sick calls, leave of absence, and vacation requests shall be submitted in accordance with this policy. See also policy *101.023 Request for Vacation, Leave of Absence, Administrative Leave*.

PROCEDURE:

Status Active PolicyStat ID 7564899

SICK LEAVE

- A. If a staff member is unable to work due to illness, communication shall be made no later than two (2) hours prior to the start of the scheduled shift.
- B. Communication shall be made by the employee (not by family members) to the Pharmacist on duty, Pharmacy Supervisor, or the Director of Pharmacy Services (DoP).
- C. Sick leave shall not be used in lieu of vacation, nor shall it be used in addition to vacation without certification of a physician that such usage is medically required.

LEAVE OF ABSENCE

A. See policy <u>101.023 Request for Vacation, Leave of Absence, Administrative Leave.</u>

VACATION REQUESTS

- A. All vacation requests shall be made in writing on the approved vacation request form no later than two (2) weeks prior to the schedule release date.
- B. Staff are encouraged to submit requests as soon as possible.
- C. Vacation requests are reviewed on a first come, first serve basis.

- D. Not more than one employee from a classification will be granted vacation at any one time if the request creates a staffing shortage.
- E. Vacation time may be taken in increments of two (2) hours. Vacation time may be allowed in increments of less than two (2) hours but not less than one (1) hour if, prior to the abence, approval to use and receive such time has been specifically granted by the supervisor or DoP.

All Revision Dates

1/22/2025, 1/1/2014, 11/1/1998, 10/1/1992

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/22/2025
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	1/22/2025

Status	Active	PolicyStat ID (17258673)
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Origination	12/17/2024	Owner	Kimberly Dillard:
Last Approved	2/7/2025		Director, Revenue Cycle
VENTURACOUNTY Effective	12/17/2024	Policy Area	Administrative - Fiscal
HEALTH CARE AGENCY Last Revised	2/7/2025		10001
Next Review	2/7/2028		

109.069 Patient Billing And Collections Policy

PURPOSE:

The Ventura County Health Care Agency (HCA), including Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) and hospital-based clinics strive to provide compassionate, quality patient care for the community we serve. This policy demonstrates HCA's commitment to our mission and vision by helping meet the needs of low income and uninsured patients in our community.

POLICY:

It is the policy of VCMC (VCMC) and SPH (SPH) to ensure that billing and collection of patient amounts due are standardized while meeting patient care needs to ensure no patient is refused medically necessary care.

This policy applies to facility charges for VCMC, SPH, and all charges provided by a physician or advanced practice clinician who is employed by Ventura County Health Care Agency (VCHCA), or for fees billed by the above Organizations, to the extent such care is provided within a Hospital Facility or a VCHCA Ambulatory location, excluding Federally Qualified Health Care locations.

Through the use of billing statements, written correspondence, and phone calls, diligent efforts will be made to inform patients/Guarantors of their financial responsibilities and available Financial Assistance options, as well as follow up with patients/Guarantors or authorized representatives (patients/Guarantors) of the patient regarding outstanding accounts. These facilities (above) will not engage in Extraordinary Collections Actions before reasonable efforts to determine whether the individual is eligible for assistance under Financial Assistance policies have been made, and collection efforts have been unsuccessful as further described below.

DEFINITIONS:

- Allowable Medical Expenses All family members' medical expenses that are eligible for federal income tax deduction, even if the expenses are more than the medical expense deduction allowed by the Internal Revenue Service (IRS). Paid and unpaid bills may be included.
- Amount Generally Billed (AGB) The amounts generally billed for emergency or other medically necessary care to individuals who have insurance covering such care. This is usually described as a percent of Gross Charges. The AGB percentages are updated annually.
- 3. Application Period The period during which VCHCA must accept and process an application for financial assistance under its Financial Assistance Policies. This submission allows VCHCA to make reasonable efforts to determine whether the individual is eligible for financial assistance under the policy or policies applied for. The Application Period begins on the date that necessary services are known, or for unscheduled care, the date patient care is provided. There is no end date patients who have received or need services can apply at any time, and applications will be processed.
- 4. **Billed Charges** Charges for items and services provided by VCHCA as published in the Charge Description Master (CDM) and available at www.vchca.org under Price Transparency.
- 5. **Charge Description Master** A list of items and services, along with their individual prices and codes, used to bill for services.
- 6. **Charity Care** Full Financial Assistance (i.e., 100% discount, free care) to qualifying patients that relieves the patient and his or her guarantor of their entire financial obligation to pay for eligible services. Charity Care does not reduce the amount, if any, that a third party may be required to pay for eligible services provided to the patient. Charity Care is differentiated from discounts or other forms of financial assistance when discussing the amount granted under a Financial Assistance program as a full waiver of the account balance (Charity Care) versus a partial waiver of the account balance (discounts or other forms of financial assistance where charges for care are reduced but not free).
- 7. **Discounted Care** Partial Financial Assistance to qualifying patients under the Discount Payment Program to relieve the patient and his or her guarantor of a portion of their financial obligation to pay for eligible services. Discounted Care does not reduce the amount, if any, that a third party may be required to pay for eligible services provided to the patient. Discounts excluded from the Financial Assistance program are usual discounts whose application is not based on an ability to pay. Also known as charges for care that are reduced but not free.
- 8. Extraordinary Collection Action (ECA) ECAs are legal or judicial actions taken to receive payment from a patient or any other individual who has accepted or is required to accept responsibility for care covered under the Financial Assistance Policy. Examples include garnishing a patient's wages, adverse credit reporting, or deferring or denying medically necessary scheduled care, all of which VCHCA does not perform. ECAs do not include any lien entitled under state law on the proceeds of a judgment, settlement, or compromise owed to an individual (or his or her representative) as a result of personal injuries for which VCHCA provided care.
 - a. Suspending ECAs when a Financial Assistance Application (FAA) has been submitted means VCHCA does not initiate an ECA, or take further action on any

previously initiated ECAs, to obtain payment for medically necessary care until either:

- i. VCHCA has determined whether the individual is eligible based on a complete application and met the reasonable efforts requirement, as defined herein, with respect to a completed FAA; or
- ii. In the case of an incomplete FAA, the individual has failed to respond to requests for additional information or documentation within a reasonable period of time (minimum of thirty (30) days) given to respond to such requests.
- iii. No civil proceeding or ECA will commence until at least one hundred eighty (180) days has elapsed since the first billing reflecting the patient due amount has been sent.
- 9. **Emergency Medical Care** Refers to Emergency Services and Care, as defined in the VCHCA Emergency Medical Treatment and Labor Act policy.
- 10. **Essential Living Expenses (ELE)** The following expenses are considered Essential Living Expenses: rent or house payment and maintenance, food, household supplies, laundry and cleaning, utilities and telephone, clothing, medical and dental payments, insurance, school or childcare, child or spousal support, transportation and auto expenses, including insurance, gas, repairs and installment payments, and other extraordinary expenses.
- 11. Family Members -
 - 1. For persons eighteen (18) of age and older
 - A spouse, domestic partner and dependent children under twenty-one (21) years of age, and dependent children of any age if those children are disabled whether living at home or not.
 - 2. For dependent persons
 - 1. Under eighteen (18), or
 - 2. Between eighteen (18) to twenty (20) years of age,
 - a. Parents, caretaker relatives and other children, and dependent children of the parents or caretaker relatives of any age if those children are disabled
- 12. **Family Income** is determined consistent with the IRS definition of Modified Adjusted Gross Income for the applicant and all members of the applicant's Family. For purposes of VCHCA's Discount Payment Program, the patient's assets or the assets of the patient's family are not considered when calculating family income. Documentation requirements of family income shall be limited to recent pay stubs or tax returns. Recent tax returns are tax return(s) which document a patient's income for the year in which the patient was first billed or twelve (12) months prior to when the patient was first billed. Recent paystubs are paystubs within a six (6) month period before or after the patient is first billed by the hospital, or in the case of preservice, when an application for Financial Assistance is submitted. The Health Care Agency may accept other forms of documentation of income but does not require such other forms.
- 13. FAP VCHCA's Healthcare Financial Assistance Policies, including Charity and Discounted

Payment policies.

- 14. **Federal Income Tax Return** The IRS form/s used to report taxable income. The IRS form must be a copy of the signed and dated forms sent to the IRS.
- 15. **Federal Poverty Level (FPL)** The poverty guidelines updated periodically in the Federal Register by the United States Department of Health and Human Services under its statutory authority.
- 16. **Financial Assistance** The reductions in payment obligation afforded to VCHCA patients if such patients qualify for assistance under these policies. This may be free care (Charity) or charges for care that are reduced but not free (Discounted Payment).
- 17. **Good Faith Estimate** an estimate of a patient's bill for health care items and services before those items or services are provided. This is provided to self-pay patients, and those who elect not to use their health care benefits as required by the Centers for Medicare and Medicaid Services (CMS).
- 18. High Medical Costs Defined as any of the following:
 - a. Annual Out-of-Pocket expenses, incurred by an individual receiving services at a VCHCA facility that exceeds the lesser of ten percent (10%) of the patient's current family income or family income in the prior 12 months.
 - b. Annual Out-of-Pocket expenses that are more than ten percent (10%) of the patient's family income, if the patient provides documentation of their medical expenses paid by the patient, or the patient's family, in the prior 12 months.
- 19. **Household Income** Cumulative income of all Family Members who live in the same household as the patient, or at the home address the patient uses on income tax returns, or on other government documents. This includes the following:
 - a. Gross wages, salaries, tips, etc.
 - b. Unemployment compensation, workers' compensation, Social Security, Supplemental Social Security Income, public assistance, veterans' payments, survivor benefits, pension or retirement income.
 - c. Interest, dividends, royalties, income from rental properties, estates and trusts, alimony, child support, assistance from outside the household, and other miscellaneous sources.
- 20. Limited English Proficiency (LEP) Group A group of people who either do not speak English, or who are unable to effectively communicate in English because it is not their native language. The size of the group is the lesser of either 1,000 individuals, or five percent (5%) of the community served by the facility, or the non-English speaking populations likely to be, affected or encountered, by the facility. The facility may use any reasonable method to determine the number, or percentage, of LEP patients that may be affected, encountered, or served by the facility, and provides translation and interpreter services at all locations. Documents for Financial Assistance are available in English and Spanish, and provided based on the patient's preferred language.
- 21. **Medically Necessary** A service is "medically necessary" or a "medical necessity" when it is reasonable and necessary to either (a) protect life, to prevent significant illness or significant disability, (b) to alleviate severe pain, or (c) to prevent, diagnose or treat an illness, injury,

condition or disease, the symptoms of an illness, injury, condition or disease, and (d) meets accepted standards of medicine.

- 22. **No Surprises Act** The No Surprises Act is a Federal regulation that prohibits out-of-network providers from balance billing patients for services received in certain circumstances. Additionally, it requires out-of-network providers to give out-of-network patients a notification regarding their rights regarding balance billing and requires that out-of-network providers give Good Faith Estimates to out-of-network patients for services they seek.
- 23. **Out-of-Pocket Costs** Costs which the patient pays from personal funds.
- 24. **Patient Financial Services (PFS)** The VCHCA department responsible for billing, collecting, and processing payments.
- 25. **Payment Plan** A series of payments, made over a period of time, to pay the patient's payment obligation for items and services provided by VCHCA. Monthly payments cannot be more than ten percent (10%) of a patient's monthly family income, excluding deductions for Essential Living Expenses.
- 26. Pending Appeal "Pending appeal" includes any of the following:
 - a. A grievance against a contracting health care service plan, as described in Chapter 2.2 (commencing with Section 1340) of Division 2, or against an insurer, as described in Chapter 1 (commencing with Section 10110) of Part 2 of Division 2 of the Insurance Code.
 - b. An independent medical review, as described in Section 10145.3 or 10169 of the Insurance Code.
 - c. A fair hearing for a review of a Medi-Cal claim pursuant to Section 10950 of the Welfare and Institutions Code.
 - d. An appeal regarding Medicare coverage consistent with federal law and regulations.
- 27. **Plain Language** Writing designed to ensure the reader understands quickly, easily, and completely as possible. Plain language strives to be easy to read, understand and use.
- 28. **Presumptive Financial Assistance** When VCHCA staff may assume a patient will qualify for 100% Financial Assistance based on information given to them, e.g., homelessness, etc.
- 29. **Qualifying Patient** A patient who meets the qualifications for Financial Assistance as defined above.
- 30. **Reasonable Payment Plan** A payment plan is a reasonable payment plan if the monthly payments are not more than 10 percent of a patient's family income for a month, excluding deductions for essential living expenses (as defined above).
- 31. **Self-Pay Liability** Any balance due by the person who is responsible for payment. This could be a patient, or the patient's guarantor (not a third-party payer).
- 32. **Third-Party Coverage** A policy of insurance or other prepaid coverage purchased for protection against certain events, such as health, automobile, general liability insurance, etc.
- 33. Uninsured Patient A patient who does not have insurance to cover the services received.

PROCEDURE: BILLING PRACTICES

VCHCA will follow standard procedures in billing and collecting on accounts related to care provided at VCHCA as follows:

- 1. Insurance Billing
 - a. For all insured patients, VCHCA will bill applicable third-party payers (based on information provided or verified by the patient/Guarantor, or appropriately verified from other sources) in a timely manner.
 - b. If an otherwise valid claim is denied (or returned unprocessable) by the payer due to an error by VCHCA, VCHCA will not bill the patient for any amount in excess of what the patient would have owed had the payer paid the claim.
 - c. If an otherwise valid claim is denied (or not processed) by a payer due to factors outside of VCHCA's control, staff will follow up with the payer and patient as appropriate to facilitate resolution of the claim. If resolution does not occur after reasonable follow-up efforts, VCHCA may bill the patient or take other actions consistent with payer contracts.

2. Patient Billing

- a. All patients/Guarantors will be billed directly and timely and receive a statement as part of VCHCA's normal billing process.
- b. For insured patients, after claims have been processed by all available third-party payers, VCHCA will bill patients/Guarantors in a timely manner for their respective liability amounts as determined by their insurance benefits.
- c. All patients/Guarantors may at any time request, and VCHCA will provide, an itemized statement for their accounts. Itemized statements are provided to all patients without insurance with the initial billing.
- d. If a patient disputes his or her account and requests documentation regarding the bill, staff will provide the requested documentation in writing within ten (10) days (if possible) and will hold the account for at least thirty (30) days before advancing the account in the collection process.
- e. VCHCA shall approve reasonable payment plan arrangements for patients/ Guarantors who indicate they may have difficulty paying their balance in a single installment and offer an extended payment plan for all patients eligible for Discounted Care.
- f. VCHCA is not required to accept patient-initiated payment arrangements and may refer accounts to a third-party collection agency if the patient defaults on an established payment plan as outlined below.
- g. Patient Financial Services leadership has the authority to make exceptions to the Patient Billing provision on a case-by-case basis for special circumstances (in accordance with operating procedures).

- 3. Collection Practices
 - Any collection activities conducted by VCHCA, or its third-party collection agents will be in conformance with all federal and state laws governing debt collection practices.
 - b. All patients/Guarantors will have the opportunity to contact VCHCA regarding Financial Assistance, payment plan options, and other applicable programs that may be available with respect to their accounts at any time.
 - c. VCHCA's Financial Assistance Policies and Applications are available free of charge and provided at vchca.org or upon request.
 - d. Individuals with questions regarding Financial Assistance may contact the Patient Financial Services office by phone or in person.
 - e. In compliance with relevant state and federal laws, and in accordance with the provisions outlined in this Policy, VCHCA may engage in collection activities, including Permissible ECAs, to collect outstanding patient balances.
 - f. General collection activities may include phone calls, statements, and other reasonable efforts in accordance with standard industry practices.
 - g. Patient balances may be referred to a third-party for collection at the discretion of the Patient Financial Services department and in compliance with all applicable federal, state, and local non-discrimination practices. VCHCA will maintain ownership of any debt referred to debt collection agencies, and patient accounts will be referred for collection only with the following caveats:
 - i. There is a reasonable basis to believe the patient owes the debt.
 - ii. All third-party payers identified by the patient/Guarantor in a prompt and timely manner that have been properly billed, and the remaining debt is the financial responsibility of the patient.
 - iii. VCHCA will not refer accounts for collection where the patient has initially applied for Financial Assistance, and reasonable efforts/timelines (as defined below) with respect to the account have not yet been completed.
 - h. Proof of income (paystubs, tax returns, etc.) will not be shared or sent to any thirdparty collection agency working on behalf of VCHCA.
 - i. VCHCA will not refer accounts for collection while a claim on the account is pending payment from a third-party payer. However, claims which remain in "pending" status with a third-party payer for an unreasonable length of time despite efforts to facilitate resolution may be re-classified as "denied."
 - j. VCHCA will not refer accounts for collection when the insurance claim was denied due to an error attributable to VCHCA. However, the patient liability portion of such claims may still be referred for collection if unpaid.
 - k. Regarding cost sharing for out-of-network patients, VCHCA will only refer the innetwork cost-sharing amount that an insured has failed to pay for out-of-network patients, excluding Emergency Room services.
 - I. Upon receipt of notice of either the filing of a Bankruptcy Petition or Bankruptcy

Discharge, VCHCA will cease all collection attempts, including assignment to a collection agency. The patient/debtor will not be contacted by any method, including phone calls, letters, or statements after receipt of the notification. All communication, if necessary, must occur with the trustee or the attorney assigned to the case.

- m. VCHCA shall not send any unpaid self-pay account balance to a third-party collection agent as long as the patient or Guarantor is engaged and cooperating with resolution efforts.
- n. Notification regarding the Hospital Bill Complaint Program is provided to patients, including on VCHCA websites, the discharge notice, and hospital postings in patient areas.
- o. Upon receipt or notification under the Hospital Bill Complaint Program, all payment collection activities by VCHCA and its collection agencies shall stop upon receipt of notice that a patient has submitted a complaint to the Department of Health Care Access and Information's ("HCAI") Hospital Bill Complaint Program. Collection agency activities will not resume until the complaint has been resolved, as confirmed by HCAI.

ECAs - Notification Requirement

- With respect to any medically necessary care provided, a patient must be notified about Financial Assistance availability as described herein, prior to initiating an ECA. The notification requirement is as follows:
- 2. Notification Letter- The Hospital Facility will notify a patient about Financial Assistance by providing the individual with a written notice (Notification Letter) at least thirty (30) days prior to initiating an ECA. The Notification Letter will:
 - a. Include a plain language summary of Financial Assistance policies;
 - b. Indicate Financial Assistance is available for eligible individuals; and
 - c. Identify the ECA(s) that VCHCA intends to initiate to obtain payment for if the amount due is not paid or an FAA is not submitted before a specified deadline, which is no earlier than the last day of the Application Period.
 - i. Reasonable Efforts when a Patient Submits an Incomplete FAA
 - 1. VCHCA will suspend any ECAs already initiated against the patient/Guarantor until Financial Assistance eligibility has been determined.
 - 2. VCHCA will provide a written notification to the patient with a list of required documentation the patient or Guarantor must provide to consider the FAA complete and give the patient thirty (30) days to provide the necessary information. The notification will include the contact information, including telephone number and physical location of the Patient Financial Services department that can provide information about and assist with the preparation of the FAA.

- ii. Reasonable Efforts when a Completed FAA Is Submitted
 - 1. If a patient submits a completed FAA during the Application Period, VCHCA will:
 - a. Suspend any ECAs to obtain payment for the medically necessary care.
 - b. Make a determination as to whether the individual is eligible under the Financial Assistance policy(ies) for the care and notify the individual in writing of this eligibility determination (including, if applicable, the assistance for which the individual is eligible) and the basis for this determination.
 - c. If VCHCA determines the individual is eligible for Financial Assistance, the following occurs:
- If the first billing to the patient has occurred within the prior five (5) years, refund the individual any amount paid for the care that exceeds the amount determined to be personally responsible for paying as a Financial Assistance program eligible individual, including statutory interest if applicable,
- ii. Take all reasonably available measures to reverse any ECA, including the removal of any adverse information that was reported to any source.
- iii. If VCHCA determines the individual is not eligible for Financial Assistance, VCHCA will have made reasonable efforts and may engage in the Permissible ECAs.

VCHCA will refrain from ECAs against a patient if he or she provides documentation that he or she has applied for health care coverage under Medicaid, or other publicly sponsored healthcare programs, unless or until the individual's eligibility for such programs has been determined and any available coverage from third parties for the care has been billed and processed.

All Revision Dates 2/7/2025

Approval Signatures

Step Description	Approver	Date
Chief Financial Officer	Michael Taylor: Chief Financial Officer, Health Care Agency	2/7/2025
Hospital Administration	John Fankhauser, MD: Chief Executive Officer, VCMC & SPH	1/31/2025
Hospital Finance	Jill Ward: Chief Financial Officer, VCMC & SPH	12/27/2024
Compliance Officer	Melissa Guevarra: Acting Compliance Officer	12/27/2024
Revenue Cycle	Kimberly Dillard: Director, Revenue Cycle	12/26/2024



Status	Active	PolicyStat ID (17258678)
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Origination	12/17/2024	Owner	Kimberly Dillard:
Last Approved	2/7/2025		Director, Revenue Cycle
VENTURACOUNTY Effective	12/17/2024	Policy Area	Administrative - Fiscal
HEALTH CARE AGENCY Last Revised	2/7/2025		lioodi
Next Review	2/7/2028		

109.070 Bad Debt Assignment Policy

POLICY

Ventura County Health Care Agency maintains a process for resolving open balances, and at times, patients unwilling to pay or arrange payment for services rendered may be referred to an outside entity for collection of unpaid encounter (account) balances. This policy addresses expectations for Collection Agencies assigned Bad Debt, and accounting of uncollectible amounts for financial, regulatory and Cost Reporting purposes.

DEFINITIONS

- 1. **Bad Debt (BD)** Amounts remaining after internal collection efforts have ceased, deemed uncollectible, and sent to a Collection Agency.
- Bad Debt Collection Agency (CA) An outside agency assigned debt collection activities for VCHCA.
- 3. **FAP** Ventura County Health Agency's Healthcare Financial Assistance Policies, including Charity and Discounted Payment policies.
- 4. Low-Income Uninsured Patient A patient eligible for assistance under one or more Financial Assistance Policies.
- 5. **Payment Plan** An agreement either orally or in writing between VCHCA and the patient, whereby VCHCA has offered, and the patient has accepted the opportunity to pay off their liability in monthly payments. Eligibility is based on certain family income thresholds, excluding deductions for Essential Living Expenses.

PROCEDURE

BD Qualifications and Assignment

Collection efforts regardless of the payer will be the same for all patients with the exception of patients that are classified as Qualified Medicare Beneficiaries (QMB). QMB eligible patients are not sent to Bad Debt, as these patients cannot be billed for any outstanding co-payments, co- insurance, or deductibles under any circumstances.

After all internal collection efforts, including offering relevant information regarding FAP's have been exhausted, encounters with remaining balances will be assigned to an external agency specializing in healthcare collections.

- 1. When an encounter is assigned to a CA, the amount that will be assigned to BD will be the amount remaining after any and all prior payments, discount adjustments, and waivers have been applied to the encounter balance. At no point will Credit Agency reporting, property liens, or wage garnishments occur.
- 2. Encounter balances meeting certain thresholds are reviewed by Patient Financial Services leadership. Additionally, VCHCA has established minimum thresholds for assigning encounters to a CA.
- 3. Part of the CA process involves a determination of whether an encounter qualifies for an alternative source of payment, and a determination whether the patient has sufficient ability to pay. For encounters identified as having an alternate source of payment, or encounters identified with a guarantor that does not have sufficient ability to pay, the CA shall return the encounter to VCHCA with an explanation of the determination and the supporting data. VCHCA will attempt to collect from the alternate source and/or work to qualify the patient for financial assistance.
 - a. Note: If the patient is identified as a low-income uninsured patient, and efforts at obtaining an alternative source of payment have ceased, any encounter balance may be considered presumptive Charity Care.
- 4. If a patient inquires whether VCHCA offers a discount from its billed amount based on a patient's status as a cash-paying patient (no third-party coverage), the CA will promptly validate the request, and notify the patient of VCHCA's Self-Pay Discount, provide and document information regarding FAP's.
 - a. If the patient desires the Self-Pay Discount, communication is provided by the CA to VCHCA and the Self-Pay Discount is processed.
 - b. If the patient desires to negotiate an additional discount above the discount provided, then the CA will notify VCHCA for authority to adjust the encounter as appropriate.
- 5. Prior to filing any legal action against a patient, the CA shall ensure 180 days has past since the initial billing, all legaland regulatory requirements related to debt collection practices are met and have confirmed multiple attempts were made and documented to reach and negotiate with the patient.

- 6. The CA shall also
 - a. Perform an analysis of the patient's income to determine whether the patient has income sufficient to justify filing any legal action; and
 - b. Have VCHCA review the analysis and receive approval from the Revenue Cycle Director or their designee before the filing of any legal action against the patient.
 - c. No Assignment or Subcontracting.
 - i. CA's may not assign or subcontract the work effort on any encounter without:
 - 1. The prior written consent of the Revenue Cycle Director or their designee; and
 - 2. A written agreement by the assignee or subcontractor to comply with this Policy and both Federal and California requirements.
- 7. General Requirements Prior to CA Action
 - a. Consistency in Billing Statements. At the time of billing, VCHCA shall provide to all low-income uninsured patients the same information concerning services received and amounts billed related to those services as it provides to all other patients who receive care at VCHCA.
 - b. Notice of Financial Assistance Availability. In its letters and statements to all patients, the CA shall include language to inform patients if they meet certain income requirements, then they may be eligible for government-sponsored payor programs or financial assistance from VCHCA. Correspondence shall also include the name/title or department and telephone number to contact for additional information.

8. Relationships with CA's

- a. Compliance with Law, Policies and Standards.
 - i. CA's contracted with VCHCA must attest to, and consistently comply with Federal and California laws applicable to the collection of consumer and patient debts.
 - ii. CA's are required to treat patients, their families, and other contacts fairly, and with dignity, compassion and respect.
 - CA's must review and comply with VCHCA's policies and standards, including, without limitation, reasonable payment plan provisions, its Self-Pay Discount, and Financial Assistance Policies.
- 9. Standards for Contracting with CA's.
 - a. VCHCA shall not engage any CA to collect on patient encounters unless:
 - i. The arrangement is set forth in a written agreement signed by the CA and the Vice President, Finance and Chief Financial Officer or their designee, and
 - ii. The written agreement attaches this Policy, or includes language that matches this Policy, as an exhibit and requires the CA to comply.

10. Recordkeeping

a. VCHCA shall maintain adequate documentation to ensure compliance with the requirements of this Policy. VCHCA shall submit this Policy to the California Department of Health Care Access and Information ("HCAI") as required by applicable law. Each CA that contracts with VCHCA is required to maintain adequate documentation to show compliance with the requirements of Federal and California consumer debt collection laws and all other requirements based on the most current version of this Policy and VCHCA's Financial Assistance and related Policies.

Bad Debt Reporting

Assignment reports are compiled based on a system-generated selection report based on age of the encounter and response to collection efforts. After the Director of Patient Financial Services or designee approves the selected assignments, the account balances will be automatically transferred from Accounts Receivable to BD via a transaction code applied in the Accounts Receivable software, which reduces the Accounts Receivable balance to zero. The accounts will then be placed on the corresponding secure portal of the CA or via automated notification to the CA.

To ensure compliance with the annual BD audit required by Medicare, a detailed accounting of encounter transactions is necessary. A report is produced annually to review encounters sent to a CA, as well as recoveries on any encounters sent at any time in the past that have payment activity within the cost reporting year under audit. Encounters will be updated with an Agency Code and updated Financial Class within the patient encounter at time of the assignment to a CA.

- 1. The following criteria must be met before including a BD encounter on the hospital's cost report:
 - a. Patients were classified as Qualified Medicare Beneficiaries at the time of service, or
 - b. Hospital business office and its CA efforts have been exhausted, or
 - c. The CA efforts have been exhausted and the CA has cancelled and returned the encounter.
 - i. The CA will update the encounter collection status, closing and returning encounters deemed uncollectible on a monthly or more frequent basis.
 - ii. The CA will provide a detailed listing of any/all cancelled and returned encounters upon request to support cost report requirements.
 - d. A minimum of 121-days has passed since the first notification to the patient of his or her outstanding balance or last patient payment date.

Note: All returned CA balances regardless of payer are adjusted to zero in VCHCA's Accounts Receivable software, with the appropriate bad debt adjustment code present in the patient accounting system prior to inclusion in that year's Cost Report filing. If any account adjustments are required after the Cost Report period being filed, they are to be reported in a future Cost Report filing.

All Revision Dates 2/7/2025

Approval Signatures

Step Description	Approver	Date
Chief Financial Officer	Michael Taylor: Chief Financial Officer, Health Care Agency	2/7/2025
Hospital Administration	John Fankhauser, MD: Chief Executive Officer, VCMC & SPH	1/31/2025
Hospital Finance	Jill Ward: Chief Financial Officer, VCMC & SPH	12/27/2024
Compliance Officer	Melissa Guevarra: Acting Compliance Officer	12/27/2024
Revenue Cycle	Kimberly Dillard: Director, Revenue Cycle	12/26/2024



Origination	12/17/2024	Owner	Kimberly Dillard:
Last Approved	2/7/2025		Director, Revenue Cycle
VENTURACOUNTY Effective	12/17/2024	Policy Area	Administrative - Fiscal
HEALTH CARE AGENCY Last Revised	2/7/2025		10001
Next Review	2/7/2028		

109.071 No Surprises Act Compliance Policy

POLICY:

Status (Active) PolicyStat ID (17258682

It is the policy of Ventura County Health Care Agency (VCHCA) to comply with the requirements of the No Surprises Act (Act), effective as of January 1, 2022. The purpose of the Act is to prevent surprise billing, which occurs when insured patients unknowingly receive out-of-network care and are billed the difference between the total amount charged and what they would have paid had their insurance been innetwork. As of January 1, 2022, VCHCA will refrain from balance billing patients who are protected under the Act any amount beyond the cost-sharing that would apply for in- network care under the patient's insurance. This applies to the following service types with some exceptions:

Emergency care

Post-stabilization care (when the patient can travel using non-medical or nonemergency medical transportation via private automobile or when the consent and notice requirement has not been met)

Air ambulance transportation

Certain non-emergency services by an out-of-network provider at an in-network facility

Staff will establish clear communication with patients during the pre-registration process for scheduled services, informing them if they are out-of-network with any co-providers, the expected costs and other provisions related to surprise billing. Patients will be given the choice to opt for out-of-network services or choose an in-network provider through the notice and consent process. Only those out-of-network patients that have completed the notice and consent process and opted into waiving their surprise billing protections may be balance billed for allowable services.

Patient Financial Services staff will review all claims for patients who have received a Good Faith Estimate (GFE). When a co-provider has rendered services while being an out-of-network provider, all attempts will be made to ensure that patients who are protected under the Act are not balance billed and initiate the independent dispute resolution process as necessary. Providers and payers may settle reimbursement disputes for out-of-network care with the help of an impartial arbitrator if they are not able to come to a mutual agreement alone. All patients receiving a GFE will also receive an application form for Financial Assistance. The Patient Financial Services Director shall routinely report the status of the review of GFE's and patient feedback related to the NSA.

PURPOSE

Surprise billing comes as an unexpected cost to patients, who may not have been aware the facility and/ or provider(s) they received care from is out-of-network. The purpose of this policy is to ensure VCHCA operates in compliance with all applicable requirements of the Act by preventing any instances of surprise billing for out-of-network care. Following this policy and procedure will help ensure VCHCA is doing its due diligence to patients and the community by preventing unexpected costs. It also protects the organization against potential monetary penalties of up to \$10,000 per violation if these conditions are not met.

SCOPE:

This policy applies to all VCHCA staff who are involved in scheduling, pre-registration, registration, financial counseling, billing, and insurance follow-up staff.

DEFINITIONS:

In-network: Facilities and/or providers that are included within a group health plan or health insurance issuer's network are called "in-network" or "participating" facilities and/or providers. Facilities or providers that are in-network with an insurer agree to provide care to covered individuals at a discounted rate.

Out-of-network: Facilities and/or providers that are not part of a group health plan or health insurance issuer's network are known as "out-of-network" or "nonparticipating" facilities and/or providers. When a facility or provider is out of network, it is not required to agree to be reimbursed a specific amount as per contracts with the health plan or health plan administrator. Some patients may not be eligible to receive benefits under their health plan when receiving out of network services.

Notice and consent: A process outlined under the Act to inform patients of their out-of-network status for certain non-emergency and post-stabilization services. Under this process, patients have the choice to either opt out of their surprise billing protections to receive out-of-network care or choose an innetwork provider instead. Completing this process exempts facilities and providers from balance billing restrictions for those patients that sign the notice and consent form to opt-out of their protections.

Balance billing: When patients are billed an amount greater than the cost-sharing that would apply if

their insurance plan had been in-network for out-of-network care provided by a co-provider; it may also be referred to as surprise billing.

Surprise bill: Any bill a patient receives that is higher than expected due to the patient receiving services from an out-of-network facility and/or provider without prior knowledge or consent.

Independent dispute resolution (IDR): To determine reimbursement for out-of-network care provided to patients who are protected under the Act, this process may be initiated by providers and/or payers if they are not able to come to an agreement through open negotiation. Under the IDR process, payers and providers submit their reimbursement offers to an IDR entity, which serves as an independent arbitrator, to determine the final reimbursement amount.

IDR entity: A third-party entity that is certified to serve as a non-partial arbitrator during IDR processes initiated between payers and providers. The IDR entity decides the final amount to be paid by payers to providers for out-of-network care.

PROCEDURE:

Identifying out-of-network patients

- A. Any front-end staff involved in scheduling, pre-registration, admission or registration will verify if a patient's insurance plan is in-network or out-of-network for co-providers using real-time eligibility software or a manual check if this step has not already been completed.
 - 1. If the patient's insurance is in-network, the account continues through VCHCA's financial clearance process.
 - 2. If the patient's insurance is out-of-network with any co-providers, staff will determine if the notice and consent exemption applies to the service.
 - a. Notice and consent does not apply to emergency services, air ambulance services, certain ancillary and diagnostic services, non- emergency services by an out-of-network provider when no in- network provider is available as an alternative.
 - b. Notice and consent may apply for certain non-emergency services provided by an out-of- network provider at an in-network facility and certain post-stabilization services.
- B. Staff will document the date, time and result of the insurance verification checks for the coprovider(s), if any, in Cerner.

Completing notice and consent

- A. Pre-service staff, including Scheduling, Pre-registration, and Registration, will complete the notice and consent process for out- of-network patients according to the timeframes established under the Act.
 - 1. For services scheduled more than three days out, notice and consent must be

completed no later than 72 hours prior to service.

- 2. For services scheduled less than 72 hours out, notice and consent must be completed the same day the appointment is made.
 - a. If the appointment is made the same day that it will occur, notice and consent must be completed no later than three hours prior to the service.
- B. VCHCA will use the standard notice and consent form developed by the Department of Health and Human Services.
 - 1. Staff must include the following information on the notice and consent form:
 - a. Notification that VCHCA and/or the co-provider(s) is out-of-network with the patient's insurance plan or coverage.
 - b. A good faith estimate of the amount the patient may be charged if they consent to out- of-network care.
 - c. Language detailing any prior authorization or care management requirements associated with the service.
 - d. Notification stating that consent is optional for patients and that they may opt for an in-network provider instead.
- C. Staff will provide the notice and consent form to patients separately and not incorporate it with any other documents or forms. The form will be shared with the patient via paper format or electronically, according to their preference.
 - 1. Staff must be available in person or over the phone to walk the patient through the form and answer any questions they have.
 - a. The form will be signed (including electronic signature) by either the patient or an authorized representative of the patient if they are not capable of giving consent.
 - b. The patient will be provided a signed copy of the form through their preferred delivery method—either in person, via mail or by email.
 - c. It is not mandatory for patients to sign the form, and if they choose not to sign the form, they will not receive care with the out-of- network provider and/or facility but may opt for any in-network facility and/or provider instead.
- D. If the patient is a non-English speaker, staff will provide a form in the patient's preferred language or provide them the help of a qualified interpreter, if needed.
 - 1. The form will be available in the 15 most common languages in VCHCA's geographic location.
 - 2. Patients who speak a language other than the 15 most common languages must be provided the help of a qualified interpreter.
- E. Staff will document the date and time notice and consent is completed, the patient's response and a copy of the signed notice and consent form in the Cerner.
 - 1. VCHCA will retain a copy of the signed notice and consent form for at least seven years after the date on which the service was provided.

Providing disclosure of patient rights

- A. VCHCA will publicly share a one-page notification outlining consumer rights related to surprise billing, including federal and state-specific protections and contact information for reporting violations in the following manners:
 - 1. Physically displayed via signage in a publicly accessible location, such as check-in areas.
 - 2. Posted on VCHCA's public-facing website.
- B. Registration staff will ensure patients have access to the disclosure notice by regularly checking that it is prominently displayed in check-in areas and directing patients to public-facing websites for further information.
- C. Any staff involved in requesting pre-service or point-of-service payments will provide the disclosure notice to nongovernmental insured patients at the time they are asked for payment, including copayments and other upfront amounts.
 - 1. If payment is not requested upfront, staff must provide the disclosure notice no later than the same day the claim is submitted to the insurer for reimbursement.
- D. Patients will be given the option of receiving the disclosure notice through the delivery method of their choice: in person, through mail or email.
- E. If the co-provider is out-of-network, the patient will be given a choice of in-network providers if possible. If this is unavailable, the patient will be instructed to contact their insurance carrier for in-network providers. If the patient prefers to continue care at VCHCA with one or more out-of-network co-providers, the Notice and Consent, aka Surprise Billing Protection Form must be completed and signed by the patient
 - 1. **Surprise Billing Protection Form Completion**: When preparing the forms for the patient or authorized representative, the following is required:
 - i. The form may not be modified, except as indicated in brackets or as may be necessary to reflect applicable state law.
 - ii. The facility must fill out the documents completely by filling in any blanks that appear in brackets and deleting the bracketed italicized text.
 - iii. Blanks that must be completed:
 - 1. Page 2 Patient Name
 - 2. Page 2 Out-of-network provider(s) or facility name
 - 3. Page 2 Total cost estimate of what you may be asked to pay
 - 4. Page 4 Patient Name
 - 5. Page 4 Out-of-network provider(s) or facility name
 - 6. Page 4 Complete the table with: Date of Service, Service Code, Description, Estimated amount to be billed
 - 7. Brackets that must be completed:
 - a. Page 2 Questions about the notice and estimate?

[Enter facility contact information]

- b. Page 2 Questions about your rights? [Enter HHS No Surprises Help Desk at 1-800-9853059]
- Page 2 Prior authorization or other care management limitations [chose option 2].
- d. Page 2 Understanding your options
- Page 2 More information about your rights and protections [Enter https://www.cms.gov/ nosurprises for the website]
- f. Page 3 Facility Name [Enter your facility name]
- g. Page 3 Date of Notice [Enter date notice was given]
- 8. The form must be given physically separate from and not attached to or incorporated into any other documents. The documents must not be hidden or included among other forms, and a representative of the provider or facility must be physically present or available by phone to explain the documents and estimates to the individual, and answer any questions, as necessary. The notice must be provided on paper or electronically as selected by the individual. The signed consent must be uploaded into Cerner, and provided to the patient or authorized representative in person, by mail or via email as selected by individual.

Ensuring compliant billing of out-of-network claims

- A. Billing and claims management staff will identify out-of-network patient accounts to check if balance billing protections apply and if the notice and consent process was fulfilled before submitting out-of-network claims.
 - 1. If the patient signed the notice and consent form and opted to go forward with out-of- network care, the patient may be balance billed for any portion of the service that is not covered by their insurance.
 - 2. If the patient received out-of-network emergency, post-stabilization, air ambulance transportation or other out-of-network non-emergency care covered under the Act and has not signed the notice and consent form, they cannot be balance billed for the service. Staff will submit the claim directly to the out-of-network payer, and no balance billing will occur for out of network amounts.
- B. Staff will ensure that all out-of-network claims are prepared and submitted to out-of- network payers according to VCHCA policy and procedure, including any information necessary for payers to accurately process the out-of-network claim
 - 1. For non-emergency services, staff will notify payers that the out-of-network care was provided at an in-network facility, whether notice and consent was satisfied and include a copy of the signed notice and consent form, if applicable.

- a. When billing patients directly, staff can fulfill the payer notification requirement by including a copy of the signed notice and consent with the bill.
- 2. For post-stabilization services, staff will notify payers whether all requirements related to notice and consent were met and include a copy of the signed notice and consent form, if applicable.
- C. Staff will ensure that all steps or actions taken on out-of-network claims are thoroughly documented, including dates, times, and efforts to identify whether the patient is protected under the Act.
- D. Claims management staff will audit out-of-network claims on an as-needed basis to ensure compliance with the Act and identify any out-of-network patients who have been inappropriately billed an amount greater than the in-network rate.
- E. If a violation occurs, staff will cancel the non-compliant bill and reimburse the patient and/or payer any amount they had already paid plus interest, at an amount determined by the HHS.
 - 1. To avoid penalties, staff will complete the above within 30 days of the violation occurring and submit any documentation necessary to prove it occurred without knowledge or intent to the appropriate parties.

Negotiating reimbursement through the IDR Process

- A. VCHCA follow-up staff will work directly with payers to secure payment for out-of- network claims when balance billing restrictions apply or notice and consent was not completed, initiating the IDR process as necessary to promote fair reimbursement.
- B. A multidisciplinary team of denial management, appeals, legal and other follow-up staff will be involved, as needed, in handling the out-of-network claims reimbursement and IDR process.
- C. Upon receiving initial payment or notice of denial from the out-of-network payer, follow- up staff will review the payment amount or denial and determine whether to accept or dispute it..
- D. For any disputes, follow-up staff will initiate open negotiation by sending written notice to the payer no later than 30 business days after receiving the initial notice of payment or denial. The written open negotiation notice must include:
 - 1. Details about the claim to be negotiated, including date of service, billing codes, and the initial payment amount or denial notice.
 - 2. An out-of-network payment offer.
 - 3. Contact information.
- E. After the open negotiation notice is sent, staff have 30 business days to negotiate with the payer to come to a mutually agreed upon out-of-network payment amount.
 - 1. Follow-up staff will compile and send documentation to the payer as needed in support of the out-of- network payment offer.
- F. If unable to come to an agreement with the payer, follow-up staff will determine if VCHCA will pursue IDR and must initiate it no later than four business days after the open negotiation period ends.

- 1. The payer may also choose to initiate IDR, even if VCHCA does not.
- G. After initiating the IDR, VCHCA staff have three business days to work with the payer to select an IDR entity.
 - 1. If unable to agree upon one within the given timeframe, HHS will select one on their behalf within another three business days.
- H. After an IDR entity has been selected, VCHCA has 10 business days to submit a payment offer, along with supporting documentation.
- I. The IDR entity has 30 business days to review the offers submitted by VCHCA and the payer and decide which one it will select. During these 30 days, staff will continue to negotiate privately with the payer.
 - 1. If an agreement is made with the payer before the 30-day period is up, the IDR process ends.
 - 2. If no agreement is made with the payer, the IDR entity selects the winning bid, and the payer will send the final reimbursement amount to VCHCA.
- J. During each step of payer negotiation and the IDR process, staff will document the dates, times, actions taken and result of negotiation and IDR in Cerner

Training staff on surprise billing compliance

- A. All revenue cycle staff will be provided training on provisions of the Act and establishing compliance with surprise billing.
 - 1. All staff will receive regular refresher training annually

Reference materials on the Act and surprise billing will be available on shared intranet sites within VCHCA.

ATTACHMENTS

Notice and Consent Form (aka Surprise Billing Protection Form)

Disclosure Notice (aka Good Faith Estimate)

All Revision Dates 2/7/2025

Attachments

- No_Surprises_Act_Disclosure_Notice_English.pdf
- No_Surprises_Act_Good_Faith_Estimate_English.pdf

Approval Signatures

Step Description	Approver	Date
Chief Financial Officer	Michael Taylor: Chief Financial Officer, Health Care Agency	2/7/2025
Hospital Administration	John Fankhauser, MD: Chief Executive Officer, VCMC & SPH	1/31/2025
Hospital Finance	Jill Ward: Chief Financial Officer, VCMC & SPH	1/9/2025
Compliance Officer	Melissa Guevarra: Acting Compliance Officer	1/2/2025
Revenue Cycle	Kimberly Dillard: Director, Revenue Cycle	12/30/2024



Origination	12/1/2009	Owner	Kimberly Dillard:
Last Approved	2/7/2025		Director, Revenue Cycle
VENTURACOUNTY Effective	12/17/2024	Policy Area	Administrative - Fiscal
HEALTH CARE AGENCY Last Revised	2/7/2025		110001
Next Review	2/7/2028		

110.030 Charity Care Policy

PURPOSE:

Status (Active) PolicyStat ID (17258697

The Ventura County Health Care Agency (HCA), including Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) and hospital-based clinics strive to provide compassionate, quality patient care for the community we serve. This policy demonstrates HCA's commitment to our mission and vision by helping meet the needs of low income and uninsured patients in our community.

POLICY:

VCMC, SPH, its outpatient locations and clinics, will offer a Charity Care Program for hospital and hospital clinic services to patients who meet the eligibility requirements described below, pursuant to Health & Safety Code sections 127400 through 127446. All medically necessary hospital services are eligible for the Charity Care Program, other than those provided in Federally Qualified Health Centers (FQHC), and an application can be submitted at any time. Services performed within HCA are presumed to be medically necessary unless HCA provides an attestation in advance that the services are not medically necessary.

PROCEDURE:

Eligibility for Participation in Charity Care Program

Self-Pay Patients: A patient qualifies for the Charity Care Program if all of the following conditions are met:

- The patient does not have third party coverage from a health insurer, health care service plan, Medicare or Medi-Cal as determined and documented by HCA; or
- The patient has incurred annual out-of-pocket medical costs at HCA that exceed the lesser of 10 percent of the patient's current family income or family income in the prior 12 months, or

annual out-of-pocket medical expenses that exceed 10 percent of the patient's family income; and

- The patient's injury is not a compensable injury for purposes of workers' compensation, automobile insurance, or other insurance as determined and documented by HCA; and
- The patient's family income does not exceed 400% of the Federal Poverty Level.

HCA staff shall make reasonable efforts to obtain from the patient, or his or her representative, information about whether private or public health insurance, including eligibility for the California Health Benefit Exchange, may fully or partially cover the charges for care. If the patient does not have proof of third party coverage, HCA staff shall provide the patient with application forms and other information explaining how the patient may be eligible for Financial Assistance and specified health coverage programs, including, but not limited to, Medi-Cal, California Children's Services, the California Health Benefit Exchange or other government-funded health care programs.

The fact that a patient is applying for any of the above described health care coverage shall not preclude such patient from applying for or qualifying for the Charity Care Program or the Discount Payment Program.

Other Circumstances: A patient may also qualify for the Charity Care Program if:

- a. The patient qualifies for limited benefits under Medi-Cal, i.e., limited pregnancy or emergency benefits, but does not have benefits for other services provided at HCA.
- b. The patient qualifies for a medically indigent adult program offered by a county other than Ventura County.
- c. Reasonable efforts have been made to locate and contact the patient, such efforts have been unsuccessful, and the HCA Director or designee has reason to believe that the patient would qualify for charity or a discount (i.e., the patient is homeless).
- d. A third party collection agency has made efforts to collect the outstanding balance and has recommended to the HCA Director or designee that charity care or a discount be offered.

Definition of Patient's Family and Determination of Family Income: The "patient's family" is defined as the following:

- 1. For persons eighteen (18) years of age and older,
 - a. A spouse, domestic partner and dependent children under twenty-one (21) years of age, and dependent children of any age if those children are disabled whether living at home or not;
- 2. For dependent persons
 - a. Under eighteen (18) or
 - b. Between eighteen (18) to twenty (20) years of age,
 - i. Parents, caretaker relatives, and other children and dependent children of the parents or caretaker relatives of any age if those children are disabled.

Documentation requirements of family income shall be limited to recent pay stubs or tax returns. Recent

tax returns are tax return(s) which document a patient's income for the year in which the patient was first billed or twelve (12) months prior to when the patient was first billed. Recent paystubs are paystubs within a six (6) month period before or after the patient is first billed by HCA, or in the case of preservice, when the application is submitted. HCA may accept other forms of documentation of income but shall not require such other forms. The patient's monetary assets or the monetary assets of the patient's family may not be considered when calculating family income.

Federal Poverty Levels: The measure of 400% of the Federal Poverty Level shall be made by reference to the most up-to-date Department of Health and Human Services poverty guidelines for the number of persons in the patient's family or household. <u>https://aspe.hhs.gov/topics/poverty-economic-mobility/</u> poverty-guidelines.

Charity Care

Balances for those patients who qualify to participate in the Charity Care Program, as determined by HCA, shall be reduced to a sum equal to \$0 with the remaining balance eliminated and classified as charity care. Charity care is free care.

Resolution of Disputes

Any disputes regarding a patient's eligibility to participate in the Charity Care Program shall be directed to and resolved by the HCA Chief Financial Officer.

Notices

To ensure that patients are aware of the existence of the Charity Care Program, the following actions shall be taken:

Written Notice to Patients - Each patient who is seen at HCA, whether admitted or not, shall receive the notice attached hereto as Exhibit 1. The notice shall be provided in English and non-English languages spoken by a substantial number of the patients served by HCA.

In addition, the notice attached hereto as Exhibit 1 shall also be clearly and conspicuously posted in locations that are visible to patients in the following areas:

- Emergency Department
- Billing Office
- Admissions Office
- Other outpatient settings
- Prominently displayed on HCA's internet website with a link to the Charity Care Program

Each bill that is sent to a patient who has not provided proof of coverage by a third party at the time care is provided or upon discharge will include a statement of charges for services rendered by HCA and the notice attached hereto as Exhibit 2. The notice shall be provided in English and non-English languages spoken by a substantial number of the patients served by HCA.

Collection Activities

HCA may use the services of an external collection agency for the collection of patient debt. No debt shall be assigned for collection until the HCA Director or his/her designee has reviewed the account, and either 1) the patient has been found to be ineligible for financial assistance, or 2) the patient has not responded to any attempts to bill or offer financial assistance for 180 days. The notice attached hereto as Exhibit 3 will be provided to the patient prior to an account being assigned to an external collection agency.

HCA shall obtain an agreement from each collection agency that it utilizes to collect patient debt that the agency will comply with the requirements of Health & Safety Code Sections 127405, 127425, 127426 and 127430, Civil Code Section 1785.27 and the Charity Care Program.

Neither HCA nor any collection agency utilized by HCA shall report adverse information to a consumer credit reporting agency. HCA will not commence civil action against the patient for nonpayment at any time prior to 180 days after the initial billing if the patient lacks third party coverage, if the patient provides information that he or she may qualify for the Charity Care Program, or if the patient provides information that he or she may incur high medical costs. For purposes of determining whether a patient has high medical costs, out-of-pocket costs and expenses means any expenses for medical cost cost sharing.

"High medical cost" is defined as: either annual out-of-pocket medical costs incurred by the patient that exceed the lesser of ten percent (10%) of the patient's current family income or family income in the prior twelve (12) months, or annual out-of-pocket medical expenses that exceed ten percent (10%) of the patient's family income.

In addition, if a patient is attempting to qualify for eligibility under the Charity Care Program or Discount Payment Program and is attempting in good faith to settle an outstanding bill with HCA by negotiating a reasonable payment plan or making regular partial payments of a reasonable amount, HCA shall not send the unpaid bill to any collection agency unless that entity has agreed to comply with Health & Safety Code Sections 127405, 127425, 127426 and 127430, Civil Code Section 1785.27 and the Charity Care Program.

Any collection agency shall comply with any payment plan entered into by a patient. HCA shall not, in working with patients eligible under the Charity Care Program or Discount Payment Program, use wage garnishments or liens on real property as a means of collecting unpaid HCA bills.

If a patient qualifies for charity/discount payment, qualification is valid going forward for twelve (12) months or until the patient's financial condition changes, and is no longer eligible for the Charity Care Program.

If a patient does not submit an application or documentation of income, HCA may presumptively

determine that a patient is eligible for charity care or discounted payment based on information other than that provided by the patient or based on a prior eligibility determination.

HCA may require a patient or guarantor to pay the entire amount of any reimbursement sent directly to the patient or guarantor by a third-party payer for HCA services. If a patient receives a legal settlement, judgment, or award under a liable third-party action that includes payment for health care services or medical care related to the injury, HCA may require the patient or guarantor to reimburse HCA for the related health care services rendered up to the amount reasonably awarded for that purpose.



EXHIBIT 1

Charity Care and Discounted Payment Program

Patients who lack insurance or have inadequate insurance, or high medical costs and meet certain lowand moderate-income requirements may qualify for discounted payments or charity care. Patients should contact the Ventura County Health Care Agency at **805-648-9553**, **vchca.org or** <u>VCHCA.PatientAssistance@ventura.org</u> to obtain further information. Emergency Department physicians, who are not employees of the hospital, must also provide a discounted payment program. Please contact **626-447-0296** for further information.

There are organizations that will help patients understand the billing and payment process. For assistance, patients may contact the Health Consumer Alliance (*https://healthconsumer.org.*)

For information and eligibility for Covered California, please visit <u>www.coveredca.com</u>.

For Medical eligibility, please visit <u>www.medi-cal.ca.gov</u>.

For a list of the hospital's shoppable services, please visit <u>https://apps.para-hcfs.com/PTT/FinalLinks/</u> Ventura_V3.aspx. or website at vchca.org

EXHIBIT 2

Notice to Accompany Bills to Potentially Eligible Patients

Our records indicate that you do not have health insurance coverage or coverage under Medicare, Medi-Cal, or other similar programs. If you have such coverage, please contact our office at **805-648-9553** as soon as possible so the information can be obtained and the appropriate entity billed.

If you do not have health insurance coverage, or have high medical costs, you may be eligible for Medicare, Medi-Cal, the Ventura County Health Care Agency's Discounted Payment Program, or the Charity Care Program. For more information about how to apply for Medicare, Medi-Cal, Presumptive Medi-Cal the California Health Benefit Exchange, or other similar programs, please contact the Ventura County Health Care Agency by telephone at **805-648-9553** the internet at vchca.org or via email at VCHCA.PatientAssistance@ventura.org and speak to a representative who will be able to answer questions and provide you with applications for these programs. An application for the Discount Payment Program is enclosed.

Emergency Department physicians, who are not employees of the hospital, must also provide a discounted payment program. Please contact **626-447-0296** for further information.

For additional assistance, patients may contact the Ventura County consumer assistance center toll free at **866-904-9362** or visit the Ventura County Human Services Agency website at *www.vchsa.org.*

EXHIBIT 3

Notice of Commencement of Collection Activities

John Doe 123 Main Street Ventura, CA 93001 Re: Encounter #: 2000000001 Balance: \$100.00

Dear Mr. Doe,

State and federal law require debt collectors to treat you fairly and prohibit debt collectors from making false statements or threats of violence, using obscene or profane language, and making improper communications with third parties, including your employer. Except under unusual circumstances, debt collectors may not contact you before 8 a.m. or after 9 p.m. In general, a debt collector may not give information about your debt to another person, other than your attorney or spouse. A debt collector may contact another person to confirm your location or to enforce a judgment.

Before assigning your account to a collection agency, a newly enacted California law requires that we notify you of the following information:

The date or dates of service of this account: XX/XX/XXXX

The name of the company your account will be assigned to: California Business Bureau How you can obtain an itemized bill from us: Please call 805-648-9553 for an itemized bill The name and type of health care coverage on record at the time of services or a statement that the hospital does not have that information: Applications for our Charity Care and Discount Payment Policies: See attached applications.

The date(s) you were originally sent a notice about applying for financial assistance: XX/XX/XXXX The date(s) you were sent a financial assistance application: XX/XX/XXXX The date a decision was made on the application if submitted: XX/XX/XXXX

Please contact us at (805-648-9553/business office) if you have any questions about this letter, or about your account/bill with us.

Respectfully VCHCA

For more information about debt collection activities, you may contact the Federal Trade Commission by telephone at 1-877-382-4357 or online at <u>www.ftc.gov</u>. Patients may also contact the Ventura County consumer assistance center toll free at **866-904-9362** or visit the Ventura County Human Services Agency website at <u>www.vchsa.org</u>.

All Revision Dates

2/7/2025, 5/3/2023, 4/14/2023, 7/30/2019, 8/1/2017

Attachments

𝗞 Charity Care Application [English]

𝗞 Charity Care Application [Spanish]

Approval Signatures

Step Description	Approver	Date
Chief Financial Officer	Michael Taylor: Chief Financial Officer, Health Care Agency	2/7/2025
Hospital Administration	John Fankhauser, MD: Chief Executive Officer, VCMC & SPH	1/31/2025
Hospital Finance	Jill Ward: Chief Financial Officer, VCMC & SPH	1/22/2025
Compliance Officer	Melissa Guevarra: Acting Compliance Officer	1/22/2025
Revenue Cycle	Kimberly Dillard: Director, Revenue Cycle	1/17/2025

Origination	2/1/2009	Owner	Kimberly Dillard:
Last Approved	2/7/2025		Director, Revenue Cycle
VENTURACOUNTY Effective	12/17/2024	Policy Area	Administrative - Fiscal
HEALTH CARE AGENCY Last Revised	2/7/2025		10001
Next Review	2/7/2028		

110.032 Discount Payment Program Policy

PURPOSE:

The Ventura County Health Care Agency (HCA), including Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) and hospital clinics strive to provide compassionate, quality patient care for the community we serve. This policy demonstrates HCA's commitment to our mission and vision by helping meet the needs of low income and uninsured patients in our community. The purpose of this policy is to provide criteria to use when determining patient eligibility for HCA discounted payment program in compliance with applicable federal and state law.

POLICY:

VCMC, SPH, its outpatient locations and clinics offer a Discount Payment Program for hospital and hospital clinic services to patients who meet the eligibility criteria described below, pursuant to Health & Safety Code sections 127400 through 127446. All medically necessary services provided by the HCA are eligible for the Discount Payment Program (DPP), and an application can be submitted at any time. Services performed within the HCA are presumed to be medically necessary unless HCA provides an attestation in advance that services are not medically necessary.

PROCEDURE:

Eligibility for Participation in the Discount Payment Program

Financially Qualified Patient

A patient who satisfies the following is found to be a financially qualified patient, and eligible for participation in the DPP.

1. A patient who is self-pay; or

- 2. A patient with high medical costs; or
- 3. A patient who has a family income that does not exceed 400 percent of the federal poverty level.

Additionally, HCA may choose to grant eligibility for this discount payment policy or charity care policies to patients with incomes over 400 percent of the federal poverty level when the process for determination is stated and consistently applied, therefore insured and underinsured patients may likewise qualify for the discount payment program.

Self-Pay Patients

A patient who does not have third party coverage from a health insurer, health care service plan, Medicare, or Medi-Cal or whose injury is not a compensable injury for purposes of workers' compensation, automobile insurance, or other insurance as determined and documented by HCA. Selfpay patients may include charity care patients.

High Medical Costs

A patient with high medical costs is a person whose family income does not exceed 400 percent of the federal poverty level and any of the following

A. A patient whose annual out-of-pocket costs incurred by the individual at the hospital that exceed the lesser of 10 percent of the patient's current family income or family income in the prior 12 months.

B. A patient whose annual out-of-pocket expenses that exceed 10 percent of the patient's family income, if the patient provides documentation of the patient's medical expenses paid by the patient or the patient's family in the prior 12 months.

C. A patient who is eligible for a lower-level determination in accordance with HCA charity care policy.

Insured and Underinsured Patients

HCA additionally will consider a patient to have high medical costs if a patient has third party coverage or whose injury is a compensable injury for purposes of workers' compensation, automobile insurance, or other insurance as determined and documented by HCA staff may qualify for the Discount Payment Program (for co-pays, coinsurances, and deductibles) if both of the following conditions are met:

- (1) The patient does not receive a discount rate from HCA because of his or her third party
 - coverage. AND (2) either A or B as stated above are satisfied.

Family Income and Federal Poverty Level (FPL)

HCA will use reference to the most up-to- date Department of Health and Human Services (HHS) poverty guidelines for the number of persons in the patient's family or household. <u>https://aspe.hhs.gov/topics/</u>

poverty-economic-mobility/poverty-guidelines

For those patients who do not qualify for charity care but qualify to participate in the DPP, the amount of the discount is determined by the Discount Payment Rate Schedule. The expected payment for services HCA provides (to any patient who is eligible under the DPP) shall not exceed one hundred percent (100%) of the greatest amount of payment HCA would receive from Medicare, Medi-Cal, or any other government sponsored health program of health benefits, in which HCA participates (based on the fee schedule of such payor). This will be determined on a case-by-case basis.

Additional Considerations

Patient Insurance Status Unknown



HCA staff shall make reasonable efforts to obtain from the patient, or his or her representative, information about whether private or public health insurance, including eligibility for the California Health Benefit Exchange, may fully or partially cover the charges for care. If the patient does not have proof of third party coverage, HCA staff shall provide the patient with application forms and other information explaining how the patient may be eligible for specified health coverage programs, including, but not limited to, Medi-Cal, Presumptive Medi-Cal, California Children's Services, the California Health Benefit Exchange, or other government funded health care programs. The fact that a patient is being screened for or applying for any of the above-described health care coverage, shall not preclude such patient from applying for or qualifying for the DPP.

Cash Pay Patients

A patient who elects not to complete the DPP application shall be eligible for the DPP Cash-Pay Patient rate of fifty percent (50%) of billed charges upon request.

Definition of Patient's Family & Determination of Family Income: The "patient's family" is defined as the following:

- 1. For persons eighteen (18) years of age and older, a spouse, domestic partner and dependent children under twenty-one (21) years of age, and dependent children of any age if those children are disabled whether living at home or not;
- 2. For dependent persons
 - a. Under eighteen (18)
 - b. Between eighteen (18) to twenty (20) years of age,
 - i. Parents, caretaker relatives and other children, and dependent children of the parents or caretaker relatives of any age if those children are disabled

HCA will limit the documentation requirements of family income to recent pay stubs or tax returns. Recent tax returns are tax return(s) which document a patient's income for the year in which the patient was first billed or twelve (12) months prior to when the patient was first billed. Recent paystubs are paystubs within a six (6) month period before or after the patient is first billed by HCA, or in the case of preservice, when the application is submitted. HCA may accept other forms of documentation of income but shall not require such other forms. The patient's assets or the assets of the patient's family are not considered when calculating family income.

Emergency Physicians

The VCMC and SPH contracted Emergency Department physicians will offer DPP. HCA staff will ensure patients are notified of the availability of such programs, as provided in the "Notice of Discount Payment Program" section of this policy.

Extended Payment Plans

HCA will offer extended payment plans where patients who are eligible to participate in the DPP shall be offered an extended payment plan for the discounted amount, with no interest accruing or being charged. Monthly payments pursuant to any repayment plan negotiated with a patient (pursuant to the Discount Payment Program), shall not exceed ten percent (10%) of the patient's income, excluding

deductions for essential living expenses.

"Essential living expenses" shall mean expenses incurred by the patient for any of the following:

- · Rent or house payments (including maintenance expenses),
- Food and household supplies,
- Utilities and phone,
- Clothing,
- Medical and dental payments,
- Insurance,
- School and childcare,
- · Child and spousal support,
- Transportation and automobile expenses (including insurance, fuel and repairs),
- · Installment payments,
- · Laundry and cleaning expenses,
- Other extraordinary expenses.

HCA staff shall request that the patient provide details supporting the essential living expenses that should be considered in determining a reasonable payment plan for the patient.

Resolution of Disputes

Any disputes regarding a patient's eligibility to participate in the DPP, shall be directed to and resolved by the HCA Chief Financial Officer.

NOTICE of Discount Payment Program

To ensure patients are aware of the existence of the DPP HCA will take the following actions:

Provide Written Notice to Patients

HCA staff will provide each patient who is seen, whether admitted or not, a copy of the notice attached hereto as Exhibit 1. The notice shall be provided in the English and non-English languages spoken by a substantial number of the patients served by HCA.

HCA will post the Notice, (Exhibit 1), in locations that are visible to patients in the following areas:

- 1. Emergency Department;
- 2. Billing Office;
- 3. Admissions Office;
- 4. Other outpatient settings;
- 5. Prominently displayed on the hospital's internet website with a link to the DPP.

Notice to Accompany Bills to Potentially Eligible Patients

Each bill that is sent to a patient, who has not provided proof of coverage by a third party at the time care

is provided or upon discharge, will include a statement of charges for services rendered by HCA and the notice attached hereto as Exhibit 2. The notice shall be provided in the English and non-English languages spoken by a substantial number of the patients served by HCA.

Collection Activities

HCA may use the services of an external collection agency for the collection of patient debt. No debt shall be assigned for collection until the HCA Director or his/her designee has reviewed the account, and either 1) the patient has been found to be ineligible for financial assistance, or 2) the patient has not responded to any attempts to bill or offer financial assistance for one hundred eighty (180) days. The notice attached hereto as Exhibit 3, will be provided to the patient prior to an account being assigned to an external collection agency.

HCA shall obtain an agreement from each collection agency that it utilizes to collect patient debt that the collection agency shall comply with the requirements of Health & Safety Code, Sections 127405, 127425, 127426 and 127430, Civil Code Section 1785.27 and the Discount Payment Program.

Neither the HCA, nor any collection agency utilized by the HCA, shall report adverse information to a consumer credit reporting agency. HCA will not commence civil action against the patient for nonpayment at any time prior to one hundred eighty (180) days after the initial billing period if the patient lacks third party coverage, if the patient provides information that he or she may quality for the Discount Payment Program or if the patient provides information that he or she may incur high medical costs. For purpose of determining whether a patient has high medical costs, "out of pocket costs and expenses" mean any expenses for medical care that are not reimbursed by insurance or a health coverage program, such as Medicare copays or Medi-Cal cost sharing.

In addition, if a patient is attempting to qualify for eligibility under the Charity Care Program or DPP and is attempting in good faith to settle an outstanding bill with HCA, by negotiating a reasonable payment plan or making regular partial payments of a reasonable amount, the HCA shall not send the unpaid bill to any collection agency unless that entity has agreed to comply with Health & Safety Code Sections 127405, 127425, 127426 and 127430, Civil Code Section 1785.27 and the Discount Payment Program.

HCA will ensure that collection agencies it engages with comply with any payment plan entered into between a patient and HCA.

HCA shall not, in dealing with patients eligible under the Charity Care Program or DPP, use wage garnishments or liens on real property as a means of collecting unpaid HCA bills.

Disqualification after Qualification

If a patient qualifies for the Charity Care/DPP(s), qualification is valid going forward for twelve (12) months or until the patient's financial condition changes and is no longer eligible/eligible for the current Program.

If a patient does not submit an application or documentation of income, HCA may presumptively

determine that a patient is eligible for the Charity Care or DPP based on information other than that provided by the patient or based on a prior eligibility determination.

HCA may require a patient or guarantor to pay the entire amount of any reimbursement sent directly to the patient or guarantor by a third-party payer for HCA services. If a patient receives a legal settlement, judgment, or award under a liable third-party action that includes payment for health care services or medical care related to the injury, HCA may require the patient or guarantor to reimburse HCA for the related health care services rendered up to the amount reasonably awarded for that purpose.



Exhibit 1

Charity Care & Discounted Payment Program

Patients who lack insurance, have inadequate insurance, or high medical costs and meet certain low and moderate income requirements, may qualify for discounted payments or charity care. Patients should contact the Ventura County Health Care Agency at **805-648-9553**, **vchca.org or** <u>VCHCA.PatientAssistance@ventura.org</u> to obtain further information. Emergency Department physicians, who are not employees of the hospital, must also provide a discounted payment program. Please contact **626-447-0296** for further information.

There are organizations that will help patients understand the billing and payment process. For assistance, patients may contact the Health Consumer Alliance (*https://healthconsumer.org*.)

For information and eligibility for Covered California, please visit <u>www.coveredca.com</u>.

For Medi-Cal eligibility, please visit www.medi-cal.ca.gov.

For a list of the hospital's shoppable services, please visit <u>https://apps.para-hcfs.com/PTT/FinalLinks/</u> Ventura_V3.aspx.

Exhibit 2

Notice to Accompany Bills to Potentially Eligible Patients

Our records indicate that you do not have health insurance coverage or coverage under Medicare, Medi-Cal, or other similar government or non-government programs. If you have such coverage, please contact our office at **805-648-9553** as soon as possible, so the information can be obtained and the appropriate entity billed.

If you do not have health insurance coverage, or have high medical costs, you may be eligible for Medicare, Medi-Cal, the Ventura County Health Care Agency's Discounted Payment Program, or the Charity Care Program. For more information about how to apply for Medicare, Medi-Cal, Presumptive Medi-Cal, the California Health Benefit Exchange, or other similar programs, please contact the Ventura County Health Care Agency by telephone at **805-648-9553**, the internet at vchca.org or via email at <u>VCHCA.PatientAssistance@ventura.org</u> and speak to a representative who will be able to answer questions and provide you with applications for these programs. An application for the Discount Payment Program is enclosed.

Emergency Department physicians, who are not employees of the hospital, must also provide a discounted payment program. Please contact **626-447-0296** for further information.

For additional assistance, patients may contact the Ventura County consumer assistance center toll free at **866-904-9362** or visit the Ventura County Human Services Agency website at <u>www.vchsa.org</u>.

Exhibit 3

Notice of Commencement of Collection Activities

John Doe 123 Main Street Ventura, CA 93001 Re: Encounter #: 2000000001 Balance: \$100.00

Dear Mr. Doe,

State and federal law require debt collectors to treat you fairly and prohibit debt collectors from making false statements or threats of violence, using obscene or profane language, and making improper communications with third parties, including your employer. Except under unusual circumstances, debt collectors may not contact you before 8 a.m. or after 9 p.m. In general, a debt collector may not give information about your debt to another person, other than your attorney or spouse. A debt collector may contact another person to confirm your location or to enforce a judgment.

Before assigning your account to a collection agency, a California law requires that HCA notify you of the following information:

The date or dates of service of this account: XX/XX/XXXX

The name of the company your account will be assigned to: California Business Bureau How you can obtain an itemized bill from us: Please call 805-648-9553 for an itemized bill The name and type of health care coverage on record at the time of services or a statement that the hospital does not have that information Applications for our Charity Care and Discount Payment Policies: See attached applications The date(s) you were originally sent a notice about applying for financial assistance: XX/XX/XXXX The date(s) you were sent a financial assistance application: XX/XX/XXXX

The date a decision was made on the application, if submitted: XX/XX/XXXX

Please contact us at (805-648-9553/business office) if you have any questions about this letter, or about your account/bill with us.

Respectfully

HCA

For more information about debt collection activities, you may contact the Federal Trade Commission by telephone at 1-877-382-4357 or online at <u>www.ftc.gov</u>. Patients may also contact the Ventura County consumer assistance center toll free at **866-904-9362** or visit the Ventura County Human Services Agency website at <u>www.vchsa.org</u>.

All Revision Dates

2/7/2025, 5/3/2023, 4/14/2023, 7/30/2019, 6/6/2019, 8/1/2017

Attachments

- 𝗞 110-032 Discount Payment Program Policy Spanish.pdf
- 𝗞 Discount Program Application [English]
- 𝗞 Discount Program Application [Spanish]
- Solution Schedule and Service Schedule.pdf

Approval Signatures

Step Description	Approver	Date
Chief Financial Officer	Michael Taylor: Chief Financial Officer, Health Care Agency	2/7/2025
Hospital Administration	John Fankhauser, MD: Chief Executive Officer, VCMC & SPH	1/31/2025
Hospital Finance	Jill Ward: Chief Financial Officer, VCMC & SPH	1/24/2025
Compliance Officer	Melissa Guevarra: Acting Compliance Officer	1/24/2025
Revenue Cycle	Kimberly Dillard: Director, Revenue Cycle	1/24/2025



VENTURA COUNTY MEDICAL CENTER

Property of the Medical Staff, Privileged and Sensitive Information CONFIDENTIAL

Medical Executive Committee Document Approvals

March 2025

a. Policies & Procedures / Clinical Practice Guidelines / Forms / Orders

1;	100.031 Processing a Death & Post-Mortem Exam (Autopsy)	page	2-10
2.	100.062 Universal Protocol for Preventing Wrong Site, Wrong Person, Wrong Procedure Incidents	page	11-21
3.	100.082 Medication Reconciliation	page	22-26
4.	100.089 Point of Care Testing, Waived Tests and Provider-Performed Microscopy (PPM)	page	27-31
5.	100.114 Initial Management of Wound Botulism Suspect	page	32-36
6.	100.232 Code Stroke - Intravenous t-PA (Alteplase) Administration	page	37-41
7.	100.257 Malignant Hyperthermia Cart Restocking Process	page	42-46
8.	100.275 Vasopressor Intravenous Administration through Peripheral Line	page	47-50
9.	100.280 Medicinal Leeches	page	51-55
10.	106.028 Isolation Precautions	page	56-61
11.	107.073 Bed Crisis/Census Alert	page	62-64
12.	108.034 Labeling of IV/Central Line/Arterial Line Sites and IV Tubing and Fluids	page	65-66
13.	108.044 Clinical Implementation Guide for: Electrocardiogram Guided Tip Confirmation System During Peripherally Inserted Central Catheter Placement	page	67-70
14.	108.057 Clostridium Difficile Screening and Testing	page	71-73
15.	AC.22 Forensic Victim Evidentiary Examinations by Forensic Examiner (FE)	page	74-81
16.	D.51 Food & Nutrition Screening/Prioritization	page	82-86
17.	ER.44 Supervising Physician in the Emergency Department	page	87-88
18.	ER.49 Documentation Standards in the Emergency Department	page	89-91
19.	ICU.22 Admission Criteria to the Telemetry Units	page	92-94
20.	ICU.29 Critical Care Electrolyte Protocol	page	95-98
21.	IS.05 Interventional Radiology Procedures	page	99-100
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23.	IS.21 Interventional Radiology Medical Emergency Response	page	103-104
24.	IS.29 Imaging Services Medication Administration	page	105-106
25.	PH.79 Multiple Dose Vials	page	107-112
26.	PH.112 Biotherapy and Chemotherapy Dose Rounding	page	113-116



Medical Executive Committee Document Approvals VENTURA COUNTY MEDICAL CENTER Property of the Medical Staff, Privileged and Sensitive Information CONFIDENTIAL

March 2025

8. Policies & Procedures / Forms / Orders

The following were reviewed and recommended for approval by the appropriate Departments, Committees, and the Medical Executive Committee

Medical Executive Committee Document Summary March 2025 Page 2

11-011	I I CILLIGI	referenced as well		20.
112_11	Triannial 112-116	Revised to note the policy is applicable to biosimilar drugs	PH.112 Biotherapy and Chemotherapy Dose Rounding	20
107-112	Triennial	Complete policy re-write to incorporate ambulatory care clinics	PH.79 Multiple Dose Vials	25
105-106	Triennial	No changes	24. IS.29 Imaging Services Medication Administration	24.



HEALTH CARE AGENCY Policy Area:

Administrative - Patient Care **References:**

100.031 Processing a Death & Post-Mortem Exam (Autopsy)

POLICY:

To outline the procedure for processing a patient death at Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH).

PROCEDURE:

DEPARTMENTAL RESPONSIBILITIES

- A. Upon death, the nurse:
 - 1. Notifies the physician (unless they are otherwise in attendance).
 - 2. Notifies the Nursing Supervisor.
 - 3. Prepares the body, per nursing protocol.
 - 4. Obtains the signature of the next of kin on the "Release of Body to the Funeral Director" form [DocuShare VCMC-546-042].
 - 5. Notifies the OneLegacy organ procurement organization at 1-800-338-6112 and calls the Nursing office with the donor number (see policy 100.048 Referral of Potential Organ and Tissue Donors). Complete the Donor Information Record.

Upon death, the nurse or unit charge nurse:

- 1. Notifies the physician (unless they are otherwise in attendance).
- 2. Notifies the family.
- 3. Notifies the Nursing Supervisor at (805) 218-3443.
- 4. Notifies the Admitting Department at (805) 652-6071.
- 5. Notifies the One Legacy organ procurement organization at 1-800-338-6112 and calls the Nursing office with the donor number (see policy 100.048 Referral of Potential Organ and Tissue Donors).
 - a. Complete Attachment A: One Legacy Contact Form [VCHCA-505-027].
- 6. Reviews criteria for reporting to the Medical Examiner's office (MEO) with the licensed practitioner (LP). Ensures that the MEO is called if criteria are met. See Attachment B: Hospital and Nursing Care Facility Reporting Form.

- 7. Completes Attachment C: Notification of Death [VCHCA-546-021].
- 8. Completes Attachment D: Release of Body [VCHCA-546-042].
- 9. Prepares the body, per nursing protocol, if death is not reportable to the MEO.
- 10. If mortuary arrangements are made, the family or the nursing staff calls the mortuary, except for deaths requiring MEO engagement.
- B. Nursing Supervisor

Completes the Organ Procurement Form.

If the mortuary is designated, calls to arrange pick up.

- Meets Security at room with Log Book and Morguelog book and morgue key and escorts body to the Morguemorgue.
- 2. Picks up Release of Remains form, and entersEnters information into log book.
- 3. In the event there is no family, notifies Social Services and enters in log.
- 4. If body has not been picked up by the fifth day, contacts Health Information Management (HIM) and follows up with Social Services.
- 5. On day seven post-mortem, will follow up with HIM to ensure paperwork is in process.

C. Security

- 1. Will be notified by the Nursing Supervisor.
- 2. Security will meet the Nursing Supervisor at patient room for removal of body.
- 3. Security and Nursing Supervisor will verify the body against the the Release of Body form<u>Attachment</u> <u>D: Release of Body [VCHCA-546-042]</u>.
- 4. Toe tag is double checked by Nursing Supervisor and Security.
- D. Responsibility of the Physician:
 - 1. Notify the family.
 - 2. Notify the Medical Examiner's Office (MEO), if appropriate, or delegate to nursing staff who have knowledge of the case.
 - a. See "Special Circumstances" below for general list of deaths that should be reported to the MEO.
 - b. If MEO takes jurisdiction, MEO completes the death certificate.
 - i. There may be cases where the MEO issues the death certificate and the body is released to the funeral home.
 - 3. If MEO declines to take jurisdiction
 - a. If family, after discussion with the physician, would like to obtain an autopsy, obtain signatures on the Consent for Autopsy (see Special Circumstances – Autopsy). If family requests an autopsy that is not within the jurisdiction of the MEO, refer the family to private autopsy. In rare circumstances the MEO in collaboration with the CMO may make the decision to provide an autopsy that is not indicated by the MEO. This must be done with the approval of the CMO. In these circumstances, see Attachment E: Authority for Autopsy [VCHCA-546-009] (see Special Circumstances – Hospital Autopsy).

- b. In conjunction with HIM, completes death certificate worksheet, provides the final diagnosis, and signs finalized death certificate.
- 4. Completes death note in Medical Record
- E. Responsibility of HIM <u>and Birth Certificates</u> upon receipt of the **Notification of Death**.
 - 1. Obtains medical record.
 - 2. For deaths where the Medical Examiner's Office declines jurisdiction, HIM facilitates (with funeral home and physician) completion of the **Death Certificate.** Death Certificate.
 - For stillbirths and Public Guardian cases, HIM completes the Application and Permit for Disposition of Human Remains and files it with the Public Health Department
 - a. For fetal deaths, Birth Certificates completes the Application and Permit for Disposition of Human Remains

For fetal deaths, Birth Certificates completes the Certificate of Fetal Death and files it with the California Department of Public Health.

Fetal and Infant (Live birth) Deaths:

- 1. Fetal Deaths (Abortus vs. Stillbirth)
 - a. A Fetal Death is indicated by the fact that after separation from the mother, the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles.
 - a. Notify Social Services of any fetal or infant death to better provide emotional support to the family and discuss options of disposition of remains.
 - b. Abortus vs Stillbirth
 - 1. If the gestational age is considered to be less than 20 weeks, the conceptus is referred to as an abortus.
 - 2. If length of gestation is undetermined and fetus is over 500 grams or over 25 cm crown-rump length, it is considered a stillborn.
 - c. Management of Abortus Fetal Death:
 - a. The abortus will be sent to Pathology as a surgical specimen.
 - i. The specimen is to be placed in formalin and properly labeled.
 - b. Family may choose to make arrangements with a funeral home for disposition of the abortus.
 - i. A physician note documenting that abortus was < 20 weeks estimated gestational age, < 500 grams in weight, and < 25 cm crown-rump length will be required by the funeral home.
 - c. If the parents request VCMC/SPH to handle disposition of the stillborn, they will sign the authorization to "Retain and Dispose of Body"<u>Attachment F: Release of Stillborn/Abortus</u> [VCHCA-546-022] form. Consent of either parent is sufficient, although both parents should sign if they are available.
 - d. Management of Stillborn Fetal Death:
 - a. All stillborn deliveries must be registered with Public Health Vital Records and recorded in appropriate Ventura County Medical Center/Santa Paula Hospital records. The procedure is as

follows:

- 1. Nursing staff will notify Birth Certificates of the following: Date and time of expulsion, sex of the fetus, mother's name/chart number and physician.
 - a. If a member from Birth Certificates is not available, a message may be left on department phone
 - b. Birth Certificates will process messages on next business day
- 2. Nursing staff will record the weight and length and gestational age in Mother's chart.
- 3. Nursing staff will record delivery information on the delivery log as follows: mother's name, date/time of delivery, chart number, gestation, sex, and weight.
- b. Nursing staff or designee will place the infant in the morgue.
 - i. If an autopsy is to be performed, routine autopsy procedures will be followed.
- c. Social Services will consult with the parents of the stillborn to determine if they wish to make arrangements with a funeral home for burial or cremation. If the parents request VCMC/SPH to handle disposition of the stillborn, they will sign the authorization to "Retain and Dispose of Body"<u>Attachment F: Release of Stillborn/Abortus [VCHCA-546-022]</u> form. Consent of either parent is sufficient, although both parents should sign if they are available.
- d. Birth Certificates will prepare the Certificate of Fetal Death, which, whenever possible, should be signed by the attending physician-within 15 hours of pronouncement of legal death.

2. Infant Death (Live Birth)

- a. Live births are distinguished from fetal deaths by regulation as follows: the complete expulsion or extraction from its mother the products of conception which, after such separation, breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. If a fetus shows any post-delivery life signs, no matter how transient, it is a live birth, regardless of the length of gestation. Routine procedures for live births will be followed (e.g., birth certificates, chart, census, etc.).
- b. If the infant expires, Health Information Management (HIM) will prepare a Death Certificate as with any other death. If the infant has lived less than 72 hours and the parents wish to donate the remains of the infant to the hospital, they may sign the "Contribution of Remains" consent and related procedures described in the preceding section should be followed.

SPECIAL CIRCUMSTANCES

A. MEDICAL EXAMINER CASES

- All deaths in the following categories must be immediately reported to the Medical Examiner's Office (MEO) by the physician in attendance or the <u>Emergency Department (ED)nursing</u> staff. (California Government Code 27491 and Health and Safety Code 10250.)
 - a. Known or suspected homicides, suicides and accidents.
 - b. Deaths involving criminal action or suspicion of a criminal act.
 - c. Poisonings and deaths related to substance abuse.
 - d. All deaths in jail or in police custody.
 - e. All deaths at state mental hospitals.

- f. All deaths related to occupational diseases or hazards.
- g. All deaths occurring outside health care facilities.
- h. All deaths wherein the deceased has not been attended by physician within 20 days preceding death.
- i. Deaths in which a physician is unable to reasonably state a cause of death (unwillingness does not apply).
- j. Deaths involving suspected contagious diseases constituting a <u>new public hazard</u>.
- k. Deaths of unidentified persons.
- I. Deaths occurring within 24 hours of admission.
 - 1. Medical Examiner policy that minimally attended deaths are reviewed.
- m. Deaths suspected to be from Sudden Infant Death Syndrome/Sudden Unexpected Infant Death.
- 2. Upon notification by the physician or ED staff, the Medical Examiner's Office determines if they will take jurisdiction of the body. If the Medical Examiner decides not to take jurisdiction, normal circumstances apply.
- 3. The Medical Examiner (ME) has the authority to determine the extent of inquiry into reportable deaths. ME investigations do not necessarily entail an autopsy. The ME may authorize attending physicians to certify reportable deaths that are clearly from natural causes.
- 4. It is the duty of the Medical Examiner's Office to notify the next of kin in all deaths coming under their jurisdiction.
- 5. Reports shall not be made to the Medical Examiner's Office (MEO) that are not appropriate simply because autopsy permission has been refused, nor shall authentic Medical Examiner's cases be withheld from the Medical Examiner's jurisdiction and autopsied by the Hospital Pathologist because permission for autopsy has been obtained. To do either of the above willfully is a punishable offense (California Penal Code, Sec. 148).
- 6. Bodies under the MEO jurisdiction are not to be released to funeral homes unless the release is approved by the Medical Examiner's Office. Refer all requests to release the body to the Medical Examiner's Office.
- 7. The family of the decedent should not be approached for permission for an academic autopsy prior to the clearance from the Medical Examiner's Office.
- 8. Removal of organs or tissue for donations should not be performed without prior clearance from the Medical Examiner (see policy <u>100.048 Referral of Potential Organ and Tissue Donors</u>).
- 9. Dressings, intravenous (IV) catheters, airways, tracheotomies or other diagnostic or therapeutic apparatus that are in the body at the time of death should not be disturbed or removed from the body prior to the arrival of the, or without the permission of, personnel from the Medical Examiner's Office.
 - a. Traumatic wounds and injuries shall not be tended to after death.
- B. HOSPITAL AUTOPSY: For deaths that do meet criteria for reporting to MEO, or, if reported, the MEO has declined to take jurisdiction
 - 1. All autopsies must be ordered by a physician and approved by the Chief Medical Officer of the Hospital.
 - a. The "Authority for Autopsy" form [DocuShare VCMC-546-009] Attachment E: Authority for

<u>Autopsy [VCHCA-546-009]</u> must be filled out and witnessed (form available at all nursing stations and from Nursing Supervisor). The physician makes the request to the next of kin. This form is then brought directly to the pathologist or the pathology secretary.

- b. The legal order of relative priority when obtaining autopsy consent is as follows:
 - 1. Spouse
 - 2. Adult son or daughter
 - 3. Either parent
 - 4. Adult brother or sister
 - 5. A guardian or conservator of the person of the deceased at the time of death.
- c. An example of the legal order is if a person is married to the deceased, then he/she is the one who should decide if there should be an autopsy. If the spouse does not want an autopsy, but an adult son or daughter requests one, the spouse's request is honored. The same is true as one goes down the priority list.
- d. The physician will, between the hours of 0800 and 2200, page the pathologist on-call to discuss the case, and determine if a directed autopsy vs. a full autopsy is needed. If after 2200, page the on-call pathologist at 0800 the next morning and order the body not to be released to the mortuary until after the autopsy. The pathology call schedule is available through the paging operator or in the pathology office.
- e. It is imperative that the pathologist receives the above two forms before the autopsy can proceed. The forms need to be delivered to Pathology directly. Do not place the forms in the chart.
- f. Autopsy Phone Consent
 - 1. When a hospital patient dies and the next of kin resides outside the area, it is often necessary to obtain consent for autopsy over the telephone.
 - 2. It shall be VCMC/SPH policy to obtain such consents through Nursing Administration. The physician will contact the Nursing Supervisor for assistance.
- g. If it is requested of the MEO to perform the medical autopsy, provide the Authority for Autopsy form to MEO.
- C. IN THE EVENT THERE IS NO FAMILY
 - 1. If there is no family, Social Services is notified by the House Supervisor or Nursing.
 - a. Social Services will complete a search to locate next of kin
 - b. Upon determination of no family by Social Services will:
 - 1. Notify HIM of Public Guardian case
 - 2. Complete deceased patient log in the Nursing Office
 - 3. Complete Public Guardian Form
 - 4. Send referral to Public Guardian
 - 2. HIM upon notification by Social Services will:
 - a. Complete death certificate
 - b. Obtain physician signature on death certificate

- c. Complete permit for disposition of human remains
- d. Electronically file Death Certificate and Permit of Disposition of RemainsElectronically file death certificate.
- 3. Public Guardian
 - a. Signs release of remains and cremation orders
 - b. Contacts mortuary
 - c. Mortuary will contact HIM regarding removal of remains
- D. IN THE EVENT THAT THE FAMILY CANNOT PROVIDE FOR THE DISPOSITION OF REMAINS
 - 1. For a neonatal death, stillbirth (20 weeks or greater estimated gestational age), or abortus (< 20 weeks estimated gestational age)
 - a. Nursing notifies Admitting in the event of a neonatal death and Social Services in the event of a fetal death.
 - b. Nursing or Social Services speaks to the family and obtains the Authorization to Retain and Dispose of Body and Contract for Cremation and sends it to HIM.
 - c. HIM obtains the physician signature on the Death Certificate or the Certificate of Fetal Death. An Application and Permit for Disposition of Human Remains is also completed by HIM and filed with Public Health.

For a stillbirth (20 weeks or greater estimated gestational age), or abortus (< 20 weeks estimated gestational age), the same procedure is followed as outlined under "Fetal and Infant (Live Birth) Deaths: Fetal Deaths (Abortus vs Stillbirth)."

- 2. If the patient is not a neonate or fetus, the same procedure is followed as outlined under "Special Circumstances: In the Event there is No family."
- 3. The Hospital Social Services Department is responsible for delivery of all personal effects to the Public Administrator that have been entrusted to the Hospital for safekeeping, including money in the patient's trust fund, and personal articles, other than clothing, received from nursing units.
- 4. Nursing is responsible for delivering personal effects to the next of kin or Social Services, when indicated.
- 5. In all other cases, the disposition of the body and personal effects will be at the discretion of the next of kin.

CRITERIA FOR IDENTIFYING DEATHS APPROPRIATE FOR HOSPITAL AUTOPSY

- A. Deaths which come under the jurisdiction of the Medical Examiner (ME) must be reported per policy <u>100.030 Critical Tests/Critical Results (Reported Verbally)(see Attachment B: Hospital and Nursing Care</u> <u>Facility Reporting Form</u>). Only after a potential Medical Examiner's case has been reported to the ME and jurisdiction declined by the Medical Examiner, can the case be considered for a hospital autopsy. In <u>discussion with the Chief Medical Officer, the physician may request a hospital autopsy.</u>
- B. An<u>A hospital</u> autopsy may be indicated in the following circumstances:
 - 1. Any death in a person with no known underlying disease or condition which would readily explain the death and where an autopsy has a reasonable likelihood of identifying the cause of death.

- 2. Any death in cases of unusual educational interest where the autopsy is not more appropriately performed in a university or research setting.
- 3. Examples of cases where an autopsy may be indicated include the following:
 - a. Identification (not just corroboration) of a hereditary or genetic condition where this information would be useful to the family of the deceased
 - b. Cases where an autopsy is likely to make a significant contribution to quality assessment.
- C. The physician who requests an autopsy is responsible for communicating to the pathologist a relevant clinical history and should discuss the indications for the autopsy with the pathologist. The requesting physician should state what questions he/she expects the autopsy to resolve.
- D. An autopsy represents a pathology consultation. After discussion with the referring physician, the pathologist will make the final determination of the extent of the autopsy. It is the practice of the Pathology Department to perform directed (or limited) autopsies.
- E. Because of the known risks of transmission of infectious diseases, the presence of certain medical conditions in the deceased represents an absolute or relative contraindication for an autopsy at Ventura County Medical Center/Santa Paula Hospital. If a relative contraindication is present, the pathologist, after discussion with the requesting physician, will decide whether the information which might be gained from the autopsy justifies the risk of disease transmission. If the pathologist chooses to do the autopsy, the pathologist will take precautions to decrease the risk of disease transmission. These extra precautions may include having the body embalmed before the autopsy and performing a limited autopsy. Because of the increased risk of disease transmission, the autopsy will generally exclude opening of the cranium or examination of the spinal cord.
 - 1. Medical conditions which represent an absolute contraindication for an autopsy at VCMC/SPH include, but are not limited to:
 - a. Jacob-Creutzfeld disease.
 - b. Any unexplained encephalomyopathy that might be secondary to a slow virus infection.
 - c. Anthrax.
 - 2. Medical conditions which represent a relative contraindication for an autopsy at VCMC/SPH include, but are not limited to:
 - a. Human immunodeficiency virus (HIV) or human T-lymphotropic virus (HTLV) infection.
 - b. Hepatitis B.
 - c. Hepatitis C.
 - d. Hepatitis non-A, non-B.
 - e. Known or suspected disseminated Coccidioidomycosis.
 - f. Known or suspected disseminated (miliary) tuberculosis.
 - 3. Because of the intended educational value of an autopsy, the physician who requests an autopsy should attend the autopsy whenever scheduling allows.
 - 4. After completion of the autopsy, the pathologist will promptly communicate relevant findings to the physicians involved in the care of the deceased and will complete the provisional anatomic diagnosis and the final autopsy report in accordance with Medical Staff Rules and Regulations and in compliance with licensing and accrediting agencies.

1/15/2025, 8/16/2022, 3/27/2020, 10/1/2016, 5/1/ 2010, 3/1/2007, 5/1/2006, 2/1/2005, 10/1/2001, 8/1/ 2001, 1/1/2000, 11/1/1998, 3/1/1995, 11/1/1989, 10/ 1/1986

Attachments

All revision dates:

- Attachment A: One Legacy Contract Form [VCHCA-505-027]
- Attachment B: Hospital and Nursing Care Facility Reporting Form
- Attachment C: Notification of Death [VCHCA-546-021]
- Attachment D: Release of Body [VCHCA-546-042]
- Attachment E: Authority for Autopsy [VCHCA-546-009]
- Attachment F: Release of Stillborn/Abortus [VCHCA-546-022]

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Hospital Administration	Minako Watabe: Chief Medical Officer, VCMC & SPH	2/11/2025
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	2/3/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	1/15/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/15/2025
Policy Owner	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/15/2025



PolicyStat ID: 17076215

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Policy Area:

7/1/2004 Upon Approval N/A 2/6/2025 3 years after approval Gwendolyn Vontoure: Director Perioperative Services Administrative - Patient Care

VENTURA COUNTY

HEALTH CARE AGENCY Policy Area: 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 <u>that</u> the patient's procedure is performed on the correct site, side and level. <u>It is the policy of</u> <u>Ventura County Medical Center/Santa Paula Hospital that the following steps be completed before every</u> 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.

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:

Hospital Wide Verification Process:

- A. Verification of the correct person, procedure and site should occur (as applicable):
 - 1. At the time the surgery/procedure is scheduled.
 - 2. With the patient awake and aware, when possible.
 - 3. Anytime the responsibility for care is transferred to another caregiver.
 - 4. Before the patient leaves the preprocedural/preoperative area.
 - 5. Immediately prior to incision or start of procedure.

SURGERY/OPERATING ROOM:

- A. The correct procedure site 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 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 (RN) will identify the patient and verify the surgery and site laterality.
- D. The 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. 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 and laterality are identified and marked.
 - 3. Consent form is present and 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.
 - If applicable, confirm antibiotic prophylaxis and potential time requirement for required re-dosing.
 - Anticipated critical events including expected duration, anticipated blood loss, and critical or nonroutine steps.
 - 10. Fire Risk Assessment
- 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.

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

Surgery/Operating Room Pre-Procedure Verification

- A. In the preoperative/preoperative area, the preoperative RN will conduct confirmation of the correct site, procedure and patient by the following means:
 - 1. Identification using two patient identifiers: name and date of birth
 - 2. The patient and/or designated caregiver will participate in the verification process to the fullest extent possible with verbal and visual responses, stating their name and pointing to the correct site location, whenever possible.
 - 3. Verification of surgical consent/informed consent will be compared to the posted surgery schedule, radiographic films, site marking and other pertinent information in the medical record.
 - 4. Verification and review of current history and physical. History and physical must have been conducted within the past 30 days.
- B. The above documents along with patient/designated caregiver identification must indicate the same procedure and site 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.

Surgery/Operating Room Marking the Surgical Site

- A. All patients undergoing surgical procedures involving the laterality of an extremity, fingers, toes, lesions and multiple spine levels will have the surgical site marked.
 - 1. All site markings will occur prior to transporting the patient to the operating room.
 - 2. Non operative sites are not marked unless clinically indicated (pedal pulse markings, no blood pressure cuff warnings).
 - 3. Site marking shall be performed by the surgeon accountable for the patient and procedure using the surgeon's initials at or adjacent to the incision site.

- 4. Site marking should occur when the patient is awake, alert, and can take part in the verification process, whenever possible. The surgeon marking the site will ask the patient or designated caregiver to state the procedure, site and side of surgery and have the patient provide visual responses such as pointing when appropriate.
- 5. <u>Before marking the site, the surgeon will verify the patient's identity, consent, medical history and physical and radiographs as applicable to confirm accuracy.</u>
- 6. The surgeon marking the site will use a designated marker with of sufficient permanence to remain visible until the procedure is performed without creating a tattoo.
- 7. The marking should be performed in a manner that it remains visible after the patient is prepped and draped.
- 8. In addition to preoperative skin marking of the general spine region, intraoperative radiographic techniques may be used for marking the exact vertebral level.
- 9. For sites that cannot be easily marked including mucosal surfaces, perineum, unstable spine fractures or when the patient refuses site marking, the surgeon will use an alternative method such as a 2nd temporary wristband with patient's name, date of birth, intended procedure and site laterality, when applicable.
- 10. For dental extractions, the surgeon will mark the side of the patient's face with the tooth number of the tooth being extracted.
- 11. If the patient refuses site marking, the surgeon will review the site marking rationale and the implications of refusing site marking. If the patient continues to refuse site marking, the surgeon responsible for marking the site will use the alternative wristband method.

Surgery/Operating Room Site Marking Exemptions

- <u>A.</u> Single organ procedures (e.g., gallbladder, uterus, bilateral procedures, open wounds or lesions, cardiac surgery, non-predetermined sites, procedures involving the teeth (use radiograph confirmation as an alternative).
- B. In emergency situations, when a physician has determined that delay is likely to compromise the patient's condition.
- <u>C.</u> <u>Alternative methods will be used with premature infants, for whom marking may result in permanent</u> <u>tattooing of the skin.</u>

Surgery/Operating Room Performing a Time Out

All members of the surgical team will participate in the case briefing and time out process, utilizing the AORN Comprehensive Surgical Checklist.

Pre-procedural Check-In

- A. Prior to bringing the patient into the operating room, the patient and/or designated caregiver will participate in the pre-procedure checklist verification with the preoperative and operating room nurse. Information reviewed will include:
 - 1. Patient identification including name and date of birth
 - 2. Procedure and procedure site verification
 - 3. Surgical and informed consent
 - 4. Site marking

- 5. History and physical
- 6. Preanesthesia assessment
- 7. Completion of nursing assessment
- 8. Diagnostic and radiologic test results
- 9. Availability of blood products
- 10. Special equipment needed
- 11. Implants
- <u>12.</u> Antibiotic prophylaxis
- 13. Administration of beta-blocker medication
- 14. Thromboembolism prophylaxis
- 15. Normothermia measures
- 16. Other pre-medications administered

Anesthesia Time Out

- A. The briefing will be conducted in the operating room prior to induction of anesthesia including the patient when possible. Information reviewed during the briefing will include:
 - 1. Patient identification including name and date of birth
 - 2. Procedure and procedure site verification
 - 3. Consent(s)
 - 4. Site marking
 - 5. Allergies
 - 6. Pulse oximeter in place
 - 7. Difficult airway or aspiration risk (if yes, has preparation been confirmed)
 - 8. Risk of blood loss >500ml (if yes, # of units available)
 - 9. Anesthesia safety check completed
 - 10. All members have discussed plan of care and addressed any concerns

Surgical Time Out

- A. The time out will be completed immediately before skin incision or start of the procedure if no incision is indicated, in the location where the procedure will be performed. During the time out, all other activities will be suspended (except in the case of a life-threatening emergency).
 - 1. Introduction of team members
 - 2. Confirmation of Patient identification including name and date of birth
 - a. If patient name and date of birth is unknown, staff will use the alias name from the patient ID band and MRN.
 - 3. Procedure and procedure site verification
 - 4. Consent(s)
 - 5. Patient position

- 6. Site marking
- 7. Fire Risk Assessment and discussion utilizing the AORN Fire Risk Assessment and Prevention Algorithm (see policy S.30 Fire Safety in the Operating Room). Discusses prevention methods to be implemented when applicable.
- 8. Relevant images are properly labeled and displayed
- 9. Equipment concerns
- 10. Surgeon will state:
 - a. Critical or non-routine steps
 - b. Case duration
 - c. Anticipated blood loss
- 11. Anesthesiologist will state:
 - a. Antibiotic prophylaxis within I hour before incision
 - b. Additional concerns
- 12. Scrub person will confirm:
 - a. Confirmation of sterilization indicators
 - b. Additional concerns
- 13. The RN will document completion of time out in the EHR.

Debrief/Sign Out

- A. Before the patient leaves the Operating Room, the RN will confirm the following with the applicable surgical team members:
 - 1. Name of the operative procedure
 - 2. Completion of sponge, sharp and instrument counts
 - 3. Specimens identified and labeled
 - 4. Equipment problems that need to be addressed
 - 5. Wound classification
 - 6. Estimate blood loss
- B. All members of the team will discuss:
 - 1. Any key concerns for recovery and management of the patient
 - 2. Team performance
 - 3. Key events
 - 4. Permanent changes needed to the preference card

Time Out for Multiple Procedures

- A. If multiple procedures are scheduled on the same case, a separate time out must be completed prior to the start of each procedure. This applies even if the procedures are performed consecutively by the same surgical team.
- B. Procedures performed by the anesthesiologist in the operating room including, but not limited to, nerve

blocks and central vascular access lines will also complete the time out process.

Surgery/Operating Room Documentation

- A. Verification of invasive procedure or surgery site/side will be documented in the following areas:
 - 1. Preop checklistPreop Checklist
 - 2. Surgical Consent
 - 3. Intraoperative Patient Care Plan
 - 4. Anesthesia Record
 - 5. Surgeon's Post-operative Operative Note
 - 6. Ambulatory Care and Bedside Procedure Universal Protocol for Correct Patient, "Procedure Site/ Side "Time Out" in the EHR (Inpatient and Ambulatory Care setting only)
- B. A pre-procedure checklist is will be 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:
 - Immediately notify the <u>Charge Nurse</u>, <u>Director of Surgery</u>, <u>Nursing</u> Supervisor, <u>Surgical Services</u> <u>ClinicalChief</u> Nurse <u>Manager</u>, <u>Chief Nurse</u> 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:

Performed Outside of the Operating Room by the Anesthesiologist:

Time Out for Procedures Performed by the Anesthesiologist

- A. For procedures performed prior to surgery by the Anesthesiologist, such as regional anesthesia or placement of a central vascular access line, a separate time out will be performed inclusive of the followin
 - 1. The time out will be performed in the location that the procedure is taking place after the patient is prepped and draped.
 - 2. The RN will initiate the time out.
 - 3. All other activities will be suspended during the time out.
 - 4. The following information will be confirmed:
 - a. Patient identification, name and date of birth
 - b. Verification of consent
 - c. Procedure to be performed

- d. Laterality and marking of the procedure site
- e. Team members agree on procedure to be performed

Documentation of Time Out for Procedures Performed by the Anesthesiologist

- A. <u>The RN who initiates and is present for the time out will document the "Procedure Time Out" in the EHR</u> which includes:
 - 1. Procedure start date/time
 - 2. Procedure end date/time
 - 3. Procedure performed
 - 4. Procedural consents
 - 5. Procedure site marked, if applicable
 - 6. Verification of procedure
 - 7. Verification of patient
 - 8. Validation of site with patient or designated caregiver
 - 9. Verbal time out completed
 - 10. Verbal team verification
 - 11. Time out comments, if applicable

Interventional Radiology, GI Lab and other Clinical Areas including Procedures Performed at the Bedside:

<u>Time Out for Procedures Performed in Interventional Radiology, GI Lab and</u> <u>other Clinical Areas including Procedures Performed at the Bedside</u>

- A. A Time Out shall be conducted immediately before the start of any invasive or high-risk procedure. inclusive of the following information:
 - 1. Patient identification, name and date of birth
 - 2. Verification of consent
 - 3. Procedure to be performed
 - 4. Laterality and marking of the procedure site, if applicable
 - 5. Fire risk factors and prevention strategies, if applicable
 - 6. Team members agree on procedure to be performed

Documentation of Time Out for Procedures Performed in Interventional Radiology, GI Lab and other Clinical Areas including Procedures Performed at the Bedside

- A. The RN who initiates and is present for the time out will document the "Procedure Time Out" in the EHR which includes:
 - 1. Procedure start date/time
 - 2. Procedure end date/time

- 3. Procedure performed
- 4. Procedural consents
- 5. Procedure site marked, if applicable
- 6. Verification of procedure
- 7. Verification of patient
- 8. Validation of site with patient or designated caregiver
- 9. Verbal time out completed
- 10. Verbal team verification
- 11. Time out comments

Debrief/Sign Out

- A. Before the patient leaves the procedure area (or once procedure is complete), the RN will confirm the following with the applicable team members:
 - 1. Procedure performed
 - 2. Specimens obtained, identified and labeled
 - 3. Implants
 - 4. Unexpected events
 - 5. Patient disposition (i.e. home, PACU, etc)

References

<u>AORN position statement: preventing wrong-patient, wrong-site, wrong-procedure events. AORN, Inc.</u> <u>Accessed November 24, 2024. https://www.aorn.org/guidelines/clinical-resources/position-statements</u>

Guideline for team communication. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.

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

http://www.jointcommission.org/hap_2017_npsgs/

<u>Universal protocol.</u> The Joint Commission (2024). https://www.jointcommission.org/standards/univeralprotocol/

All revision dates:

2/6/2025, 7/10/2024, 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 Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Committees: Medicine & Surgery	Stephanie Denson: Manager, Medical Staff Office	2/27/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	2/6/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	2/6/2025
Policy Owner	Gwendolyn Vontoure: Director Perioperative Services	2/6/2025



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1/1/2006 Upon Approval N/A 2/20/2025 3 years after approval Sara Pendleton: Medication Safety Officer Administrative - Patient Care

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

100.082 Medication Reconciliation

POLICY:

Ventura County Medical Center (VCMC)-and, Santa Paula Hospital (SPH), and Ambulatory Care Clinics shall reconcile all patients' medications within 48 hours of admission at any point of entry, at transitions of care unless an urgent situation indicates that immediate care take precedence, and prior to discharge.

Definitions:

1. **Medications** includes "any prescription medications, sample medications, herbal remedies, vitamins, nutraceuticals, over-the-counter drugs, vaccines, diagnostic and contrast agents used on or administered to persons to <u>diagnose_diagnose</u>, treat, or prevent disease or other abnormal conditions, radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives, intravenous solutions (plain, with electrolytes and/or drugs); and any product designated by the Food and Drug administration (FDA) as a drug. This definition of medication does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases."¹

2. **Best Possible Medication History (BPMH)** is a medication history obtained by a clinician which includes a thorough history of all regular medication use (prescribed and non-prescribed), using a number of different sources of information.²

See Attachment A for Quick Tips on Obtaining a Best Possible Medication History.³

3. **Medication reconciliation** is the process of identifying the medications currently being taken by an individual, and these medications are compared to newly ordered medications, and discrepancies are identified and resolved.¹

Per Joint Commission <u>National Patient Safety Goal (NPSG)</u> 03.06.01, medication reconciliation "is intended to identify and resolve discrepancies -- it is a process of comparing the medications a patient is taking (or should be taking) with newly ordered medications. The comparison addresses duplications, omissions, and interactions, and the need to continue current medications."⁴

4. **Point of entry** includes all admissions to any nursing unit, department, or area where a licensed personnel could or would have the potential to administer medications. Exclusions are encounters during which medications are not given.

5. **Transitions of care** is the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation center) to another.⁵ **Intra-hospital transfer** is the stepping up or down between levels of care.

6. **Undocumented Intentional discrepancy** is when the Licensed Provider (LP) has made an intentional choice to add, change, or discontinue a medication but this choice is not clearly documented.²

7. **Unintentional discrepancy** is one in which the LP unintentionally changed, added, or omitted a medication the patient is taking prior to admission.^{2,6-8}

PROCEDURE:

- A. Obtaining and documenting the patient's home medication history or list into the electronic health record (EHR) is the collaborative responsibility of <u>licensed</u> providers, nurses, pharmacy staff, and <u>licensed</u>-health care personnel (<u>e.g., medical assistants</u>) involved in the patient's medication management.
- B. If a medication history or list cannot be obtained despite best faith effort, the health care professional shall document this effort into the EHR.⁴
- C. 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) <u>and/or outpatient encounters</u> shall be completed by the LP.
- D. The patient (or caretaker as needed) shall be provided with written information on the medications the patient should be taking when the patient is discharged from the hospital <u>and/or released from the outpatient encounter</u>. This includes explanations about the importance of medication information management.⁴

EMERGENCY DEPARTMENT (ED) ADMISSION

When available, a pharmacy technician shall obtain a BPMH for ED patients and document this into the EHR (See California State Senate Bill 1254). 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.

DIRECT ADMISSION

When available, a pharmacy technician shall obtain a BPMH for high risk patients and document this in the EHR within 48 hours of admission (see California State Senate Bill 1254). The admitting nurse shall assist in obtaining and documenting the medication history in the EHR when the pharmacy technician is not available. The admitting LP shall review and reconcile the home medications in the EHR within 48 hours of admission.

TRANSFER PROCEDURES

Transfer reconciliation within the inpatient setting is required and any unintentional discrepancies shall be brought to the attention of the accepting provider(s) for clarification.

PRE-ADMISSION

For planned surgical procedures, the home med list shall be obtained by the surgical service before admission. Preop nursing shall document the home meds into the EHR. Upon admission, the surgical service or accepting service shall be responsible for completing medication reconciliation upon transfer out of recovery (post-anesthesia care unit, PACU) and prior to discharge. Unintentional discrepancies shall be brought to the attention of the surgical service or accepting service for clarification.

OUTPATIENT/AMBULATORY

Patients seen in the <u>ambulatory care setting (e.g., ED, infusion center, outpatient/ambulatory setting</u> <u>radiology</u>) shall have medications reconciled across the continuum of care. Upon departure, the patient shall receive a reconciled, active medication list.

DISCHARGE PROCEDURES

- A. It is the discharging providers' responsibility to reconcile the patient's medications prior to any discharge orders being placed. Unintentional discrepancies shall be brought to the attention of the discharging provider for clarification. If the discharging provider cannot be reached, chain of command shall be followed:
 - 1. Resident who placed discharge orders --> Senior resident --> Attending provider --> Medical Director of Inpatient Quality --> Chief Medical Officer
 - 2. Nurse practitioner/Physician assistant --> Attending provider --> Medical Director of Inpatient Quality --> Chief Medical Officer
 - Surgical resident --> Surgical attending provider --> Medical Director of Inpatient Quality --> Chief Medical Officer
- B. When a patient is discharged, a complete list of the patient's medications shall be communicated to the patient. When a patient is referred to, or transferred to another setting, service, practitioner, or level of care outside the health care system, a complete list of the patient's medications shall be communicated to the next provider.
- C. Patients shall be educated regarding the importance of managing their medication information.
- D. Documentation and communication of discharge medication orders occurs via:
 - 1. The medication reconciliation form which is given to the patient should be faxed, mailed or sent via courier directly to the next facility/clinic/provider of care. When the next provider of care is unknown, the patient is responsible for providing the information to the next provider.
 - 2. The physician discharge order form and Medication Administration Record for next provider of service shall be completed when transferring a patient to a receiving facility/treatment setting.
 - 3. A discharge summary for the patient's primary care provider.

CALIFORNIA STATE SENATE BILL 1254

On January 1, 2019 Senate Bill 1254 requires a pharmacist at a hospital pharmacy of >100 beds to obtain and document in the EHR an accurate medication history or list for each admitted high risk patient during the pharmacy's normal hours of operation as pharmacy staffing permits. The law allows for the facility to establish the criteria for identifying high risk patients in addition to establishing the time frame for completion. The facility shall also be responsible for training, competencies, and quality assurance.

Admission - At VCMC only, a medication reconciliation pharmacy technician shall be responsible for obtaining and documenting the BPMH for high risk patients within 48 hours of admission. See attachment B - Pharmacy Tech Home Med List Program.

The Pharmacy department shall maintain training, competencies, and quality assurance for pharmacy staff involved in obtaining and documenting a BPMH and pharmacy staff involved in providing discharge

medication education.

Outpatient Ambulatory Care Clinics

Patients seen in the outpatient ambulatory care clinic setting shall have medications reconciled across the continuum of care. Upon departure, the patient shall receive a reconciled, active medication list.

- A. Medication history is conducted by clinic staff anytime there is a patient encounter with an LP.
 - <u>1.</u> <u>Clinic Staff responsible for performing the medication history are Medical Assistants (MA), Licensed Vocational Nurses (LVN), Registered Nurses (RN), or Licensed Practitioners (LPs).</u>
 - 2. The medication history is documented in the EHR under "Document Medications by History."
- B. Medication Reconciliation is completed by the LP during a patient encounter with an LP.
 - <u>1. Medication Reconciliation is performed during every patient encounter to address omissions, duplications, and unintentional discrepancies.</u>
 - Medications can be added, deleted, changed, or continued under the function of "Medication Reconciliation" within the EHR. Medications can be reconciled in the EHR from the medication list or the dashboard.
 - 3. All patients shall be provided with a printed list of current medications upon discharge from the clinic.

References

1. Joint Commission Glossary. Accessed 10/22/2021, 6/8/2023.

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3. The Leapfrog Group. Best Possible Medication History (BPMH) Quick Tips. Society of Hospital Medicine MARQUIS2. <u>https://www.leapfroggroup.org/sites/default/files/Files/</u> <u>MARQUIS%20BPMH%20Tri%20Fold%20Pocket%20Guide_0_0.pdf?token=-MLkuYsN</u> Accessed 10/22/ 2021, 6/8/2023.

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All revision dates:

2/20/2025, 9/12/2023, 9/17/2019, 4/1/2012

Attachments

- Attachment A Best Possible Medication History Quick Tips
- Attachment B Pharmacy Tech Home Med List Program

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	2/20/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	1/23/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/23/2025
Policy Owner	Sara Pendleton: Medication Safety Officer	1/23/2025



PolicyStat ID: 15644612

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Policy Area:

10/1/2010 Upon Approval N/A 4/16/2024 3 years after approval Erlinda Roxas: Director, Laboratory Services Administrative - Patient Care

VENTURA COUNTY

HEALTH CARE AGENCY Policy Area: References:

100.089 Point of Care Testing, Waived Tests and Provider-Performed Microscopy (PPM)

POLICY:

A limited number of "bedside" laboratory tests (Point of Care Testing or POCT) have been approved by the Laboratory Director at Ventura County Medical Center/Santa Paula Hospital to be available to clinicians to provide rapid test results in the hospital and to help with treatment decisions in the clinics.

Laboratory procedures that are done at the point of care are performed under the CLIA Laboratory Certificate for Provider-Performed Microscopy Procedures issued by CMS to Ventura County Medical Center/Santa Paula Hospital. Procedures that are approved by the Laboratory Director as Waived Tests or are listed as Provider-Performed Microscopy Procedures (CDC) are the only tests that may be performed at the point of care. Point of care testing sites include bedside and nursing stations in both hospitals, Ambulatory Care clinics, and the Inpatient Psychiatric Unit and clinics.

PROCEDURE:

Overall responsibility for Point of Care Testing lies with the Laboratory Director. The Laboratory Director will designate a Point of Care Testing Coordinator. The Point of Care Testing Coordinator will:

- 1. Assist in the development of policy and procedures.
- 2. Review all procedures at least annually.
- 3. Oversee Quality Control/Quality Assurance.
- 4. Help educate staff at Point of Care testing sites.
- 5. Act as a liaison between the VCMC Laboratory and the staff and departments performing Point of Care testing.
- 6. Validate new tests, new analyzers, and, when required, new reagents.
- 7. Coordinate, assist, or perform initial competency assessment.
- 8. Participate at least monthly in departmental reviews of all glucose analyzer testing and of all Inpatient point of care patient tests, quality control and instrument maintenance logs. Ambulatory Care Administration maintains documentation of patient testing, quality control and instrument maintenance logs.
- 9. Act as a liaison between the POCT sites and the manufacturer should there be analyzer problems or

breakage that cannot be resolved on site by the POCT coordinator.

WAIVED TESTING:

The following waived tests that are performed at Point of Care Testing sites utilize testing instrumentation:

- Blood Glucose by Nova Statstrip method
- Hemoglobin A1c (Glycohemoglobin) by Siemens DCA Vantage Hemocue HB201DM for hemoglobin
- HemoCue Hb 801 System for hemoglobin
- Cepheid Gene Xpert COVID-19 Molecular Test for SARS-CoV-2/Flu/RSV
- Cepheid Gene Xpert COVID-19 Molecular Test for SARS-CoV2
- LeadCare II System for blood lead by Magellan Diagnostics

The following waived tests that are performed at Point of Care Testing sites do not utilize any testing instrumentation:

- BinaxNOW Antigen Test Card method for SARS-CoV2
- Dipstick for urinalysis by Multistix 10SG method (10 test pads per strip)
- Dipstick for urine tests by Labstix method (5 test pads per strip)
- · Fecal occult blood by Hemoccult Sensa method
- Fecal occult blood by InSureONE method
- <u>Urine drug of abuse by Hemousure</u> First Sign Drug of Abuse Cup Test-by Hemosure
- One Step Fentanyl Drug of Abuse Dip Card Test by HemosureUrine drug of abuse by Abbott iCASSETTE Fentanyl Urine Test Cassette
- · Streptococcus A Screen by OSOM Ultra Strep A Test method
- Urine pregnancy test by ICON 25 hCG method
- Urine pregnancy test by Medline hCG Pregnancy Test Cassette method
- Urine pregnancy test by Medline hCG COMBO+ Pregnancy Test Cassette method

Physician privileging for non-instrumentation Waived Testing is coordinated through the Medical Staff Office and the physician credentialing process. Other waived tests may be added only after review by the Point of Care Testing Committee and approved by the Laboratory Director.

PROVIDER-PERFORMED MICROSCOPY (PPM):

A physician or mid-level practitioner may perform Provider-Performed Microscopy Procedures (PPM). Midlevel practitioners include licensed Physicians' Assistants and Nurse Practitioners. The primary instrument used is a microscope and the specimen is considered labile.

The following PPM procedures may be performed:

- 1. Wet mount for presence or absence of bacteria, fungi, parasites and human cellular elements
- 2. Potassium hydroxide (KOH) preparations
- 3. Pinworm examination
- 4. Fern test
- 5. Post-coital direct, qualitative examination of vaginal or cervical secretions
- 6. Urine sediment examinations
- 7. Nasal smears for granulocytes

- 8. Fecal leukocyte examinations
- 9. Qualitative semen analysis (presence or absence of sperm and detection of motility)
- 10. Initial and annual competency assessment for physicians performing PPM is coordinated through the Medical Staff Office and the physician credentialing process. In addition, the physician may perform Amniotest, pH of vaginal secretions.
- 11. "When a physician performs waived testing that does not involve an instrument, there is no Joint Commission requirement for documentation of competency assessment when the test is a logical part of his or her specialty and the organization has specifically privileged the physician for that test." Through the medical staff credentialing process, individual physician may be privileged for those specific waived tests appropriate to their scope of practice and no further assessment of skills or documentation of competence would be required. 1

COMPETENCY PROGRAM

- A. The Laboratory Director, or a qualified designee, will orient, train and assess the competency of staff and independent practitioners who perform waived testing.
 - i. Clinical Nurse Managers (or those requested by a Clinical Nurse Manager, the Mental Health Clinic Coordinator, or Ambulatory Care Administration) are determined to be the "qualified designee/ superuser" after initial training from the Laboratory Point-of-Care Coordinator.
 - ii. "Qualified designees/superuser" are required to perform annual competencies.
 - iii. Documentation of the initial training and annual competencies of the "qualified designees/ superuser" are kept by the Laboratory Point-of-Care Coordinator.
 - iv. Documentation of the initial training and annual competency of staff members (Clinic Assistants, medical assistants, LVN's, RN's, or Nurse Practitioners) are kept by the Clinical Nurse Manager or qualified designee.
- B. Initial orientation will include the safe use and maintenance of any instrumentation.
- C. Competency is performed initially and annually and includes at least two of the following methods per person per test:
 - i. Performance of a test on a blind specimen
 - ii. Periodic observation of routine work by the supervisor or qualified designee
 - iii. Monitoring of each user's quality control performance
 - iv. Use of a written test specific to the testing
- D. Initial and Annual Competency:

The "qualified designee" will ensure that all new staff receives instruction of testing devices and operating policies and procedures. Initial and annual competencies will be documented utilizing two (2) methods of competency assessment (see #iii above).

Competency Assessment and Remedial Action:

 In the event that an employee fails to demonstrate satisfactory performance on the competency assessment, the deficiency is to be identified on the competency assessment form. Retraining and reassessment of the employee competency must occur when problems are identified with employee performance. The deficiency will be resolved before the competency assessment is completed. Any deficiency noted for registry or temporary employees will also be reported to their employer.

- Employees who do not pass initial competency evaluation may not perform those functions including patient testing without direct supervision.
- Retraining is provided and competency reassessed and ensured by the section supervisor.
- If the employee does not pass the initial competency during the probation period, the probation period may be extended and further retraining will be provided.
- If the employee still cannot pass the competency after retraining, the Laboratory can exercise probationary termination.
- If the employee does not pass the annual competency, retraining will be provided. The competency will be repeated within 30-60 days. If the employee still cannot successfully complete the competency, disciplinary actions will be taken as recommended by the Human Resources Department.
- · Completed competency assessments are to be filed in the employee's personnel file.

Quality Control:

The supervisor or manager of each Point of Care testing site will review and document each review at least monthly Quality Control and patient test results and also any required instrument maintenance. Each testing site is responsible for the performance and reporting of results for waived test Quality Control and patient tests, for instruments used in testing, and for supplies.

PATIENT RESULTS:

Test results for waived testing are documented in the patient's medical record. Quantitative test results in the patient's medical record for waived testing will include documentation of the reference ranges (normal values) for that test and age specific when appropriate.

IT maintains the network components of the NovaBiomedical "Novanet."

WAIVED TESTING OVERSIGHT:

Point of Care Testing Committee:

- Laboratory Director
- Medical Director
- Nursing Administration Representative
- Ambulatory Care Administration Representative
- · Point of Care Coordinator

The Point of Care Testing Committee will meet when necessary to discuss adding any new test or new equipment, to resolve compliance problems, or to delete any test.

The Laboratory Point of Care Coordinator will periodically review and document the review of Point of Care initial and annual competency assessment.

REFERENCES:

The Joint Commission Frequently Asked Questions, "Physician Competency For Waived and P.P.M.P

Testing," November 24, 2008.

All revision dates:

4/16/2024, 3/14/2024, 11/26/2018, 6/1/2016, 8/1/ 2012

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Hospital Administration	Minako Watabe: Chief Medical Officer, VCMC & SPH	1/15/2025
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	8/9/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	8/7/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	8/7/2024
Policy Owner	Erlinda Roxas: Director, Laboratory Services	8/7/2024



PolicyStat ID: 17362610

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Policy Area:

4/15/2020 Upon Approval N/A 4/15/2020 3 years after approval Sul Jung: Associate Director of Pharmacy Services Administrative - Patient Care

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

100.114 Initial Management of Wound Botulism Suspect

Policy

Botulism antitoxin shall be obtained in a timely manner for the treatment of wound botulism.

Procedure

- A. Table 1 provides step-by-step instructions on how to obtain Botulism Antitoxin. This policy and procedure may be printed to track and document the time when each assignment is initiated after a patient has been identified as potentially having wound botulism. The steps in Table 1 may be performed simultaneously.
- B. Due to the fast advancing nature of the disease, it is imperative to have *open communication* throughout the whole process among all those who are involved in the case, including physicians (Emergency Department, Intensive Care Unit, Infectious Disease, residents), nurses, California Department of Public Health (CDPH), Ventura County Public Health, Center for Disease Control and Prevention (CDC), laboratory phlebotomist, pharmacist and California Highway Patrol (CHP)/courier.
- C. When clinically possible, administer antitoxin prior to surgical wound debridement and obtain cultures prior to the administration of penicillin. For those who have penicillin allergy, metronidazole may be given as an alternative but only give after antitoxin is given.

Table 1. Step-by-Step task for obtaining Botulism Antitoxin			
			Initial s
Emergency Department	1. Emergency Department (ED) attending physician to call Intensive Care Unit and General Surgery STAT to inform them of wound botulism suspect.		
	2. ED attending physician calls CDPH directly at 213-620-2855 to discuss the case.		
	3. ED attending physician notifies Infectious Disease (ID) physician.		
	4. ED attending physician calls Ventura County Public Health		

1. Note: Antitoxin does not reverse existing paralysis but rather prevents further progression.

	Department at 805-981-5201 during hours of 8 am to 4 pm. For after hours, call Ventura County Public Health at 805-214-7057.		
	5. Once approved by CDPH, ED attending orders antitoxin in the electronic health record as a STAT medication – Botulinum Antitoxin Heptavalent (H-BAT). This medication is only available from CDC quarantine site near LAX airport.		
	 6. ED attending physician orders PH Lab Referral (tested for botulism via Mouse bio assay) in the electronic health record. Specimen type: Whole blood Suspected pathogen: Botulism Comments: Draw 30 mL of whole blood into red top tubes. This will take more than one tube. 		
Laboratory	 7. Laboratory personnel to collect 30 mL of blood in red-top tubes. This specimen is to be sent to the Ventura County Public Health laboratory for processing immediately. Each tube must be labeled with patient's name, date of birth, "pre-antitoxin serum", date, time of collection, and either employee ID or Cerner ID of the staff collecting the specimen. Bundle the tubes. Obtain and complete the California Department of Health Services Botulism Analysis laboratory request form (MDL176). See Attachment A. 		
Pharmacy	8. Pharmacist on duty will wait for phone call from CDC. If more than 10 minutes has passed since the ordering of the Botulinum Antitoxin Heptavalent and has not received a phone call from the CDC, call ordering prescriber to have them contact CDPH again.		
	9. Once in contact with the CDC, obtain the following information: Name of the CDC agent: Phone number:		
	Address:		
	10. Immediately call Ventura-based CHP at 805-662-2640 to ask for assistance with transportation. Introduce yourself and use the following script when communicating with CHP: <i>"We have a patient with a life-threatening condition at Ventura County Medical Center. There is a life saving treatment that has been approved by the California Department of Public Health and released by the CDC and is only available at a CDC quarantine site near LAX airport. Administration of this treatment to the patient must occur as</i>		

	<i>transport</i> from LAX **Emphasize the or	Please help us arrange for one-way X to VCMC" ne-way transport to cut time of travel. eed to obtain approval from Los Angeles		
	transportation of the an	11. Once CHP dispatcher gets approval for one-way transportation of the antitoxin, provide them with the contact information of the CDC agent listed on step #9.		
	Angeles-based Courier or call hospital on-call o 0) and page the courier	HP cannot provide the service, call a Los r from the pre-determined list in Table 2 courier by calling hospital operator (Dial r on-call as an emergency page (STAT). n appropriate courier, explain and provide ntact information.		
	13. Once transportation the status.	n has been set up, inform the physician of		
	physician. Prepare the	rrives at VCMC, inform the ordering e medication per instructions and		
	complete verification of	f the medication order.		
	15. Hand-deliver the m	f the medication order. edication along with the package tration to the nurse providing direct		
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Nurse Administration **See the package insert for complete information**

- A. Set up the administration using the Infusion Pump and a 15-micron sterile, non-pyrogenic, low protein binding in-line filter.
- B. The botulism antitoxin administration must be slowly titrated. Start at the starting infusion rate and increase as tolerated according to Table 3).
- C. Monitor vital signs and any infusion related symptoms with each infusion rate titrations and/or every 30 minutes until 1 hour post completion of infusion.
- D. If patient develops hypersensitivity reaction, DISCONTINUE administration immediately and start emergency care.
 - 1. Urticaria, pruritus, erythema, angioedema, bronchospasm with wheezing or cough, stridor, laryngeal edema, hypotension, tachycardia
- E. If patient develops discomfort or infusion-related adverse reaction, decrease the infusion rate and contact the physician.

1.	Infusion reaction:	Chills, fever,	headaches,	nausea,	vomiting	

Table 3. BAT Dosing Guide and Intravenous Infusion Rate				
Patient Group	Dose	Starting Infusion Rate (first 30 minutes)	Incremental Infusion Rate if Tolerated (every 30 minutes)	Maximum Infusion Rate
Adults (≥ 17 years)	One vial	0.5 mL/min	Double the rate	2 mL/min
Pediatric (1 year to < 17 years)	20 – 100% of adult dose	0.01 mL/kg/min Do not exceed the adult rate.	0.01 mL/kg/min	0.03 mL/kg/min Do not exceed the adult rate
Infants (< 1 year)	10% of adult dose regardless of body weight	0.01 mL/kg/min	0.01 mL/kg/min	0.03 mL/kg/min

Reference

A. Botulinum Antitoxin Heptavalent (H-BAT) Package Insert. Accessed 1/17/2020.

All revision dates:

4/15/2020

Attachments

California Department of Health Services Botulism Analysis Lab form MDL176.pdf

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Committees: ED & Medicine	Stephanie Denson: Manager, Medical Staff Office	2/27/2025
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	2/7/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/28/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	1/28/2025
Policy Owner	Sul Jung: Associate Director of Pharmacy Services	1/28/2025

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PolicyStat ID: 17362612

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8/12/2019 Upon Approval N/A 3/8/2022 3 years after approval Melody Donate: Stroke Coordinator Administrative - Patient Care

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

100.232 Code Stroke - Intravenous t-PA (Alteplase) Administration

POLICY:

To improve patient outcomes by establishing guidelines for the prompt treatment of strokes, including Ischemic stroke, with consideration of Intravenous t-PA (alteplase) for patients who present to Ventura County Medical Center (VCMC) or Santa Paula Hospital (SPH). A Registered Nurse (RN) from the Emergency Department (ED) or Intensive Care Unit (ICU) is responsible for the timely administration of t-PA. An RN may prepare intravenous t-PA (alteplase) at SPH if the pharmacy is closed.

PROCEDURE:

Critical Elements

Usual Dosage Range and Route:

- 1. Verify that the attending physician has reviewed the inclusion/exclusion criteria and consulted with VCMC Neurology attending and/or telemedicine neurology consultant.
- 2. Verify that administration will start within 4.5 hours of symptom onset or time last known well.
- 3. t-PA (alteplase) dose is 0.9 mg/kg to a maximum of 90 mg.
 - First 10% of calculated dose given as intravenous bolus dose.
 - Remaining 90% of calculated dose given in an infusion over 1 hour.
- 4. Document NIH Stroke Score before and after t-PA.
- 5. During t-PA infusion: Vital signs/neuro checks every 15 minutes for 2 hours, then every 30 minutes for 6 hours, then every hour for 16 hours (24 hours total).
- 6. If the patient's neurologic status declines during the t-PA infusion, stop infusion and page the Stroke Neurologist and/or attending physician (prepare for emergent CT as ordered).

Equipment:

- 1. One (1) vial of t-PA (alteplase)100 mg or two vials of t-PA (alteplase) 50 mg each
- 2. One (1) 10 mL syringe
- 3. Two (2) 19-guage needles

- 4. One (1) blunt cannula
- 5. One (1) mini-spike
- 6. Standard pump tubing
- 7. Intravenous infusion pump
- 8. 50 mL bag of 0.9% sodium chloride
- 9. Alcohol wipes
- 10. Two (2) patient labels
- 11. Two (2) medication labels

Administration Protocol:

- 1. It is appropriate to mix t-PA prior to CT even if not used: See below procedure for return t-PA that is mixed but not administered.
- 2. Verify the bolus dose, infusion dose and discard dose with the Stroke Neurologist or attending physician.
- 3. For patients at SPH, reconstitute the vial of t-PA with the supplied preservative-free water.
 - a. Direct stream of water into lyophilized cake
 - b. Swirl but DO NOT SHAKE (slight foaming is common)
 - c. Let stand several minutes to allow large bubbles to dissipate
 - d. Final concentration is 1 mg/mL
 - Using a 10 mL syringe, withdraw the bolus dose directly from the alteplase bottle. See attached dosing sheet (Attachment A) for bolus dose based on patient weight. Fill out patient/medication label with all required information (patient name, medication, dosage, time, date, RN Signature). Write "BOLUS DOSE" and affix label to syringe.
 - Enlist a second RN to complete an Independent Double Check of medication, bolus dose, infusion dose, infusion rate and discard dose.
 - · Administer bolus dose via intravenous push method over one minute
 - Document administration of bolus dose on Medication Administration Record in EMR including time, dose, route, initials and signature.
 - Fill out patient/medication label with all required information (patient name, medication, dosage, time, date, RN signature). Write "INFUSION DOSE" and affix label to alteplase bottle.
 - Draw waste dose from bottle and verify waste amount by verifying with second RN completing an Independent Double Check.
 - Connect alteplase bottle to IV Pump tubing, carefully priming to avoid discarding any medication.
 - Verify patency of IV site and tubing connections.
 - Verify that all ordered blood work has been drawn and sent.
 - Attach noninvasive blood pressure cuff to other arm.
 - Set infusion pump rate according to dosing sheet and start infusion with a total infusion of 1 hour. Document infusion start time and name of ordering neurologist/attending physician.

- When pump alarms "no flow above", there is still some t-PA left in the tubing which must be infused. Remove the IV Tubing connector from the alteplase bottle and attach it to a newly spiked 50 mL bag of 0.9% sodium chloride. Continue the infusion until the preset volume is completed.
- Document the end time of infusion. Expect to see significant volume remaining in 50 mL 0.9% sodium chloride bag.
- 4. For patients at VCMC, the Pharmacy will provide the reconstituted and labeled bolus dose and infusion dose of t-PA.
 - Enlist a second RN to complete an Independent Double Check of medication, bolus dose, infusion dose and infusion rate.
 - Administer bolus dose via intravenous push method over one minute.
 - Document administration of bolus dose on Medication Administration Record in EMR including time, dose, route, initials and signature.
 - Connect alteplase infusion dose to IV Pump tubing, carefully priming to avoid discarding any medication.
 - Verify patency of IV site and tubing connections.
 - · Verify that all ordered blood work has been drawn and sent.
 - Attach noninvasive blood pressure cuff to other arm.
 - Set infusion pump rate according to dosing sheet and start infusion with a total infusion of one
 (1) hour. Document infusion start time and name of ordering neurologist/attending physician.
 - When pump alarms "no flow above", there is still some t-PA left in the tubing which must be infused.
 Remove the IV Tubing connector from the alteplase bag and attach it to a newly spiked 50 mL bag of 0.9% sodium chloride. Continue the infusion until the preset volume is completed.
 - Document the end time of infusion. Expect to see significant volume remaining in 50 mL 0.9% sodium chloride bag.

Precautions and Side Effects:

- 1. Hemorrhage (GI, GU, catheter puncture site, intracranial, retroperitoneal, pericardial, gingival, epistaxis)
- 2. New ischemic stroke
- 3. Bruising
- 4. Anaphylaxis
- 5. Laryngeal edema
- 6. Rash, urticaria

Protocol for Returning Unused Medication:

When t-PA is mixed, but not administered, or the packaging is damaged, the reconstituted and unused t-PA shall be returned to the Pharmacy for credit from the drug manufacturer.

- If t-PA is removed from Pyxis but not reconstituted and the packaging is intact, place in unit bin for return to Pharmacy.
- If t-PA is reconstituted or the packaging is not intact and the medication was not used, place a patient identification label on any container holding reconstituted drug (t-PA bottle, syringe, IV bag or IV tubing.

Remove blunt cannula or needles from syringes). Place containers in a plastic bag if necessary to prevent spillage and place in Pharmacy bin on unit for return.

Monitoring and Care during after t-PA Infusion:

- 1. Vital signs and neurological checks:
 - · Every 15 minutes for 2 hours after starting infusion
 - Then every 30 minutes for 6 hours
 - Then every 60 minutes for 16 hours
- 2. Monitor blood pressure closely and notify physician of systolic blood pressure above 180 mmHg and/or diastolic blood pressure above 105 mmHg.
- 3. Nothing by mouth (NPO) until swallow screen has been performed and patient passes the swallow screen.
- 4. Bed rest.
- 5. Strict recording of intake and output.
- 6. Avoid placement of NG tubes, bladder catheters or intra-arterial lines within 24 hours of t-PA treatment.
- 7. Intramuscular injections should be avoided in the immediate 24 hours after completing t-PA infusion.
- 8. Follow physician order for follow-up non-contrast head CT scan at 24 hours post treatment before starting anticoagulants or antiplatelet drugs.

Competency to Respond to a Call for t-PA:

Competency of each nurse to be completed as follows:

- 1. Prior to responding to a Code Stroke, ED and ICU RNs will be oriented on the preparation and administration procedure for t-PA during a Code Stroke.
- 2. After the orientation, each RN will complete a skill competency, successfully demonstrating and understanding the procedure (see Attachment B).
- 3. t-PA competency will be re-evaluated yearly.

All revision dates:

3/8/2022, 8/12/2019

Attachments

- Attachment A: t-PA Dosing Chart for Stroke Patients
- Attachment B: t-PA Assessment and Competency

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Committees:	Stephanie Denson: Manager, Medical Staff Office	2/27/2025

Approver	Date
Sul Jung: Associate Director of Pharmacy Services	2/7/2025
Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/14/2025
Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	1/14/2025
Melody Donate: Stroke Coordinator	1/14/2025
	Sul Jung: Associate Director of Pharmacy Services Danielle Gabele: Chief Nursing Executive, VCMC & SPH Sherri Block: Associate Chief Nursing Executive, VCMC & SPH



VENTURA COUNTY

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11/10/2021 Upon Approval N/A 1/24/2025 3 years after approval Danielle Gabele: Chief Nursing Executive, VCMC & SPH Administrative - Patient Care

HEALTH CARE AGENCY Policy Area: References:

100.257 Malignant Hyperthermia Cart Restocking Process

POLICY:

Malignant Hyperthermia (MH) Cart checks and the restocking process is essential to the access of supplies needed, in the event of patients with a potentially lethal syndrome caused by a hypermetabolic response of the skeletal muscle. This can be triggered in susceptible individuals by volatile inhalation agents and succinylcholine.

See policy <u>100.097 Malignant Hyperthermia</u> for assessment and treatment for malignant hyperthermia.

PROCEDURE:

Malignant Hyperthermia Cart Overview

- A. MH Carts must have the listed contents visible on the outside of the cart (see Attachment A Malignant Hyperthermia Cart Medication and Supply List).
- B. MH carts must be locked with a red, serially-numbered, breakable lock at all times.
- C. MH carts must be easily accessible to Department Personnel.
- D. Malignant Hyperthermia Carts shall be located in the following locations:

Malignant Hyperthermia Cart Locations			
Hospital	Unit Location	IV Fluids	Insulin, regular vials
Ventura County Medical Center (VCMC)	NT OR <u>Core</u> (near IR)	NT OR Core Refrigerator	NT OR Core Refrigerator
	NT OR CS	Main Pharmacy	Main Pharmacy
	Central Supply (replacement cart only)	Non-applicable (N/A)	N/A
Santa Paula Hospital (SPH)	1 0R	1OR Pyxis Refrigerator	1OR Pyxis Refrigerator
	Central Supply (replacement cart only)	N/A	N/A

<u>NT LDR Pyxis Refrigerator</u> (Outside the C-Section OR suite on 2nd floor)	<u>NT OR</u>	
Main Pharmacy Fridge (replacement fluids only. No cart)	<u>Main Pharmacy</u> <u>Fridge</u> <u>(replacement insulin</u> <u>only. No cart)</u>	_
1OR Core	<u>1OR Core Pyxis</u> Refrigerator	<u>10R Core Pyxis</u> Refrigerator
<u>Central Supply</u> (replacement cart only. No meds)	Non-applicable (N/A)	<u>N/A</u>
	(Outside the C-Section OR suite on 2nd floor) Main Pharmacy Fridge (replacement fluids only. No cart) 1OR Core Central Supply (replacement cart only. No	(Outside the C-Section OR suite on 2nd floor)Main Pharmacy Fridge (replacement fluids only. No cart)Main Pharmacy Fridge (replacement insulin only. No cart)1OR Core10R Core Pyxis RefrigeratorCentral Supply (replacement cart only. NoNon-applicable (N/A)

Delivery Room; CS=C-section

Malignant Hyperthermia Cart Checking

A. Department Personnel

- 1. Complete the MH cart checklist once every calendar day and upon replacement of the cart following use (See Attachment B Malignant Hyperthermia Cart Checklist).
 - a. Examine the external red, serially-numbered breakable lock to ensure it is intact.
 - b. Record the lock number on the checklist.
 - c. Check expiration dates of central supply items and medications.
 - d. Record the expiration date of the item that is due to expire first on the checklist.
 - e. Ensure that the bucket for ice is located on top of the cart and indicate that it is present on the checklist.
 - f. After completing the checklist, the Department Personnel must sign the sheet.
- 2. Checking the MH cart in advance of the calendar day is not permitted.
- 3. For replacement carts, document the new lock number and time in the "Remarks/Corrections" section of the checklist.

B. Pharmacy Department

- 1. A Pharmacist shall inspect the MH cart for expired medications every month.
- 2. The Pharmacist shall break the red, serially-numbered lock and visually inspect the medications within the MH cart.
- 3. Any MH cart medications that are expiring or medications that will be expiring in the current and/or following month shall be replaced.
- 4. Replace the red, serially-numbered lock to secure the MH cart.
- 5. The Pharmacist shall apply a new medication sticker to the outside of the MH cart and record the following:

- a. New lock number
- b. Name of the medication that is due to expire first
- c. Expiration date
- d. Initials of the inspecting Pharmacist
- 6. The Pharmacist shall record the date of the inspection and the new MH cart lock number on the daily checklist.

Malignant Hyperthermia (MH) Cart Replacement

- A. MH carts shall be replaced after a crisis event or if a supply item or medication in the cart has expired.
- B. For expired supply items, **Department Personnel** are responsible for the following:
 - 1. The MH cart binder shall be removed from the cart before leaving the unit.
 - 2. The MH cart shall be taken to pharmacy by licensed personnel to drop off the medications.
 - 3. The MH cart shall then be delivered to Central Supply and a replacement MH cart retrieved.
 - 4. Transport the replacement MH cart back to Pharmacy for medications.
 - 5. Once the Pharmacy process is complete, the MH cart is ready for its final destination. Place the MH binder on the MH cart and document the new red lock number under "remarks/corrections" section of the MH cart checklist.
- C. For expired medications, Department Personnel are responsible for the following:
 - 1. The MH cart binder shall be removed from the cart before leaving the unit.
 - 2. The MH cart shall be taken to pharmacy by licensed personnel.
 - 3. Pharmacy shall replace the medication(s) and secure the cart with a new red, serially-numbered lock.
 - 4. Once the Pharmacy process is complete, the MH cart is ready for its final destination. Place the MH binder on the MH cart and document the new red lock number under "remarks/corrections" section of the MH cart checklist.

D. Central Supply

- 1. A replacement MH cart is available in Central Supply. The cart is fully stocked with in-date supply items and does not contain medications.
- 2. Central Supply shall restock any returned MH cart.
 - a. Check for and replenish used supplies
 - b. Check for and replace any expired equipment and supplies
 - c. Check proper function of mechanical devices
- 3. Central Supply shall secure the MH cart with a lock to indication that the supplies and equipment have been checked and replenished.
- 4. A new MH cart sticker shall be applied to the outside of the MH cart with the following:
 - a. Name of the supply item due to expire first

- b. Expiration date
- c. Initials of the person who restocked the MH cart

E. Pharmacy Department

- 1. Pharmacy staff shall open the MH cart by breaking the red lock unless already broken (e.g. carts used in a crisis event).
- 2. Pharmacy staff shall remove all medications to enable the MH cart to be processed by Central Supply if indicated.
 - a. In the event the MH cart was used for a crisis event, the patient shall be charged for any medications administered.
- 3. Medications shall be checked, replenished, and initialed by a Pharmacy technician or Pharmacist.
 - a. At VCMC only, the Kitcheck Program shall be used.
 - b. Medication expiration dates are noted on the billing sheet and placed within the medication section of the MH cart (See Attachment C Malignant Hyperthermia Billing Sheet).
- 4. The Pharmacist shall check the medications for accuracy of contents and expiration.
- 5. The Pharmacist shall secure the replacement MH cart with a red, serially-numbered lock. These red locks are stocked and controlled by the Pharmacy Department only.
- 6. The Pharmacist shall apply a new medication sticker to the outside of the MH cart and record the following:
 - a. New lock number
 - b. Name of the medication to expire first
 - c. Expiration date
 - d. Initials of the Pharmacist
- 7. The MH cart is now ready for delivery to its final destination.

All revision dates:

1/24/2025, 3/8/2022, 11/10/2021

Attachments

- Attachment A Malignant Hyperthermia Cart Medication and Supply List
- Attachment B Malignant Hyperthermia Cart Checklist
- Attachment C Malignant Hyperthermia Cart Medication Billing Sheet

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	2/19/2025

Step Description	Approver	Date
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	1/24/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/24/2025
Policy Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/24/2025



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HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

100.275 Vasopressor Intravenous Administration through Peripheral Line

<u>Policy</u>

The administration of vasopressors may be infused intravenously through peripheral intravenous lines when a central intravenous line is not available.

Background

Vasopressors are used in the setting of hypotension to maintain physiologic hemodynamic parameters. A large international database study found that every one hour delay in vasopressor initiation was associated with a 7% increase in mortality.¹ Hence, the updated sepsis guideline by the Surviving Sepsis Guideline of 2016 recommends the use of vasopressor earlier if needed – within 1 hour of recognition of septic shock.² Central line placement is recommended with the use of vasopressor due to the risk of extravasation. However, central line placement is associated with adverse events such as failure to obtain line, vascular injury, pneumothorax, hemothorax, air embolism, cardiac arrhythmias, hematoma formation, brachial plexus/ neural injury, and higher rate of central-line associated blood stream infection compared to peripheral intravenous line (PIV).³ Use of a PIV for the administration of vasopressors may benefit the patient by shortening the time to administration of important hemodynamic stabilizing medication and leading to faster clinical benefits.

Procedure

- A. Only one vasopressor may be used for PIV administration. Administration of more than one vasopressor requires placement of a central line.
- B. The following conditions must be met prior to administering any vasopressor through a PIV:
 - 1. Patient must have two (2) working PIV in place.
 - 2. PIV for vasopressor use ideally will be placed in upper extremity contralateral to the blood pressure cuff. Do not use lower extremity PIVs to infuse vasopressors.
 - 3. The antecubital fossa and veins next to joints, tendons, nerves, or arteries should be avoided as well as any IV

sites requiring more than 1 venipuncture.

4. Intravenous line size 20 gauge or larger.

- 5. Confirm blood return from the PIV access prior to starting vasopressor.
- 6. Clearly label the PIV at the site of connection indicating use of line dedicated to peripheral vasopressor.
- 7. Do not use a deep peripheral line (ultrasound guided) catheter > 1.75 inches long.
- 8. PIVs that are proximal to the antecubital fossa may not be used for vasopressors.
- 9. Emergent situation allowable exceptions: Any upper extremity standard length peripheral line is acceptable until patient is stable to obtain a line described from 1-8.
- C. The following vasopressors, concentrations and maximum doses are permitted for PIV administration. Doses higher than listed maximum infusion rates may temporarily be administered while actively obtaining central line.
 - 1. Licensed practitioner (LP) must use hospital approved order set (Adult IV Titratable Medication Vasoactive) and specifies the route of administration as via PIV.

Medication	Concentration	Recommended maximum dose	
Norepinephrine	4 mg/250 mL	15 mcg/min	
Dopamine 400 mg/250 mL 10 m		10 mcg/kg/min	
Phenylephrine	25 mg/250 mL	240 mcg/min	
Epinephrine	2 mg/250 mL	10 mcg/min	

- D. Assess PIV every shift and as needed for patency by blood return and/or ease of flushing without resistance.
- E. The PIV site used to administer vasopressors must be monitored for signs and symptoms of extravasation every two (2) hours and documented under "Infiltration Score" on the nursing flow sheet.
 - 1. Signs and symptoms to monitor:¹
 - a. Signs: Swelling, redness or blanching, blister formation, unexplained reduced IV flow rate, necrosis (2-4 days later), ulceration
 - b. Symptoms: Tightness, burning, pain or aching tingling sensation, itchiness
 - 2. Infiltration Score on electronic health record (EHR):

Adult Lines - Devices Infiltration Score		tion Score		
1	Peripheral IV		Grade	Clinical Criteria
	Central Line		0	No symptoms of infiltration
~	Arteriovenous Access PCA Warming/Cooling Anesthesia	A Peripheral IV	1	Skin blanched, edema is less than1 inch ir any direction, cool to touch, with or without pain
	Pertoneal Dialysis Cath	Forearm Over the need Forearm Over the need Activity	2	Skin blanched, edema less than 1-6 inche in any direction, cool to touch, with or without pain
		Response to Activity Number of Attempts Site Condition Drainage Description Infiltration Score	3	Skin blanched or translucent, gross edem greater than 6 inches in any direction, cod to touch, mild to moderate pain, possible numbness
		Care	4	Skin blanched or translucent, skin tight, leaking, skin discolored, bruised, swollen, gross edema greater than 6 inches in any direction, deep pitting tissue edema, circulatory impairment, moderate to severe pain, infiltration with any amount of blood, irritant, vesicant

- F. Duration of administration of vasopressor through a PIV should be re-assessed every 24 hours. The reason for duration greater than 24 hours must be documented in the EHR by the licensed practitioner (LP) (progress note).
- G. Nursing staff shall immediately alert the medical team if extravasation of vasopressor is suspected or occurs. Tissue injury is defined as erythema, blistering, skin breakdown, or necrosis in the site of extravasation. Treatment of extravasation shall be initiated immediately. See Extravasation policy (100.250 Management of Extravasation/Infiltration Due to Non-Chemotherapy Medication Administration)
- H. An Adverse Drug Reaction form must be completed and reviewed by the ICU committee and P&T Committee.

Reference:

1. Lewis T, Merchan C, Altshuler D, Papadopoulos J. Safety of the peripheral administration of vasopressor agents. Journal of intensive care medicine. 2019 Jan;34(1):26-33.

2. Rhodes A, Evans LE, Alhazzani W, Levy MM, Antonelli M, Ferrer R, Kumar A, Sevransky JE, Sprung CL, Nunnally ME, Rochwerg B. Surviving sepsis campaign: international guidelines for management of sepsis and septic shock: 2016. Intensive care medicine. 2017 Mar 1;43(3):304-77.

3. Ballieu P, Besharatian Y, Ansari S. Safety and Feasibility of Phenylephrine Administration Through a Peripheral Intravenous Catheter in a Neurocritical Care Unit. Journal of intensive care medicine. 2019 Nov 22:0885066619887111.

4. Loubani, Osama, Green, Robert. A Systemic review of extravasation and local tissue injury from administration of vasopressors through peripheral intravenous catheter and central venous catheters. Journal of Critical Care 2015; 30:653.e9-e17.

5. Cardenas-Garcia, Jose et al. Safety of peripheral intravenous administration of vasoactive medications. *Journal of hospital medicine* 2015; 10:581-585.

6. Nguyen TT, Surrey A, Barmaan B, Miller S, Oswalt A, Evans D, Dhindsa H. Utilization and extravasation of

peripheral norepinephrine in the emergency department. The American Journal of Emergency Medicine. 2020 Jan 8.

All revision dates:

11/1/2024, 6/14/2023, 9/13/2022

Attachments

No Attachments

Approval Signatures

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Intensive Care Unit Committee	Stephanie Denson: Manager, Medical Staff Office	3/5/2025
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	1/21/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/15/2025
Intensive Care Unit	Kelly Johnson: Director, ICU/DOU/Telemetry	1/15/2025
Intensive Care Unit	Tara Paterson: Medical Director, Critical Care Services	12/7/2024
Intensive Care Unit	Sul Jung: Associate Director of Pharmacy Services	11/1/2024



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N/A Upon Approval N/A 3 years after approval Sara Pendleton: Medication Safety Officer Administrative - Patient Care

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

100.280 Medicinal Leeches

PURPOSE:

Describe the process of ordering, storing, dispensing and disposing of leeches.

Standardize the use of leeches at Ventura County Medical Center (VCMC) in compliance with medication management policies and procedures.

Ensure multidisciplinary work flows align with hospital policies and procedures.

POLICY:

Ventura County Medical Center (VCMC) appropriately orders, stores, dispenses, administers, and disposes of medicinal leeches in accordance with FDA regulations and standards for patient safety and medication use management.

- Only FDA approved medicinal leeches will be used on patients.
- Leeches shall be maintained at a period automatic replenishment (PAR) level deemed sufficient for institutional needs by the Pharmacy department.
- Leeches shall be distributed by Pharmacy to nursing units upon a prescriber order on an as needed basis for an 8 hour supply.
- Used leeches shall be disposed in a manner compliant with hospital and pharmacy standards for handling biohazardous material.

DEFINITION(S):

Leech: An amphibious parasite of the species Hirudo medicinalis that is bred for medical use.

Used Leech: Any leech that has left the confines of the distributing pharmacy for patient use regardless of whether the leech as been administered to the patient.

PROCEDURE(S):

Equipment

- 1. Medicinal Leeches
- 2. Hirudo salt

- 3. Distilled water
- 4. Dedicated transfer device
- 5. Container with wide opening and lid
 - 1. Bulk container (e.g., Leech mini mobile home LE-3100)
 - 2. Patient specific dispensing container

Styrofoam cooler with cooling measures

6. Labels

Roles and Responsibilities

Licensed Practitioner (LP)

Licensed provider shall order medicinal leeches using the Medicinal Leech order set and shall indicate the desired number of leeches, frequency, and duration of therapy.

Pharmacy

- A. Bulk Ordering/Receiving Leeches
 - 1. Pharmacy shall oversee and manage inventory levels of leeches.
 - 2. Leeches shall be ordered directly by pharmacy through an appropriate vendor.
 - 3. Pharmacy will document vendor batch number when new leech shipment is received. The batch number should follow the leeches throughout the system.

B. Storage

- 1. Temperature
 - a. Leeches shall be stored in a refrigerator (2-8° C) and light protected when not in use.
 - b. It is important to avoid direct sunlight and/or sudden changes in temperature whenever possible when transferring leeches between containers.
- 2. Salt/Water Solution
 - a. Leeches shall be maintained in an appropriate 2:1 Hirudo salt and distilled water solution
 - i. 0.5 grams of Hirudo salt into each liter of water.
 - ii. The salt/water mixture must be made as needed and not stored in advance.
 - iii. Do not keep any remaining mixture for future use.
 - b. Change the salt/water mixture every other day or more often if the water looks cloudy.
 - i. Dispose of dead leeches appropriately (see Disposal) and increase the frequency of water changes to daily.
 - ii. After three daily water changes without further leech mortality, you may return to changing the water every other day.
- 3. Container
 - a. Leeches from different batches must always be stored in separate containers.

- i. Do not mix new leeches with earlier batches or shipments.
- ii. Leeches from different batches and shipments must always be stored in separate bulk storage containers.
- b. Leeches shall be maintained in an appropriate bulk storage container until ready for dispensing.
 - i. Do not overcrowd the leeches. Follow vendors instructions for use.
 - ii. Leave room for air at the top of the mobile homes.
 - iii. Follow the vendor recommendations for the approximate capacity of leeches per mobile home. This will vary based on the size of the container.
 - iv. Label the container with the date that the water was last changed and the leech batch number.

C. Container Cleaning and Disinfection

- 1. Once leeches have been used, empty the bulk container of any remaining water.
- 2. Thoroughly rinse with distilled water.
- 3. Wash the container with a hospital approved detergent. Mix the detergent per manufacturer's instructions for use. Rinse thoroughly.
- 4. Disinfect the container with an approved disinfectant wipe (e.g., Super-SaniCloth) and allow to air dry completely. Do NOT use bleach.
- 5. After disinfectant has completely air dried, thoroughly rinse the container two times with distilled water to remove all traces of disinfectants which may harm leeches.
- 6. After rinsing twice, the bulk container may be used again for a new batch of leeches (see Storage above)

D. Repackaging and Dispensing for Administration

- 1. PPE (gloves and eye protection) shall be worn at all times when handling leeches and the containers.
- 2. Upon notification of patient specific leech order, pharmacy shall repackage leeches for transport.
- 3. Pharmacy shall repackage leeches from bulk supply into a patient specific container on demand.
 - a. Place up to 2 leeches into a single, patient specific container.
- 4. Leeches shall not be repackaged in advance of need.
- 5. Pharmacy shall label each container with a pharmacy patient label, dispense date/time, and instructions for disposal.

E. Disposal

- 1. Used leeches shall not be reused or returned to the pharmacy.
- 2. To terminate used leeches, nursing staff shall place 70% isopropyl alcohol in patient specific container with leeches and seal the container letting is stand for five (5) minutes.
- 3. After all the used leeches have been terminated, nursing staff shall ensure the container is tightly seemed before placing the container in the proper hazardous waste container for disposal.

Antimicrobial Stewardship Committee

- A. Antimicrobial Stewardship committee will review patient cases where leeches were applied.
- B. The medicinal leech order set will contain a concurrent antimicrobial prophylactic order
 - 1. Antimicrobial prophylaxis is necessary for patients using leeches.
 - 2. Recommended prophylactic regimen: Prophylaxis should begin at least one hour prior to the initiation of leech therapy and should continue while leeches are in place and for 24 hours after removal of all leeches

Nursing

See Lippincott Procedures for the handling, administration, documentation, monitoring, and disposal of medicinal leech therapy.

REFERENCE(S):

- 1. Leeches USA Medicinal Leeches Leeches USA Accessed 10/18/2024
- McCracken JA, Koehler SM, Sharma R. Rethinking antimicrobial prophylaxis in patients receiving medicinal leech therapy. American journal of health-system pharmacy. 2022;79(1):e14-e19. doi:10.1093/ ajhp/zxab330
- Palm NM, Wesolowski JC, Wu JY, Srinivas P. Implementation of a Leeches + Antimicrobial Prophylaxis Order Panel to Optimize Medicinal Leech Use at a Tertiary Care Academic Medical Center. Journal of pharmacy practice. 2022;35(3):427-430. doi:10.1177/0897190021993683
- Kruer RM, Barton CA, Roberti G, Gilbert B, McMillian WD. Antimicrobial Prophylaxis during Hirudo medicinalis Therapy: A Multicenter Study. Journal of reconstructive microsurgery. 2015;31(3):205-209. doi:10.1055/s-0034-1395395

All revision dates:

Nursing Administration

Nursing Administration

Attachments		
No Attachments		
Approval Signat	ures	
Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutic Committee	s Sul Jung: Associate Director of Pharmacy Services	2/7/2025

Sherri Block: Associate Chief Nursing Executive, VCMC & SPH

Danielle Gabele: Chief Nursing Executive, VCMC & SPH

1/23/2025

1/23/2025

Step Description	Approver	Date
Policy Owner	Sara Pendleton: Medication Safety Officer	1/23/2025



	PolicyStat ID: 17686929		
Origination:	9/1/1996		
Effective:	Upon Approval		
Last Approved:	N/A		
Last Revised:	3/3/2025		
Next Review:	3 years after approval		
Owner:	Magdy Asaad: Infection		
	Prevention Manager		
Policy Area:	Administrative - Environment of		
	Care		

HEALTH CARE AGENCY

VENTURA COUNTY

References:

106.028 Isolation Precautions

POLICY:

Isolation precautions are used to care for the patient with a transmissible infectious agent. The purpose of isolation precautions is to interrupt the transmission of disease and prevent transmission of infection to staff and other patients.

The use of isolation precautions is a two-tiered process. Standard precautions are used for all patients and the category of isolation precautions is added according to the mode of transmission of the disease.

The following policy applies unless advised/directed otherwise by Infection Prevention and/or Infectious Diseases. All Ventura County Medical Center (VCMC), Santa Paula Hospital (SPH) and hospital-based Ambulatory Care clinic staff shall follow the guidelines below which are designed to prevent transmission of organisms to patients, care providers and multi-use equipment. Multiple drug-resistant organisms (MDRO), defined by the CDC as microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents, are a threat to patient and staff health and safety. It is essential to keep these organisms contained. Compliance with the following transmission-based precaution guidelines is required to prevent transmission of organisms and enhance patient and staff safety.

See References for an alphabetical list of infectious diseases and the correct category of isolation to be used.

PROCEDURE:

Initiation of Isolation Precautions:

- 1. The nurse may initiate isolation precautions based on information obtained in the nursing assessment. The nurse then informs the physician of the need for an Isolation Precautions order.
- 2. Physician orders the appropriate isolation/precautions.
- 3. Infection Prevention department representative, Infectious Diseases physician or Infection Control Committee (ICC) Chairman may initiate isolation precautions.
- 4. Post the appropriate Isolation/Precautions sign outside the patient room.

Discontinue Isolation Precautions:

A physician's order is required.

Patient Transport

- 1. Notify receiving department of isolation status by entering the information in the electronic health record (EHR). Verbal communication must also occur with the receiving department prior to the patient's arrival.
- 2. Limit movement of the patient throughout the hospital or clinic.
- 3. When transport or movement is necessary, cover or contain the infected or colonized areas of the patient's body. Airborne and droplet isolation precautions require a surgical mask be placed on the patient.
- 4. Remove and dispose of contaminated PPE and perform hand hygiene prior to transporting patients on Contact Precautions.
- 5. Don clean PPE to handle the patient at the transport location.
- 6. Family members and visitors are required to conform to this policy and wear appropriate Personal Protective Equipment (PPE) as directed.

Airborne Precautions

Diseases requiring airborne precautions are transmitted via airborne droplet nuclei or small particles in the respirable size range carrying infectious agents.

Patient Placement

1. Place the patient in a designated negative air pressure room.

Santa Paula Hospital:

Call the Maintenance Department at 652-3219 between 0800 and 1700h. After hours, page the Maintenance Department through Paging at 652-6075.

- 2. The doors of these rooms must remain closed at all times when the rooms are being used for airborne isolation.
- 3. In the event that additional negative air pressure rooms are required, contact the nursing supervisor or the Maintenance Department.

All staff entering airborne isolation rooms shall follow the proper procedure: enter the anteroom and allow the anteroom doors to completely close. Once the green light is illuminated, staff may enter the patient room. Once in the patient room, the green light will signal that the patient room doors have completely closed.

- 1. Place the patient in a private room, until airborne isolation room is available.
- 2. Patients in airborne isolation rooms must have doors closed.
- 3. RNs should respond to pressure alarms in a timely manner. If staff is unable to deactivate the alarm, call Facilities Maintenance at ext. 6683 for assistance.

Surgery Patients: Any patient who has been placed on Airborne Isolation for suspected or diagnosed illness and has surgery will be recovered in the OR suite and then be transported to the negative pressure room with the appropriate staff.

Ambulatory Care Clinics: Each clinic has a designated room for isolation precautions.

Behavioral Health Clinics: Clinic Administrator or designee will be made aware and client or participant will be instructed to wait outside until consultation is made with trained medical personnel, the Ventura County Behavioral Health Safety Officer or Infection Control. Client or participant may be referred for medical clearance.

Respiratory Protection

- 1. Healthcare workers shall wear a N95 mask or Portable Air-Powered Personal Respiratory (PAPR) when in patient room.
- 2. Susceptible persons should not enter the room of patients known or suspected to have rubeola (measles) or varicella (chickenpox) if other immune caregivers are available.
- 3. Visitors shall wear a surgical mask. Visitors may be offered respiratory protection (i.e., N95) and should be instructed on the use of the respirator before entering an Airborne Illness Isolation (AII) room.

Droplet Precautions

Diseases requiring droplet precautions are transmitted a short distance, approximately three (3) feet, from the respiratory tract of infectious individuals to susceptible mucosal surfaces of the recipient.

Patient Placement

- Patients on droplet precautions should be placed in a private room.
- Cohorting only after discussion with Infection Prevention.

Respiratory Protection

• Wear a surgical mask.

Contact Precautions

Diseases requiring contact precautions are transmitted by infectious agents via direct and indirect contact with the patient or their environment.

Isolation supplies (PPE's, masks, etc.) are now kept in hallways closets adjacent to patient rooms.

Gloves and gown

- 1. Gloves and gown must be worn upon entering the room.
- 2. Gloves and gown must be removed immediately upon exiting the room.
- 3. Perform hand hygiene after removal of gloves and gown.

Hand Hygiene and the Patient with Clostridium Difficile Infection:

- 1. Wash hands with soap and water.
- 2. Do not use alcohol gel for hand hygiene.
- 3. Use the Contact Precautions sign with the brown color for patients with Clostridium difficile infection.

Patient Care Equipment

- 1. Do not share patient care equipment.
- 2. Return to the designated department for cleaning and disinfection.

Room Cleaning After Discharge

Proper cleaning and disinfection of the patient's room after discharge is important to prevent the spread of infection from a contaminated environment. Inspection of the mattress for intactness between patients is also recommended.

- 1. Isolation sign remains outside of the room after discharge.
- 2. The room is thoroughly cleaned, and then disinfected using the hospital-approved disinfectant (e.g. bleach-based disinfectant for Clostridium difficile).
- 3. The housekeeper reverses the isolation sign in its holder so that nursing staff know the room has been cleaned and disinfected and is ready for the next patient.

Multi-Drug Resistant Organism (MDRO) Isolation Quick Sheet

	Current Infection WITH Active Drainage/ Excretions	Current Infection WITHOUT Active Drainage/Excretions	Colonization	History of
Methicillin-Resistant Staphylococcus Aureus (MRSA)	\checkmark			
Candida Auris (CAURIS)	*	✓	✓	✓up to4years
Carbapenem-Resistant Enterobacteriaceae (CRE)	✓	✓	✓	✓ up to 1 year
Vancomycin-Resistant Enterococcus (VRE)	√			
Resistant pseudomonas, <u>Carbapenem-Resistant Pseudomonas</u> <u>aeruginosa (CRPA),</u> resistant acinetobacter spp, or resistant stenotrophomonas spp	✓			
Extended-Spectrum Beta-Lactamase (ESBL)				

Candida Auris Screening and Isolation

Screen patients coming from high acuity post-acute care facilities including long-term acute care hospitals [LTACHs] and ventilator-capable skilled nursing facilities [vSNFs]) if they are admitted to ICU unit.

Empiric contact isolation should be applied on admission of those patients pending screening results.

Consider screening such patients if they have high risk and admitted to other location.

Patients with risk factors for acquiring C. auris, including:

- mechanical ventilation
- indwelling medical devices, including central lines, feeding tubes, urinary catheters, etc.
- · receipt of complex or high acuity medical care
- · frequent or long healthcare stays, especially at high-risk facilities

106.028 Isolation Precautions. Retrieved 3/5/2025. Official copy at http://vcmc.policystat.com/policy/17686929/. Copyright ©Page 4 of 62025 Ventura County Medical System

· colonization or infection with other multidrug-resistant organisms

Extended-Spectrum Beta-Lactamase (ESBL): No Isolation needed

Clostridioides difficile: Contact precautions are required until 48 hours after resolution of all symptoms (fever, abdominal pain, and diarrhea)

Diarrhea for *Clostridioides difficile* testing is defined as 3 or more watery stools in a 24 hour period). Only stool corresponding to 6 or 7 on the Bristol Stool Chart will be accepted by the laboratory for C. difficile testing.

Other MDRO's: As identified by Infection Control Committee.

Personal protective Equipment (PPE) utilization for care of all patients under Standard Precautions:

- Wear gloves when anticipating contact with blood or other potentially infectious materials, mucous membranes, or nonintact skin, or potentially contaminated intact skin.
- Change gloves and sanitize hands during patient care if the hands will move from a contaminated bodysite (e.g., perineal area, wound) to a clean body-site (e.g., face).
- Wear a gown to protect skin and prevent soiling or contamination of clothing during procedures and patient-care activities when contact with blood, body fluids, secretions, or excretions is anticipated
- Use PPE to protect the mucous membranes of the eyes, nose and mouth during procedures and patientcare activities that are likely to generate splashes or sprays of blood, body fluids, secretions and excretions. Select masks, goggles, face shields, and combinations of each according to the need anticipated by the task performed. If a patient is coughing, use a mask.
- During aerosol-generating procedures (e.g., bronchoscopy, suctioning of the respiratory tract [if not using in-line suction catheters], endotracheal intubation) in patients who are not suspected of being infected with an agent for which respiratory protection is otherwise recommended (e.g., M. tuberculosis, SARS or hemorrhagic fever viruses), wear one of the following: a face shield that fully covers the front and sides of the face, a mask with attached shield, or a mask and goggles (in addition to gloves and gown)

Contact Precautions

MRSA - methicillin resistant staph aureus

VRE - Vancomycin Resistant Enterococcus faecium, Enterococcus faecalis

CRE - Carbapenamen Resistant Escherichia coli and/or Klebsiella pneumoniae

Acinetobacter baumanii - multidrug resistant

Stenotrophomonas maltophilia - multidrug resistant

Clostridium difficile – Enteric Contact Precautions

If there is any evidence of multidrug resistance with any other organisms, please contact the Infectious Disease physician for guidance. In addition, continue isolation practices for other communicable diseases according to policy.

References:

- Centers for Disease Control and Prevention <u>CDC Isolation Transmission-Based Precautions Guidelines</u>
- Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory

Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings <u>https</u>://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html.

 Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, Healthcare Infection Control Practices Advisory Committee (HICPAC) Management of Multidrug-Resistant Organisms in Healthcare Settings 2006; <u>https</u>://www.cdc.gov/infectioncontrol/ guidelines/mdro/Last update: February 15, 2017.

	3/3/2025, 6/11/2024, 7/31/2020, 9/17/2019, 6/13/
All revision dates:	2019, 5/1/2016, 11/1/2013, 2/1/2012, 7/1/2011, 9/1/
	2008, 5/1/2006, 12/1/1999

Attachments

No Attachments

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	3/3/2025
Policy Owner	Magdy Asaad: Infection Prevention Manager	3/3/2025



PolicyStat ID: 15076551 Origination: 3/9/2021 Effective: Upon Approval Last Approved: N/A 7/29/2024 Last Revised: Next Review: 3 years after approval Owner: Danielle Gabele: Chief Nursing Executive, VCMC & SPH Policy Area: Administrative - Operating **Policies**

HEALTH CARE AGENCY

VENTURA COUNTY

References:

107.073 Bed Crisis/Census Alert

POLICY:

An overflow plan may be enacted when it is felt patient care demands cannot be met safely due to physical capacity, equipment, supplies and/or staffing limitations. The alert may be enacted specific to an individual unit, service, or the organization.

The priority will always continue to be providing safe care. This may mean that some care may be omitted or decreased in frequency to assure required care needs are met.

The priority will always continue to be providing safe care. This may mean that some care may be omitted or decreased in frequency to assure required care needs are met.

PROCEDURE:

A. Initiation -

- Initiation of the alert will be at the direction of the Chief Medical Officer (CMO) or the Administrator on Duty (AOD).
- The initiation of the alert will be based upon a variety of factors which may include but not be limited to the following:

1. More than 8 - 10 patients holding without hold nurses; or 8 - 10 patients boarding with hold nurses with high acuities (e.g. ICU, DOU).

2. More than 12 holds with hold nurses.

3. Number of PACU admits to be placed in comparison to beds available.

B. Communication -

The Hospital Operator will be directed by the CMO or AOD to send the following alert:

"Bed Crisis: ___X___ patients holding in the ED. Please address discharges first thing this morning. Attending physicians please assist teams in expediting discharges."

To the following individuals:

- Medicine Residents
- Surgery Residents

- Orthopedic Residents
- The five (5) attending physicians for the Inpatient Medicine teams
- The General Surgery attending on service
- The Orthopedic Surgery attending on service
- The Neurosurgery attending on service
- The ICU Intensivists on service.
- A. Initiation -
 - Initiation of the alert will be at the direction of the Chief Medical Officer (CMO) or the Administrator on Duty (AOD).
 - The initiation of the alert will be based upon a variety of factors which may include but not be limited to the following:
 - 1. More than 8 10 patients holding without hold nurses; or 8 10 patients boarding with hold nurses with high acuities (e.g. ICU, DOU).
 - 2. More than 12 holds with hold nurses.
 - 3. Number of PACU admits to be placed in comparison to beds available.
- B. Communication -

The Hospital Operator will be directed by the CMO or AOD to send the following alert:

"Bed Crisis: X patients holding in the ED. Please address discharges first thing this morning. Attending physicians please assist teams in expediting discharges." To the following individuals:

- <u>Medicine Residents</u>
- <u>Surgery Residents</u>
- Orthopedic Residents
- The five (5) attending physicians for the Inpatient Medicine teams
- The General Surgery attending on service
- <u>The Orthopedic Surgery attending on service</u>
- The Neurosurgery attending on service
- The ICU Intensivists on service.
- <u>Case Management Director and Supervisor</u>
- C. Next Steps
 - <u>Ancillary services leaders will reprioritize work to see patients who require services to be</u> <u>discharged.</u>
 - Medicine and surgery teams postpone teaching rounds until after discharge rounds are complete.
 - <u>Housekeeping: triage room requests in collaboration with nursing supervisor to ensure rooms are</u> <u>turned over in order of need.</u>
 - <u>Unit Medical Office Assistants (MOA) work with case management to coordinate transportation for</u> any patients with discharge orders for whom rides are not immediately available.

The Medical Staff Office at the direction of the Chief Medical Officer (CMO) or designee will notify medical staff chairs, medical staff leadership and hospitalists to assist in early disposition and discharge of patients.

All revision dates:

7/29/2024, 3/9/2021

Attachments

No Attachments

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Hospital Administration	Minako Watabe: Chief Medical Officer, VCMC & SPH	1/15/2025
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	8/5/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/29/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/29/2024
Policy Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/29/2024



PolicyStat ID: 17574467 **Origination:** 3/21/2019 Effective: Upon Approval Last Approved: N/A Last Revised: 3/21/2019 Next Review: 3 years after approval Owner: Sherri Block: Associate Chief Nursing Executive, VCMC & SPH Administrative - Nursing

HEALTH CARE AGENCY Policy Area:

VENTURA COUNTY

References:

108.034 Labeling of IV/Central Line/Arterial Line Sites and IV Tubing and Fluids

POLICY:

To direct the nursing practice of Ventura County Medical Center, Santa Paula Hospital and Ambulatory Care clinics, in collaboration with Infection Prevention and based on the Centers for Disease Control and Prevention (CDC) and Infusion Nurses Society (INS)recommendations, on the process of labeling any catheter insertion, dressing change and IV tubing (see Attachment A).

PROCEDURE:

Equipment:

· Labels

Therapy Types: Peripheral intravenous Intravascular (PSV), Arterial, Central Venous

1. IV administration set priming:

Select the correct label in accordance to the date it must be replaced as indicated by the type of infusate and Lippincott Nursing Practice Guidelines. Write in the initiation date, time and your initials on the label.

2. IV bag preparation:

Label the bag with the patient's name and identification number, the date and time of initiation, the bag number (if applicable), the ordered rate and your initials.

3. IV solution change:

Label the new IV solution container with the date, time, and your initials of change/initiation.

4. IV administration set (tubing) change:

Select the correct label in accordance to the date it must be replaced as indicated by the type of infusate and Lippincott Nursing Practice Guidelines. Write in the initiation date, time and your initials on the label.

5. IV secondary line drug infusion:

Select the correct label in accordance to the date it must be replaced as indicated by the type of infusate and Lippincott Nursing Practice Guidelines. Write in the initiation date, time and your initials on the label.

Dressing Change(s)

Transparent semipermeable dressings should be changed every 5 to 7 days, and gauze dressings

should be changed every 2 days. If signs and symptoms of infection are present or if the dressing becomes visibly soiled, loosened, or dislodged, an immediate dressing change is necessary to closely assess, clean, and disinfect the site.

- 1. **Central venous tunneled and non-tunneled catheter dressing change:** Label the dressing with the date, time and your initials on the date you changed the dressing.
- 2. **IV dressing change:** Label the dressing with the date, time and your initials on the date you changed the dressing.
- 3. **Peripherally inserted central catheter (PICC) dressing change:** Label the dressing with the date, time and your initials on the date you changed the dressing.
- 4. Wound dressing change: Label the dressing with the date, time and your initials on the date you changed the dressing.

REFERENCES:

- 1. O'Grady, N.P., Alexander, M., Burns, L.A., Dellinger, E.P., Garland, J., Heard, S.O., . . . Healthcare Infection Control Practices Advisory Committee (HICPAC). (2011). Guidelines for the prevention of intravascular catheter-related infections, 2011.
- Safe Injection Practices to Prevent Transmission of Infections to Patients, Injection Safety | CDC. This
 page illustrates Sections III.A.1.b, III.A.1.c, IV.H, and IV.I from the 2007 Guideline for Isolation
 Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.
- 3. Standard 41. Vascular access device (VAD) assessment, care, and dressing changes. Infusion therapy standards of practice. (2016). Journal of Infusion Nursing, 39, S81–S84. (Level VII)
- 4. Groski, L, Hadaway, L, Hagle, ME, McGoldrick, M, Orr, M, & Doellman, D. (2016). Infusion therapy standards of practice. J Infus Nurs, 39

All revision dates:

3/21/2019

Attachments

No Attachments

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	2/15/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	2/11/2025
Policy Owner	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	2/11/2025

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Policy Area:

PolicyStat ID: 17417582

3/14/2023 Upon Approval N/A 1/17/2025 3 years after approval Sharon Waechter: Clinical Nurse Manager, Nursing Education Administrative - Nursing

VENTURA COUNTY

HEALTH CARE AGENCY Policy Area: References:

108.044 Clinical Implementation Guide for: Electrocardiogram Guided Tip Confirmation System During Peripherally Inserted Central Catheter Placement

POLICY:

To provide guidelines to facilitate standardization of practice for insertion by Registered Nurses (RN) of Peripherally Inserted Central Catheter (PICC) using Electrocardiogram (ECG) Guided catheter tip confirmation.

SCOPE:

- 1. This applies to RNs at Ventura County Medical Center who have successfully completed population appropriate training and demonstrated competency in Vascular Access device insertion, care and maintenance, patient/caregiver education across the care continuum.
- 2. RNs must also have completed the online education course on the ECG guided tip confirmation system (TCS) and yearly ECG PICC competency checkoff.

DEFINITION(S):

The ECG guided TCS is indicated for guidance and positioning of the PICC. The ECG TCS provides real-time catheter tip location information by using the patient's cardiac electrical activity. ECG TCS is indicated for use as an alternative method to chest x-ray and fluoroscopy for PICC tip placement confirmation in adult patients. Limiting but not contraindicated situations for this technique are in the patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythms. In such patients, who are easily identifiable prior to PICC insertion, the use of an additional method is required to confirm catheter tip location.

EQUIPMENT:

- 1. Sherlock 3CG Tip Confirmation System
- 2. Site Right Portable Ultrasound Machine
- 3. PICC Catheter with Sherlock 3CG Tip Positioning System (TPS) Stylet

 108.044 Clinical Implementation Guide for: Electrocardiogram Guided Tip Confirmation System During Peripherally Inserted
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 Central Catheter Placement. Retrieved 3/5/2025. Official copy at http://vcmc.policystat.com/policy/17417582/. Copyright ©
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PROCEDURE(S):

- 1. Prepare ECG Sensor:
 - a. Enter patient identification information (name, medical record number, date of birth).
 - b. Slide the fin assembly onto the sensor until fully seated and place the sensor in protective cover. Do not use excessive force when connecting or disconnecting the fin assembly to or from the sensor or equipment damage may occur.
 - c. Position sensor on patient's chest with the top of sensor above the sternal notch and centered on the sternum. Place sensor as flat as possible for best result.
 - d. Prepare and attach the external ECG electrodes to the lead wires. Ensure electrode locations are oilfree, completely dry, and on intact skin (e.g., not over open wounds, lesions, infected, or inflamed areas. Discontinue electrode use immediately if skin irritation occurs.
 - e. Attach electrodes to all the lead wires. Remove backing and press firmly onto skin at the specified locations:
 - Place BLACK electrode lead wire on patient's lower right shoulder
 - Place RED electrode lead wire on lower left side, inferior to the umbilicus and laterally along the mid-axillary line. CAUTION: Placement of the red lead wire outside of this region may result in reduced ECG performance.

2. Evaluate baseline ECGs:

- a. Turn on TCS and note external waveform.
- b. Verify that P-wave is present and identifiable and consistent on the main screen.
- c. If no persistent or regular P-wave is identified, continue with procedure utilizing magnetic tracking and external measurements followed by tip confirmation via alternative method (i.e., x-ray or fluoroscopy).
- d. Adjust ECG scale as needed to endure that entire ECG waveforms are visible in the ECG window throughout the insertion procedure.

3. Catheter Tip Guidance and Positioning

- a. Follow Tip Locating System (TLS) "Instructions for Use" for magnetic navigation.
- b. Insert catheter until the magnetic navigation shows stylet icon (Sherlock Spyglass) moving consistently downward.
- c. Continue to slowly advance the catheter until the catheter is inserted to the external measurement determined prior to insertion and/or negative P-wave deflection is noted. Do not rely on ECG signal detection for catheter tip positioning when there are no observable changes in the intravascular P-wave. In this case, rely on magnetic tracking and external measurement for tip positioning and use chest X-ray or fluoroscopy to confirm catheter tip location as per policy and clinical judgement.
- d. <u>Press the Activate</u> FREEZE <u>button function</u> on TCS. This will save the current waveform on the rightside reference screen for later comparison. Repeat as needed.
- e. SLOWLY adjust catheter tip position until the maximum P-wave amplitude is reached. Compare main screen waveform to reference screen waveform while closely monitoring for negative P-wave deflection.

- f. If negative deflection prior to P wave present, adjust catheter tip position to maximum P-wave amplitude with no negative deflection
- g. Advance or retract catheter from maximum P-wave to place tip in desired location (the cavoatrial junction of the superior vena cava).
- h. Note catheter exit site marking (centimeters from exit site to hub) and document on TCS screen.
- i. To record waveforms at the final catheter tip position, pressactivate FREEZE buttonfunction on TCS. Press the Activate "PRINT" button function to save image
- 4. PICC RN/ Vascular Access Specialist inserting the catheter will notify the RN/ provider for authorization of line use. The PICC RN/ Vascular Access Specialist may order radiograph at his or her discretion when clinically indicated. PICC RN/Vascular Access Specialist will place an order to use the vascular access device.
- 5. TCS Documentation: Upon successful insertion and TCS confirmation, the PICC RN/ Vascular Access Specialist will follow Ventura County Medical Center process to ensure the ECG waveform determining optimal tip position will be entered into the medical record.
- 6. When ECG TCS is used to determine optimal PICC tip placement in the SVC, no radiographic confirmation is required. ECG technology has been proven to be a more accurate determination of tip placement than radiographs (per INS Standards). If there is a discrepancy between tip confirmation with ECG TCS and chest X-ray (CXR) read, ECG TCS is considered to be the more accurate of the two technologies. The Vascular Access Specialist inserting the catheter may approve use of the line per policy when the appropriate change in the P wave is noted. At the time of placement, the external catheter measurement will be documented.

REFERENCES:

- a. Infusion Nurses Society (2016). Policies and Procedures for Infusion Nursing, (4th Ed.) Norwood, MA: Author
- b. BARD Access Systems (2013). Sherlock 3CG Tip Confirmation System, www.bardaccess.com
- c. Appl Health Econ Health Policy (2016). Sherlock 3CG Tip Confirmation System for Placement of Peripherally Inserted Central Catheters: A NICE Medical Technology Guidance, Megan D. www.springerlink.com

All revision dates:

1/17/2025, 3/14/2023

Attachments Image: Sherlock PICC Tip Confirmation Sheet.pdf Approval Signatures Step Description Approver Medical Staff Committees: Stephanie Denson: Manager, Medical Staff Office Family Medicine & Medicine Stephanie Denson: Manager, Medical Staff Office

ck: Associate Chief Nursing Executive, VCMC & SPH	1/21/2025
Sabele: Chief Nursing Executive, VCMC & SPH	1/21/2025
aechter: Clinical Nurse Manager, Nursing Education	1/21/2025
	Gabele: Chief Nursing Executive, VCMC & SPH /aechter: Clinical Nurse Manager, Nursing Education



PolicyStat ID: 17720312

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Policy Area:

11/4/2022 Upon Approval N/A 3/4/2025 3 years after approval Danielle Gabele: Chief Nursing Executive, VCMC & SPH Administrative - Nursing

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

108.057 Clostridium Difficile Screening and Testing

Policy and Functions to be Performed:

To provide a guideline and standardized procedure for the Registered Nurse (RN) to obtain Clostridium dificile Clostridioides difficile (C. Diff) specimen.

It is the policy of Ventura County Medical Center and Santa Paula Hospital that all standardized procedures are developed collaboratively and approved by the Interprofessional Practice Committee (IPC), whose membership consists of Physicians, Registered Nurses (RN), Pharmacists, Advanced Practice Nurses and Administrators. Standardized procedures are reviewed every three years.

To outline and define responsibility in performing interventions requiring a physician order in accordance with the California Board of Registered Nursing and the Nursing Practice Act, all approved standardized procedures will be kept in Policy Stat. The Registered Nurse, as outlined in the Nurse Practice Act, Business and Professions Code Section 2725, is authorized to implement appropriate standardized procedures or changes in treatment regimen after observing signs 3 and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and determining that these exhibit abnormal characteristics.

Nursing will utilize this procedure for all hospitalized patients presenting with diarrhea that meet the criteria as listed on the algorithm. Nursing will enter an order for C.diff PCR power plan in Cerner for those patients who meet the criteria and will follow the required steps. This protocol was developed in partnership with nursing leadership and medical staff leadership including infection prevention. All revisions will be presented to the appropriate medical staff committees for approval.

Nursing will utilize this procedure for all hospitalized patients presenting with diarrhea upon admission.

Purpose:

According to the CDC, Clostridium difficile infection (CDI) now rivals MRSA as the most common organism to cause healthcare-associated infections and is one of the most problematic pathogens in healthcare institutions. There are several infection prevention strategies to combat this spore-producing organism. This nurse-driven protocol focuses on the importance of early identification and isolation of patients with suspected CDI. Important steps to take to mitigate the potential for spread include early identification of patients presenting with diarrhea that meets the criteria as stated on the algorithm, prompt initiation of contact isolation, and prompt stool collection.

Roles and Responsibilities

- A. Scope of supervision required
 - 1. The RN is responsible and accountable to the Chief Nurse Executive or designee.
 - 2. Overlapping functions are to be performed in areas which allow for a consulting provider to be available to the RN by phone or in person.
 - 3. Provider consultation is to be obtained under the following circumstances
 - a. Emergency conditions requiring prompt medical intervention
 - b. Upon the request of the patient, RN or physician
 - c. Anytime any deviation from this procedure is necessary
- B. Requirements for the RN
 - 1. Active California RN license
 - 2. Life support certification: Basic
 - 3. Special training: formal orientation to OG/NG tube placement and maintenance with demonstrated competency validation
- C. Evaluation of the RN competence
 - 1. Initial upon hire to department: the Nurse director/delegate will assess the RN's ability to perform the procedure
 - 2. Annually: the Nurse director/delegate will evaluate the RN's ability to perform this procedure during performance review cycle
- D. All RNs are deemed competent to perform this procedure after completing initial nursing orientation upon hire. Records of orientation completion are available in the Nursing Education department.

Procedure

- A. Nursing will utilize the steps as outlined on the algorithm to direct care for patients with diarrhea. Note in addition that only stool type 6 or 7 on the Bristol Stool Scale meets criteria to be sent for C diff testing.
 RN will order C diff test under the standardized protocol order type which requires a physician or licensed practitioner (LP) co-sign.
- B. Upon admission to any VCMC or SPH department, the nurse will determine if the patient already has known C Diff infection and/or is undergoing C diff treatment, or if the patient is on stool softeners (or was within last 24 hours). If yes, the nurse does not need to collect a specimen and will just place the patient in contact isolation.
- C. In all other cases, the nurse will follow the attached algorithm to for C. diff testing. The order for test must be entered into Cerner using the workflow in the attachment.
- D. If PCR is negative, RN can discontinue contact isolation.
- A. The RN will complete an admission intake in the electronic health record (EHR) for all admitted patients. As part of this intake, the RN will ask the patient if they have had > 3 loose stools in the last 24 hours. If answer to this question is yes based on patient response or RN assessment of loose stools, the electronic health record (EHR) will generate an order for C diff PCR. As soon as possible, the specimen should be collected and sent to the lab for testing.

- B. NOTE: Loose stool is determined by the Bristol Stool scale (score 6 or 7). See attachment.
 C. If PCR is negative, RN can discontinue contact isolation. If positive, a reflex toxin test will be completed to determine colonization versus active infection.
 Document in patient chart the following:

 A. Admission intake in EHR
 B. Patient stool patterns and output
 C. Complete the lab specimen task
 D. Label the specimen appropriately with patient identifying information
 - E. Other details as appropriate.

All revision dates: 3/4/2025, 1/10/2025, 1/2/2024, 11/4/2022

Attachments

Attachment C: Bristol Stool Form Scale

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	3/4/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	3/4/2025
Policy Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	3/4/2025



VENTURA COUNTY

PolicyStat ID: 16172936 **Origination:** 5/15/2019 Effective: Upon Approval Last Approved: N/A Last Revised: 3/5/2025 Next Review: 3 years after approval Owner: Jessica Flanagan: Forensic Nurse Examiner Program Coordinator Ambulatory Care - Safe Harbor

HEALTH CARE AGENCY Policy Area: References:

AC.22 Forensic Victim Evidentiary Examinations by Forensic Examiner (FE)

POLICY:

The Forensic Examiner (FE) at the Forensic Examination Program shall conduct forensic examinations of adults and children who are victims of sexual assault, domestic violence, and physical abuse in accordance with the California Nursing Practice Act/ Scope of Regulation, Business and Professional Code, California Health and Safety Code 1281, Penal Code sections 13898, 13823-13823.11, and 1160; and Ventura County Healthcare Agency policies. Examination findings and evidence collected will be provided to the agency requesting and authorizing the examination (i.e., law enforcement or Child and Family Services).

PROCEDURE:

The following is the standardized procedure for the examination, documentation, treatment, and communication of findings of sexual assault, domestic violence, and child <u>sexual assault and physical abuse</u> victims.

Definitions:

- Forensic Examiner (FE): A licensed clinical person professional that has completed specialized education and clinical preparation in the medical forensic care of the patient who has experienced sexual assault or abuse.
- California State Mandated Form: State of California form used to document sexual assault detailsthe examination and findings by the Forensic Examiner, I(i.Ee., 923, 924, 925, 930, 900, 950, 502) or the electronic equivalent.
- Children and Family Services: (CFS)
- Sexually Transmitted Infection: (STI)
- Law Enforcement: (LE)
- Centers for Disease Control and Prevention: (CDC)
- Ventura County Medical Center: (VCMC)
- Violence against Women and Department of Justice Reauthorization act of 2005: (VAWA 2005)
- Ventura Family Justice Center: (VFJC)
- Safe Harbor: Location in which forensic exams may be performed

Procedure Key Points:

<u>The FE will adhere to the standardized procedure for the examination, collection of evidence, Pregnancy and STI testing, and the administration of medication (Attachment C and G).</u>

The FE will adhere to a standardized procedure for the examination, collection of evidence and the administration of prescription medication.

- A. The FE shall perform a forensic examination on a victim that presents with a complaint of sexual assault, domestic violence or child sexual <u>for</u> physical abuse and is accompanied or referred by LE, CFS or in accordance with the <u>Violence Against Women and Department of Justice Reauthorization Act of 2005</u> (VAWA 2005).
- B. The FE is required to follow the recommendations outlined in the <u>state protocolappropriate California</u> <u>State Protocol</u> when preforming an examination for collection of forensic evidence <u>https://www.ncjrs.gov/</u> <u>pdffiles1/ovw/241903.pdfand documentation</u>.
- C. The FE shall utilize state forms <u>900Cal OES 2-900</u>, <u>-</u>923, <u>924</u>, <u>-</u>930, <u>-</u>950, <u>-</u>502 <u>or the electronic</u> <u>equivalence of such forms</u> for documenting the examination. <u>For VAWA 2005 forensic exams</u>, <u>FEs will</u> <u>utilize 2-923 exam form pages 2-8; the patient will sign the 2-924 consent form</u>.

Medications administered to sexual assault victims will be given according to established treatment guidelines for prevention of sexual transmitted infections and/or the prevention of pregnancy. Medications given will be in accordance with the CDC guidelines for sexual assault, and the current Forensic Examination Program Standardized Procedure for Administration of Medication to Sexual Assault Victims (Attachment C).

Forensic Examination Procedure Followed by FE:

- 1. LE or CFS shall contact the Safe Harbor office to request a forensic evidence examination. Outside of regular Safe Harbor business hours, the requesting agency will contact the on call after hours telephone service, who will then contact the FE on call. The FE will respond to one of the three Safe Harbor centers within one hour (or one and one half hours if traveling to the further center) after being notified, and will then conduct the forensic examination. Exceptions:
 - a. If a victim presents with significant acute injury and/or trauma, the medical needs of the patient shall be addressed by a physician prior to the forensic examination. The victim should be transported to the VCMC or Santa Paula Hospital Emergency Department (or other nearest emergency department).
 - b. If a victim with medical complaints presents to a hospital, either self referred or by ambulance, and reports a sexual assault incident, that patient will be registered as an emergency department patient and undergo a required medical screening examination. The hospital will call local LE to report the assault. The LE agency will provide authorization for a sexual assault evidentiary examination. Upon discharge from the hospital, the LE agency will transport or direct the victim to Safe Harbor or the VFJC.
 - c. If a victim without medical complaints presents to a hospital, either self referred or by ambulance, and reports a sexual assault, the victim will not be registered as an emergency room patient. The victim will be placed into a private area, and law enforcement will be called. LE will then transport or direct the victim to Safe Harbor.
 - d. At the request of LE and the treating physician, the FE may respond to a local hospital for the

AC.22 Forensic Victim Evidentiary Examinations by Forensic Examiner (FE). Retrieved 3/5/2025. Official copy at http://vcmc.policystat.com/policy/16172936/. Copyright © 2025 Ventura County Medical System

purpose of forensic evidence collection on a victim who cannot be medically discharged, and when evidence collection would be compromised by waiting until the patient is medically discharged.

- e. If an adult sexual assault victim does not wish to cooperate with the criminal investigation in regards to a sexual assault case, but is willing to have an evidentiary examination, an exam will be performed in accordance with VAWA 2005.
- 2. Per California Penal Code Section 679.04 (a), a rape crisis advocate will be requested to be present for the forensic interview and examination. During Safe Harbor business hours, the program coordinator will request a rape crisis advocate be present. After business hours, the advocate will be requested by the after hours telephone service or LE.
- 3. The FE will obtain information from the victim (name, date of birth, contact information), and will obtain consent for the forensic examination, evidence collection, interview and photography per the state protocol.
- 4. With the consent and knowledge of the victim, the FE will conduct a recorded medical interview of the assault history provided by the victim..
 - At the beginning of the recording, the FE shall state the examiners name, victim name, date, time, and who is in the room.
 - The recording of the interview will be given to the authorizing agency by request, and a copy will be kept in a secure electronic database.
 - The medical interview will include current and past medical history, including a review of symptoms.
- 5. If the victim has Limited English Proficiency and the FE is unable to communicate competently, the FE will ensure reasonable language accommodation using the AT&T Language Line.
- 6. A forensic examination and collection of evidence will be performed according to state protocols and local LE policy.
- 7. A colposcope with a camera or digital image system will be used for examination and documentation of the condition of the genitalia.
 - a. State forms 923, 925, 930, or 950 will be used to document the forensic examination.
 - b. Photography will be utilized to document other physical evidence from the body, if applicable.
 - c. Photographic evidence will be stored by the Forensic Examination Program in a secure electronic database and will not be released without a court order or request from the District Attorney's Office or authorizing LE agency. If photographs are requested by the District Attorney's Office, they will be sent electronically in an encrypted format by the Medical Coordinator or copied onto a CD and transported by an approved County Courier.
 - d. Photographs may be reviewed by the requesting LE agency after the completion of the examination or by appointment with the Medical Coordinator.
- 8. The FE will collect blood and/or urine from the victim for toxicology at the request of LE or at the discretion of the FE when warranted by the history or condition of the patient. The samples will be given to LE to be transported to the crime lab.
- 9. The genital examination of the sexual assault victim may include, depending on assault history, a vaginal speculum on female victims and or an anal scope examination on post-pubescent victims age 12 years and older (Attachment A and B).
- 10. A urine pregnancy test will routinely be done on all pubescent and adult premenopausal females.

- 11. Under the supervision of the Medical Director, the FE may administer prescription medication to (1) provide prophylaxis for STI's or provide post-coital contraception. Medication will be offered to the victim if the sexual assault examination reveals an indication for medication due to physical findings and/or history of vaginal, oral, or rectal penetration, or the risk of pregnancy (Attachment C).
- 12. The victim must not have allergies or medical history that would contraindicate use of the particular medication.
 - a. For the administration of post coital contraception, the victim must have a negative pregnancy test at the time of the examination and sign a consent for emergency contraception medication.
- 13. The victim shall be given written aftercare instructions specific to the assault.
 - a. If, during the course of the examination, it is discovered the victim has a medical condition either related or unrelated to the sexual assault that requires medical treatment or follow up, the victim shall be referred to the VCMC emergency room or Simi Valley emergency room.
 - b. Information on referral sources for crisis intervention, mental health therapy, California State victims of crime aid or medical follow-up shall be provided to the victim by a victim advocate.
 - c. A laboratory slip will be provided to the victim of sexual assault. Labs can be drawn at any Ventura County hospital or clinic free of charge to the victim. The victim should be instructed to obtain labs the next business day. The results of the labs will be given to the victim as needed, generally within two to three weeks, by the Medical Coordinator of the Forensic Examination Program.
- 14. Procedures for evidence chain of custody shall be followed. Evidence collected shall be given to the LE agency present at the time of the examination.
- 15. Paper charts will be kept locked at Safe Harbor for ten years. After ten years, paper charts will be destroyed per Health Care Agency policy. An electronic copy of all charts will be stored using the Forensic Examination Program's approved electronic records storage database. Copies of records will be released per Safe Harbor policy.

<u>1. LE or CFS shall contact the Safe Harbor office to request a forensic evidence examination. Outside of</u> regular Safe Harbor business hours, the requesting agency will contact the on-call after-hours telephone service, who will then contact the FE on call. The FE will respond to the appropriate facility within 90 minutes for the forensic examination. Exceptions:

- A. If a victim presents with significant acute injury and/or trauma, the medical needs of the patient shall be addressed by a physician prior to the forensic examination. The victim should be transported to the VCMC or Santa Paula Hospital Emergency Department (or other nearest emergency department).
- B. If a victim with medical complaints presents to a hospital or outpatient medical facility, either selfreferred or by ambulance, and reports a sexual assault incident, that patient will be registered as a patient and undergo a required medical screening examination. The facility will call local LE to report the assault. The LE agency will provide authorization for a sexual assault evidentiary examination. Upon discharge from the hospital or clinic, the LE agency will transport or direct the victim to Safe Harbor or the VFJC.
- C. If a victim without medical complaints presents to a hospital or outpatient setting, either self-referred or by ambulance, and reports a sexual assault, the victim will not be registered as a patient. The victim will be placed into a private area, and law enforcement will be called. LE will then transport or direct the victim to Safe Harbor.
- D. At the request of LE and the treating physician, the FE may respond to a local hospital for the purpose of

forensic evidence collection on a victim who cannot be medically discharged, and when evidence collection would be compromised by waiting until the patient is medically discharged. The Forensic examiner will provide recommendations for pregnancy and STI testing and prophylaxis to the treating provider.

E. If an adult sexual assault victim does not wish to participate with the criminal investigation in regards to a sexual assault case, but is willing to have a forensic examination, an exam will be performed in accordance with VAWA 2005.

2. Per California Penal Code Section 679.04 (a), a victim advocate will be requested to be present for the forensic interview and examination as part of the multidisciplinary response.

3. The patient will be registered in the VCMC electronic health record with the prefix SANE-Last name, First name (SANE-Doe, Jane).

<u>4. Following the State of California state protocol, the FE will explain the information and consent sections of the examination process and obtain the patient's signature for the examination.</u>

5. If the victim has Limited English Proficiency and the FE is unable to communicate competently, the FE will ensure reasonable language accommodation using the HCA translation service.

6. A forensic examination and collection of evidence will be performed according to state protocols and local LE policy.

7. A urine pregnancy test will routinely be done on all pubescent and adult premenopausal females. Point of Care STI testing will be offered to all

8. Under the supervision of the Medical Director, the FE may administer prescription medication to provide prophylaxis for STI's or provide post-coital contraception. Medication will be offered to the victim if the sexual assault examination reveals an indication for medication due to physical findings and/or history of vaginal, oral, or rectal penetration, or the risk of pregnancy (Attachment C). STI testing will be offered to the patient based on patient history and physical assessment (Attachment G).

- A. The victim must not have allergies or medical history that would contraindicate use of the particular medication.
 - a. For the administration of post-coital contraception, the victim must have a negative pregnancy test at the time of the examination and sign a consent for emergency contraception medication.
- B. The victim shall be given written aftercare instructions specific to the assault.
 - a. If, during the course of the examination, it is discovered the victim has a medical condition either related or unrelated to the sexual assault that requires medical treatment or follow up, the victim shall be referred to the VCMC emergency room or Simi Valley emergency room.
 - b. Information on referral sources for crisis intervention, mental health therapy, California State victims of crime aid or medical follow-up shall be provided to the victim by a victim advocate.
 - c. A laboratory slip will be provided to the victim of sexual assault. Labs can be drawn at any Ventura County hospital or clinic free of charge to the victim. The victim should be instructed to obtain labs the next business day. The results of the labs will be given to the victim as needed, generally within two to three weeks, by the Medical Coordinator of the Forensic Examination Program.
- <u>C.</u> <u>Procedures for evidence chain of custody shall be followed. Evidence collected shall be given to the LE agency present at the time of the examination.</u>

 <u>D.</u> Paper charts will be kept locked at Safe Harbor for ten years. After ten years, paper charts will be destroyed per Health Care Agency policy. An electronic copy of all charts will be stored using the Forensic Examination Program's approved electronic records storage database. Copies of records will be released per Safe Harbor policy.

FE Training or Special Education Requirements:

The FE shall complete a course/program with a curriculum in compliance with the medical-forensic examination standards set forth in California Penal Code Section 13823.11. The FE shall demonstrate competency in the following:

- 1. Medical interviewing. Medical history-taking.
- 2. Identifying and describing pertinent female and male genital and anorectal anatomical structures.
- 3. The spectrum of potential evidence and physical findings present in these cases.
- 4. STI evaluation and prophylaxis.
- 5. Indications for both medical and forensic follow-up.
- 6. Obtaining both crisis intervention and longer term counseling.
- 7. Utilizing patient history to perform a complete forensic medical examination.
- 8. Forensic examination techniques.
- 9. Using enhancement techniques for detection and documentation of findings, i.e., colposcopy, digital camera, forensic photography, and Toluidine Blue.
- 10. Collecting, labeling, documenting, and preserving all types of evidence for analysis by the crime laboratory.
- 11. Maintaining and documenting chain of custody for evidence.
- 12. Identifying and documenting injuries.
- 13. Interpreting physical findings.
- 14. Collecting toxicology and reference samples.
- 15. Completing the standard CalEMACal OES form used for forensic medical results of the exams.
- 16. Preventing loss, degradation, and contamination of evidence.
- 17. Proper evidence collection and preservation procedures.
- 18. Developing conclusions and interpretations of findings.
- 19. Discussing findings and assessments with law enforcement, social service investigator, and attorneys.
- 20. Providing expert witness testimony in a court of law.

This standardized procedure will be performed only by an FE that is contracted to work specifically at the Forensic Examination Program in Ventura County.

Method for Initial Evaluation of FE Competence:

- 1. The FE working at the Forensic Examination Program must initially be proctored by an experienced FE until deemed competent by the Medical Coordinator and/or the Medical Director.
- 2. The Forensic Examination Program Medical Director and/or Medical Coordinator will review all examiner's

charts. The FE shall have regular competency evaluations (Attachment D).

3. A record of the forensic examiners qualified to perform sexual assault examinations through the Forensic Examination Program per this standardized procedure shall be kept by the Medical Coordinator.

Supervision Required to Perform Procedure:

As described in California Penal Code Section 13823.5 (e), professional registered nurses must work in consultation with a physician knowledgeable about sexual assault evidentiary examinations. A physician does not have to be present for the evidentiary examination. The FE's at the Forensic Examination Program work in consultation with the Medical Director of the Forensic Examination Program.

Special Circumstances Under Which an FE Must Immediately Communicate with an Emergency Department Physician or Safe Harbor Medical Director:

If a victim presents with findings or complaints as outlined in Criteria for Physician Consultation, the victim will be referred to a local emergency department for evaluation and/or treatment after speaking to the emergency department physician on duty and/or discussing with the Forensic Examination Program Medical Director (Attachment D).

Setting or Department Where Procedure May Be Performed:

- 1. The FE shall perform the forensic examination within the designated examination room at one of the Safe Harbor centers.
- 2. The FE may also respond to local hospitals or other medical facilities in the event that a victim cannot be transferred to Safe Harbor and there is a likelihood that forensic evidence may be lost if the exam is delayed.
- 3. Suspect examinations will be performed at the requesting LE agency department, or at VCMC or SPH Emergency Department (Attachment F).

Documentation:

The following information shall be documented in the victim's medical chart:

- 1. Vital signs
- 2. Height and weight
- 3. Past medical and surgical history
- 4. Statement of victim's current condition
- 5. Medication allergies
- 6. Current medications
- 7. Medications: name, dosage, route, time given, and amount of drug(s) administered
- 8. Documentation of a negative pregnancy test and signed consent prior to administration of progesterone therapy
- 9. Copy of aftercare Discharge instructions

The state form 923, 925, 930, or 950 must be completed

A typed narrative report shall be filed in the chart within three (3) days of the examination

Attachments:

- · Attachment A Vaginal Speculum Insertion and Exam Work-flow
- · Attachment B Anoscope Insertion and Exam Work-flow
- Attachment C Administration of Medication to Sexual Assault Victims.
- · Attachment D Criteria for Physician Consultation by Forensic Examiner
- Attachment E Annual FE Competencies
- · Attachment F Forensic Suspect Evidentiary Examinations by FE
- · Attachment G Adult or Child Aftercare Instructions

All revision dates:

3/5/2025, 7/24/2020, 4/7/2020, 5/15/2019

Attachments

- Attachment A Vaginal Speculum and Insertion Exam
- Attachment B Anoscope Insertion and Exam
- Attachment C Administration of Medication to Sexual Assault Victims
- Attachment D Criteria for Physican Consultation by Forensic Examiner
- Attachment E Forensic Examiner Competencies
- Attachment F Examination of Persons Suspected of Commiting Sexual Assault
- Attachment G STI Testing

Step Description	Approver	Date
Medical Staff Committees: Interdisciplinary Practice Committee & ED Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	12/6/2024
Chief Medical Officer, AC	Allison Blaze: Chief Medical Officer, Ambulatory Care	11/19/2024
Director of Nursing, AC	Cynthia Fenton: AC Director of Nursing	7/16/2024
Forensic Nurse Examiner Program Coordinator	Jessica Flanagan: Forensic Nurse Examiner Program Coordinator	7/8/2024



PolicyStat ID: 12518671

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Policy Area:

11/1/1992 Upon Approval N/A 2/25/2025 3 years after approval Fernando Medina: Director, Support Services Dietary - Patient Care

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

D.51 Food & Nutrition Screening/Prioritization

POLICY:

For <u>Dietarythe Food and Nutrition Services</u> Department staff to identify and prioritize patients for whom nutritional intervention is an integral part of therapy during hospitalization.

Nutritional screening is completed by nursing within 24 hours of admission. Based upon diagnosis and criteria from the nutritional screening, the dietitian or dietetic technician-will assign each patient a priority level (with Level III being the highest risk).

Exception:	Infants admitted to Couplet Care
	Patients designated as observation or short stay
	 Patients discharged within 24 hours of admission
	Patient and chart are not available
	NICU - see separate policy

PROCEDURE:

- 1. Nutritional screening will be completed by nursing staff within 24 hours of admission as part of the admission assessment.
- 2. Patients will be assigned an initial priority level by the dietitian or diet technician based on admitting diagnosis, the nutrition screen, anthropometrics, and chart records.
- 3. Criteria for establishing priority level are as follows:

NUTRITION CARE PROTOCOL - PEDIATRIC FLOORS

Levels of Nutritional Risk

	Screen	Assess	Reassess
Priority Level III - Highest Nutritional Risk	24 HOURS	48 HOURS	5-7 DAYS
Nutrition Risk Adolescents with Body Mass Index (BMI) <5 th % Failure to thrive (< 5 th % wt/ht, BMI < 5 th %) Gastrointestinal obstruction Metabolic disorders			

D.51 Food & Nutrition Screening/Prioritization. Retrieved 3/5/2025. Official copy at http://vcmc.policystat.com/policy/ 12518671/. Copyright © 2025 Ventura County Medical System

New onset Type 1 or Type 2 Diabetes			
New Onset Type 1 or Type 2 Diabetes with DKA			
Nutrition support at home (PN / Tube feeding)			
Sepsis			
Severe burns			
Short bowel syndrome			
Adolescents with Body Mass Index (BMI) <5 th %			
Failure to thrive (< 5 th % wt/ht, BMI < 5 th %)			
Gastrointestinal obstruction			
Metabolic disorders			
New onset Type 1 or Type 2 Diabetes			
DKA			
Nutrition support at home (Parenteral Nutrition (PN) or Enteral Nutrition			
(<u>EN</u>)			
<u>Sepsis</u>			
Severe burns			
Short bowel syndrome			
Unintentional weight loss			
Priority Level II - Moderate Risk	24	4 DAYS	5-10
Fhoney Level II - Moderate Nisk	HOURS	4 DATS	DAYS
	HOURS		DATO
Cardiac disease, Congestive Heart Failure Cancer			
Cerebrovascular accident / Seizures Cystic Fibrosis			
Decubitus ulcers / infected or non-healing wound			
Diabetes Mellitus (Type 1 or 2, established)			
Cardiac disease, Congestive Heart Failure			
Cancer			
Cerebrovascular accident / Seizures			
<u>Cystic Fibrosis</u>			
Decubitus ulcers / infected or non-healing wound			
Diabetes Mellitus (Type 1 or 2, established)			
Readmitted DM			
DM (not newly diagnosed nor new onset)			
Dysphagia			
Fecal impaction			
HIV/AIDS			
Hyperbilirubinemia			
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Infants admitted to Pediatric unit who were horn to substance obusing			
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mothers (ISAM) or small for gestational age (SGA)			
mothers (ISAM) or small for gestational age (SGA) Kidney disease / infection Liver disease			
Infants admitted to Pediatric unit who were born to substance abusing mothers (ISAM) or small for gestational age (SGA) Kidney disease / infection Liver disease Long term or stable parenteral nutrition (PN) / tube feedings (on follow up assessment only)			
mothers (ISAM) or small for gestational age (SGA) Kidney disease / infection Liver disease Long term or stable parenteral nutrition (PN) / tube feedings (on follow up assessment only)			
mothers (ISAM) or small for gestational age (SGA) Kidney disease / infection Liver disease Long term or stable parenteral nutrition (PN) / tube feedings (on follow up assessment only) Multiple trauma			
mothers (ISAM) or small for gestational age (SGA) Kidney disease / infection Liver disease Long term or stable parenteral nutrition (PN) / tube feedings (on follow up assessment only)			

> 0 F 9/			
≥85%			
Ruptured appendicitis			
Wt / Lt or BMI 5-25%ile			
Dysphagia			
Fecal impaction			
HIV/AIDS			
Hyperbilirubinemia			
Infants admitted to Pediatric unit who were born to substance abusing			
mothers (ISAM) or small for gestational age (SGA)			
Kidney disease / infection			
Liver disease			
Long term or stable (PN) / (EN) (on follow up assessment only)			
Multiple trauma			
Pancreatitis			
Poor appetite >5 days/ Vomiting or diarrhea >5 days			
Pediatric BMI >85%			
Ruptured appendicitis			
Wt / Lt or BMI 5-25%ile			
Priority Level I - Low Risk	24	6 DAYS	10-14
,	HOURS		DAYS
All other conditions, including, but not limited to:			
Appendicitis			
Asthma			
Bronchiolitis / Pneumonia Comfort measures / Terminal care			
Gallbladder disease			
Minor surgery / Orthopedic procedures			
Term neonate (increase 1 level for micropremie BW<1500grams			
readmitted in 1 st year of life)			
All other conditions, including, but not limited to:			
Appendicitis			
Asthma			
Bronchiolitis / Pneumonia			
Comfort measures / Compassionate care			
Gallbladder disease			
Minor surgery / Orthopedic procedures			
Term neonate (increase 1 level for micropreemie BW<1500grams			
readmitted in 1 st year of life)			
<u>reaumilieu m reaven or me)</u>			

NUTRITION CARE PROTOCOL - ADULT FLOORS

Levels of Nutritional Risk

	Screen	Assess	Reassess
Priority Level III - Highest Nutritional Risk	24 HOURS	48 HOURS	5-7 DAYS
<75% desirable weight for height <u>IBW</u> CHF (readmitted within 14 days for CHF)			

D.51 Food & Nutrition Screening/Prioritization. Retrieved 3/5/2025. Official copy at http://vcmc.policystat.com/policy/ 12518671/. Copyright © 2025 Ventura County Medical System

COPD with a BMI < 20 Malnutrition New onset Type 1 or 2 Diabetes Nutrition support at home (PN/tube feedingEN) Or nutrition support initiated upon screen Severe burns Jnintentional weight loss >10# in 3 months MHIPU w/PMH of other Level III diagnosis, screen as a Level III Priority Level II - Moderate Nutritional Risk 485% weight for height Acute MI/Acute Coronary Syndrome Bariatric surgery patients - here for bariatric surgery or hx of bariatric	24 HOURS	4 DAYS	7-10 DAYS
surgeryPMH Cancer CHF (<u>new</u> diagnosis or history) CVA Cystic Fibrosis Decubitus ulcers/infected or non-healing wound Diabetes Mellitus (Type 1 or 2, established) Dysphagia			
Gestational Diabetes Mellitus			
GI related problems			
HV/AIDS Hyperemesis of pregnancy Kidney disease/infection Liver disease Long term or stable PN/Tube feeds <u>EN</u> (on f/u assessment only) Multiple trauma (use clinical judgement) Pancreatitis Surgical patient > 75 years old Poor appetite > 5 days/Vomiting or diarrhea > 5 days			
Priority Level I - Low Risk	24 HOURS	6 DAYS	10-14 DAYS
All others including: Angina/AFIB Appendicitis Asthma/COPD with a BMI \geq 20 Bronchitis/ Pneumonia COPD with a BMI \geq 20 Bronchitis/ Pneumonia Comfort measures/ Compassionate care Gallbladder disease Kidney Stones			

D.51 Food & Nutrition Screening/Prioritization. Retrieved 3/5/2025. Official copy at http://vcmc.policystat.com/policy/ 12518671/. Copyright © 2025 Ventura County Medical System

All other MH IPU including w/ Pl screen as a Level I	h transfers to and from acute care hos MH of DM. Cardiac Issues, Stroke, witi rm (>30 day Stays) reassess at 21-30	hout complicat		
All revision dates: Attachments	2015, 7/1	, , ,	5/15/2019, 3/21/ 3, 8/1/2010, 4/1/)1, 12/1/1997	,
No Attachments Approval Signatures				
Step Description	Approver		Date	
Medical Executive Committee	Stephanie Denson: Manager, Medica	I Staff Office	pending	
Dietary Department	Fernando Medina: Director, Support	Services	2/25/2025	



PolicyStat ID: 17362608

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: M Policy Area:

1/1/2017 Upon Approval N/A 3/8/2022 3 years after approval Julia Feig: Clinical Nurse Manager, Emergency Services Emergency Services

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

ER.44 Supervising Physician in the Emergency Department

POLICY:

A qualified member of the Medical Staff will be designated to supervise the provision of emergency services.

PROCEDURE:

Ventura County Medical Center (VCMC) Supervising Physician Qualifications:

- Board Certified in Emergency Medicine or;
- A minimum of six (6) months or 600 hours of continued work experience in the Department of Emergency Medicine under the direct or indirect supervision of a qualified supervising physician, satisfactory review of a minimum of five (5) trauma activations and the approval of the Emergency Department Medical Director.
- Physicians who completed primary training in 2016 and beyond who are NOT board certified or board eligible by the appropriate emergency medicine or pediatric emergency medicine board may provide care in the emergency room but CANNOT participate in trauma care. For example: if a physician who completed Family Medicine primary training in 2017, they would NOT be eligible to participate in trauma call panel.

Santa Paula Hospital (SPH) Supervising Physician Qualifications:

- Board Certified in Emergency Medicine or;
- A minimum of six (6) months or 600 hours of continued work experience in the Department of Emergency Medicine under the direct or indirect supervision of a qualified supervising physician, satisfactory review of a minimum of five (5) trauma activations or major cases and the approval of the Emergency Department Medical Director.

Call Schedule:

- When multiple concurrent physicians are scheduled, the call schedule will indicate the supervising physician for each shift.
- During shifts in which a single physician is scheduled, the physician scheduled will be a supervising physician.

All revision dates:

3/8/2022, 1/1/2017

Attachments

No Attachments

Step Description	Approver	Date
Emergency Department Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/9/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	1/9/2025
Policy Owner	Julia Feig: Clinical Nurse Manager, Emergency Services	1/9/2025



PolicyStat ID: 17310506

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Policy Area:

12/1/1989 Upon Approval N/A 1/2/2025 3 years after approval Julia Feig: Clinical Nurse Manager, Emergency Services Emergency Services

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

ER.49 Documentation Standards in the Emergency Department

POLICY:

To establish documentation requirements for Emergency Department (ED) patients at Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH).

PROCEDURE:

- A. An ED record shall be kept for every patient receiving emergency service in the patient's electronic health record (EHR), which shall be part of the official hospital record. This record shall contain:
 - Adequate patient identification and hospital medical record number, date of birth and consents for treatment. When consents are not available or when unable to obtain, documentation will be made. All the paperwork shall be labeled and scanned into the patient's EHR.
 - 2. Date and time of patient arrival and discharge from the ED.
 - 3. Means of arrival and by whom transported.
 - 4. The patient's chief complaint.
 - 5. Physician Charting Will Include:
 - a. History of injury or illness including emergency care given prior to arrival
 - b. Physical findings with diagrams of injury, if indicated and vital signs.
 - c. Laboratory and radiographic studies ordered and results.
 - d. Impressions, diagnosis, treatment orders and the results of the treatment.
 - e. Instructions in the language understood by patient for after-care given to the patient or relatives, and appointments in writing for return visits to the ED or to other clinics or physicians. When after-care sheets are given to patients, it shall be noted on the chart, in the patient's EHR.
 - f. Disposition, means and condition of the patient on discharge.
 - 6. Nurses Charting to include:
 - a. Nursing Assessment to include nursing history (emotional and physical) based on ED "Standards of Care."
 - b. Vital signs to include blood pressure, pulse, temperature, respiratory rate, oxygen saturation,

and level of pain on admission as part of the Emergency Severity Index (ESI) scoring assessment.

- i. ESI 1 patients or critical patients including traumas, vital signs should be repeated every 5 to 15 minutes until patient's status stabilizes, then every 2 hours after that.
- ii. ESI 2-3 patients vital signs should be repeated every 2 hours.
- iii. ESI 4-5 patients with abnormal vital signs should have then repeated every 2 hours until they normalize, then every 4 hours after that.
- iv. ESI 4-5 patients with normal vital signs should have vital signs repeated every 4 hours.
- v. Rectal or axillary temperatures should be taken on all pediatric patients under the age of two (2) years depending on chief complaint.
- vi. Any abnormal vital signs should be promptly reported by the nurse or technician who takes them to the attending physician. (See Attachment A).
- vii. <u>Once a patient is medically cleared for placement at a psychiatric facility vital sign</u> <u>frequency can be reduced to once per shift.</u>
- c. Weight in kg on all patients, naked weight on all children under one (1) year old.
- d. Head circumference on pediatric patients when deemed appropriate by attending physician.
- e. Fetal heart tones (FHTs) on all pregnant patients over 12 weeks gestation.
- f. Allergies, medications currently used and tetanus immunization status.
- g. Medication Reconciliation form on all patients in the ED shall be completed by the RN.
- h. Document patient's level of pain initially and any changes in the level or severity as applicable.
- i. If medications are administered in the ED, note name, dosage, route of administration, site of administration if parental, time administered and results. Document in the patient's EHR.
- j. Any change in patient's condition.
- 7. Conclusions and documentation if the patient leaves against medical advice, label against medical advice (AMA) form and have scanned into patient's EHR.
- 8. Patients, patient's relatives, guardians, law enforcement or other responsible person's signature on receipt of discharge instructions.
- 9. Document in EHR if a patient leaves without being seen or leaves before treatment is completed (per policy 100.211).
- 10. All patient records are confidential. Refer to Administrative policy 100.018.
- 11. Patient authorization to release information for follow up care to his or her physician or health care organization is addressed.
- B. Trauma Flow Sheet to be used on all Code Yellow Tier I and Tier II patients.

DOCUMENTATION

As above

REFERENCES:

Title 22, California State requirements

ER.49 Documentation Standards in the Emergency Department. Retrieved 3/5/2025. Official copy at http://vcmc.policystat.com/policy/17310506/. Copyright © 2025 Ventura County Medical System

Page 2 of 3

The Joint Commission Standards Emergency Nurses Association - Standards of Care

> 1/2/2025, 9/13/2024, 1/28/2020, 11/1/2016, 12/1/ 2013, 11/1/2011, 8/1/2011, 1/1/2011, 12/1/1998, 1/1/ 1995, 10/1/1992

All revision dates:

Attachments

ER.49 Attachment A.docx

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Emergency Department Committee	Stephanie Denson: Manager, Medical Staff Office	3/5/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	1/2/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/2/2025
Policy Owner	Julia Feig: Clinical Nurse Manager, Emergency Services	1/2/2025



PolicyStat ID: 15659766

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Policy Area:

1/1/1998 Upon Approval N/A 4/15/2024 3 years after approval Kelly Johnson: Director, ICU/ DOU/Telemetry Intensive Care Unit

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

ICU.22 Admission Criteria to the Telemetry Units

POLICY:

The Telemetry Units provide care for and continuous cardiac monitoring of patients in stable condition and having or suspected of having a cardiac condition or a disease requiring telemetry monitoring, recording, retrieval and display of cardiac electrical signals. ICU 2 is further defined as a specialty unit in relation to the specialized chemotherapy and oncological care provided to those patients diagnosed with cancer.

PROCEDURE:

Patient transfers from the Intensive Care Unit (ICU), Definitive Observation Unit (DOU), and/or Emergency Department/clinic referrals shall meet criteria for telemetry admission as outlined below.

CRITERIA FOR ADMISSION OF PATIENTS

The ACC/AHA practice standards based on expert consensus (not randomized control trials) recommends cardiac monitoring for ischemia, QT interval, Class I, and some Class II patients. It is not indicated in Class III patients:

- **Class I:** at risk of an immediate, life-threatening arrhythmia—typically ICU appropriate patients (i.e. patients in the first 48 hours of ACS or with high grade lesions awaiting intervention, acute heart failure, 2nd and 3rd degree AV block, temporary pacing, long QT syndrome, WPW with rapid anterograde conduction, IABP, post cardiac arrest, post cardiac surgery, post-PCI or ablation with complication, post pacemaker placement with pacemaker dependence and conscious sedation.
- **Class II:** individuals presenting with chest pain syndromes, syncope, known arrhythmia with active arrhythmia medication titration, heart failure, post-PCI, post-ablation or post-pacemaker placement without complications.
- **Class III:** includes rate-controlled atrial fibrillation, chronic PVCs, ESRD on HD and low risk post-surgical patients.
- A patient is deemed appropriate for downgrade from telemetry when they meet the criteria for telemetry removal based on the telemetry removal protocol (Attachment A)

EXCLUSION CRITERIA FOR ADMISSION

A. Patients who meet Class I criteria within the first 48 hours of onset of symptoms. (consider ICU or DOU)

- B. Patients who meet Class III criteria. (consider Med-Surg)
- C. Patients requiring insulin drip.
- D. Severe alcohol withdrawal (with or without delirium tremens) requiring high doses of benzodiazepines.

Additional Criteria includes:

- A. Admission by members of Medical Staff, Residents, Emergency Department physicians.
- B. Initiation of telemetry monitoring requires a patient status change order indicating the need for telemetry level of care

SAFETY PRECAUTIONS

- A. Each patient on the Telemetry/Oncology unit will be assessed daily by the attending physician or designee.
- B. The need for continued telemetry should be reassessed by provider every 24 hours.
- C. Appropriate patient status orders must be completed for all admissions indicating the need for telemetry.
- D. Telemetry Monitor alarms are "on," without exception.
- E. Patients on telemetry will be monitored by telemetry technicians who have been deemed competent in the recognition of arrhythmias.
- F. IV infusions and IV push medications allowed on the Telemetry unit are listed on the <u>Intravenous</u> <u>Medication Guidelines for Adults</u>.

PATIENT CARE

A. Care is provided by Registered Nurses who have been deemed competent in the care of telemetry patients with support from ancillary staff, including nursing assistants.

EQUIPMENT

- A. Medical System Telemetry with monitoring screen.
- B. Alarm System Response: by audible indicator and viewing information center with text information.

DOCUMENTATION

- A. An admission assessment documented in electronic health record within eight (8) hours of admission.
- B. Nursing care plan and psychosocial questionnaire within eight (8) hours of admission.
- C. Patient Care Note and Interventions.
- D. EKG strip upon admission, every shift and PRN status change.
- E. Indication for continuing telemetry monitoring must be documented daily.

KEY POINTS

- Report status changes promptly to physician.
- Unconfirmed dysrhythmia:
 - i. Assess patient

- ii. Call rapid response
- iii. Physician notification/assessment
- Efforts to protect the neutropenic patient may warrant consideration to prevent infectious exposures by omitting patients requiring isolation.
- This unit does not have capability of direct observation.
- All patients admitted to the Telemetry unit should have functional intravenous access at all times. The IV access is to be placed prior to the patient's admission to the Telemetry unit.
- Discontinuation of telemetry monitoring should be considered as soon as clinically appropriate, as outlined in Attachment A.

References:

Sandau et. al., (2017). Update to Practice Standards for Electrocardiographic Monitoring in Hospital Settings: A Scientific Statement From the American Heart Association. Circulation 136(19), 276-344. <u>https://doi.org/10.1161/CIR.00000000000527</u>

All revision dates:

4/15/2024, 11/26/2018, 1/1/2017, 12/1/2004

Attachments

Tele Removal Workflow.xlsx

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medicine Committee	Stephanie Denson: Manager, Medical Staff Office	2/27/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/15/2025
Intensive Care Unit	Kelly Johnson: Director, ICU/DOU/Telemetry	1/15/2025
Intensive Care Unit	Tara Paterson: Medical Director, Critical Care Services	12/7/2024



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11/15/2023 Upon Approval N/A 10/15/2024 3 years after approval Sul Jung: Associate Director of Pharmacy Services Pharmacy Services

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

ICU.29 Critical Care Electrolyte Protocol

Purpose:

An electrolyte repletion protocol is fundamental to the management of critically ill patients in the ICU. It lessens the chance of iatrogenic induced arrhythmias, weakness, polyneuropathy, and ongoing malnutrition.

<u>Note:</u> This protocol does not include electrolyte combination products. If a patient requires more aggressive electrolyte repletion or combination electrolyte products, contact provider.

Exclusions: Crush injuries, hypothermic patients, burns, rhabdomyolysis, tumor lysis syndrome, any type of dialysis (continuous renal replacement therapy, hemodialysis, peritoneal dialysis, ultrafiltration), acute decompensated heart failure, pregnant patients, patient is receiving parenteral nutrition, patient is on fluid restriction for intravenous repletion therapy, hyponatremia (sodium < 130 mg/dL), Scr >2 mg/dl, 50% increase in Scr from baseline, CrCL< 30 mL/min (using Cockcroft Gault formula), or urine output less than 0.5 mL/kg/hr for previous 3 hours or more, contact provider to discontinue repletion orders.

Procedure:

- A. This order set can only be utilized in the ICU at VCMC and SPH in patients with ongoing continuous cardiorespiratory monitoring.
- B. These orders will be initiated by a provider but due to the dynamic physiology that occurs throughout a patient's ICU stay, may be revoked at any time. Refer to exclusions and individual electrolyte sections for holding criteria.
- C. Replace critical values first unless otherwise indicated by provider.
 - 1. If there are multiple critical values or symptomatic abnormalities (e.g., EKG changes, mental status changes) then contact the provider.
 - 2. Oral route will be the preferred route of administration. (PO = oral, FT = feeding tube)
- D. Nurse will order post replacement laboratory as described within this protocol.
- E. If patient is not responding to replacement as ordered, contact the provider.
 - 1. Patient's lab value is not within normal range after 2 rounds of replacement have occurred, contact provider.
- F. Notify provider if any of the exclusions criteria develop during hospitalization.

Hypokalemia

Do not initiate or stop current repletion plan in patients who have the following. Contact provider if patients have any of the following:

1. Serum chloride > 115 mEq/L

Table 1. Po	tassium enteral reple	tion as	potassium	chloride e	nteral replet	ion
Serum [K ⁺] mEq/L	Medication	Route	Frequency	Duration	Total dose in mEq	Monitor
3.5 – 4	20 mEq tablet or liquid	PO/ FT	Once	Once	20	Routine AM lab
3 – 3.4		PO/ FT	Every 2 hours	3 doses	60	12 hours after completion of total dose
2.5 – 2.9 Notify physician	2x20 mEq tablet or 40 mEq liquid	PO/ FT	Every 2 hours	2 doses	80	4 hours after completion of total dose
< 2.5	Start repletion by usir	ig intrav	enous formu	lation by u	sing Table 2	or 3.

Table 2. P	otassium intravenous	repleti	on as potassium	chloride –	PERIPHER	RAL line
Serum [K⁺] mEq/ L	Medication	Route	Rate	Duration	Total dose in mEq	Monitor
3.5 – 4	<mark>20 mEq/250 mL NS</mark> 20 mEq/250 mL NS	IV	OverInfuse over 2 hours	Once	20	Routine AM lab
3 – 3.4	<u>40 mEq/500 mL NS</u>	IV	Infuse each bag over <u>24</u> hours	2 doses <u>Once</u>	40	4 hours after completion of total dose
2.5 – 2.9 Notify physician	40 mEq/500 mL NS	IV	Infuse each bag over 4 hours	2 doses	80	2 hours after completion of total dose
<mark>< 2.5</mark> < 2.5	2x20 mEq tablet or 40 mEq liquid UDC	PO/ FT*	Once	Once	120	1 hours after completion of total
<u>Notify</u> physician	40 mEq/500 mL NS	IV	Infuse each bag over 4 hours	2 doses		dose
	*IF oral route is availal equal 120 mEq total.	ble. If no	ot available, give al	I three dos	ses as IV po	tassium chloride to
Table 3. P	otassium intravenous	repleti	on as potassium	chloride –	CENTRAL	line
Serum [K⁺] mEq/ L	Medication	Route	Rate	Duration	Total dose in mEq	Monitor
3.5 – 4	20 mEq/50 mL NS	IV	Once	Once	20	Routine AM lab

	<u>20 mEq/50 mL NS</u>		<u>Infuse over 2</u> <u>hours</u>			
3 – 3.4	40 Meq/100 mL NS	IV	Infuse each bag over <u>24</u> hours	2 doses <u>Once</u>	40	4 hours after completion of total dose
2.5 – 2.9 Notify physician	40 mEq/100 mL NS	IV	Infuse each bag over 4 hours	2 doses	80	2 hours after completion of total dose
<mark>< 2.5</mark> < 2.5	2x20 mEq tablet or 40 mEq liquid UDC	PO/ FT*	Once	Once	120	1 hours after completion of total
<u>Notify</u> physician	40 mEq/100 mL NS	IV	Infuse each bag over 2 hours	2 doses		dose
	*IF oral route is availa equal 120 mEq total.	ble. If no	ot available, give al	I three dos	ses as IV po	tassium chloride to

Hypomagnesemia

Table 4. Mag	Table 4. Magnesium intravenous repletion as magnesium sulfate						
Serum [Mg] mg/dL	Medication	Route	Rate	Duration	Total dose in gram	Monitor	
1.6 – 2	2 g/50 mL premix	IV	Over 2 hours	Once	2	Routine AM lab	
1 – 1.5	4 g/100 mL premix	IV	Over 4 hours	Once	4	4 hours after infusion has completed	
< 1 Notify physician	4 g/100 mL premix	IV	Infuse each bag over 4 hours	2 doses	8	2 hour after infusion has completed	

Hypophosphatemia

Do not initiate or stop current repletion plan in patients who have the following. Contact provider if patients have any of the following:

- A. Serum sodium > 150 mEq/L
- B. Serum calcium > 10 mg/dL

Table 5. Phospho	orus enteral repletion	n			
Serum [Phos] mg/dL	Medication	Route	Frequency	Duration	Monitor
2.6 – 3	2 Neutraphos tabs	PO/FT	Once	1 dose	Routine AM lab
2 – 2.5		PO/FT	Every 4 hours	2 doses	4 hours after PO/FT dose
< 1.9	Start repletion by using intravenous formulation by using Table 6-8. Notify physician if level < 1.5				

Serum [Phos] mg/ dL	Bag size	Route	Rate	Duration	Total Dose in mMol	Monitor
2 – 2.5	15 mMol/ 100 mL NS 15 mMol/ 100 mL NS	IV	Infuse over <u>32</u> hours	Once	15	Routine AM lab
1.5 – 1.9	<u>30 mMol/</u> 250 mL NS	IV	Infuse each bag over 3<u>4</u> hours	2 doses Once	30	2 hours after total infusion is completed
< 1.5 Notify physician	<u>45 mMol/</u> 250 mL NS	IV	Infuse each bag over <u>36</u> hours	3 doses <u>Once</u>	45	1 hour after total infusion is completed

All revision dates:

10/15/2024, 11/15/2023

Attachments

No Attachments

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Intensive Care Unit Committee	Stephanie Denson: Manager, Medical Staff Office	2/27/2025
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	1/28/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/15/2025
Intensive Care Unit	Kelly Johnson: Director, ICU/DOU/Telemetry	1/15/2025
Intensive Care Unit	Tara Paterson: Medical Director, Critical Care Services	12/7/2024
Intensive Care Unit	Sul Jung: Associate Director of Pharmacy Services	10/15/2024



VENTURA COUNTY

PolicyStat ID: 17362585

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Policy Area:

3/2/2009 Upon Approval N/A 3/8/2022 3 years after approval Matt McGill: Director, Imaging Services Imaging Services

HEALTH CARE AGENCY Policy Area: References:

IS.05 Interventional Radiology Procedures

POLICY:

Interventional Radiology at Ventura County Medical Center is provided by an Interventional Radiologist utilizing their expertise in image-guided procedures.

PRE-PROCEDURE

- 1. Labs usually required: PT/INR, PTT, CHEM 7, CBC. Labs shall have been performed within 30 days of the procedure as indicated.
- 2. Diet: standard precautions. See protocol per policy <u>100.070 Moderate and Deep Sedation</u>.
- 3. Medications: Hold anticoagulants, diuretics and diabetic medications as indicated.
- 4. Pre-treatment for known contrast allergy history, as indicated.
- 5. History and physical within the last 30 days.

Patient Preparation

Upon arrival of the patient, preoperative care will be performed, including confirmation of orders, ensuring the patient signs consent forms and having the patient change into a hospital gown. A peripheral intravenous (IV) line will be placed by the preoperative staff for the administration of antibiotics, intravenous fluids and sedation if needed. Inpatients will be asked to arrive with a peripheral IV in place, accompanied by their hospital chart. The patient shall have standard monitoring in Interventional Radiology. The patient will be placed on the exam table and the area of interest will be prepped using sterile technique. The area will be draped to provide a sterile field of operation with an opening to access the site of entry.

Exam Process

The Interventional Radiology procedure shall be performed by an Interventional Radiologist using image guidance according to standard practice. Moderate sedation shall be used as indicate.

POST-PROCEDURE

The Radiologist will write post-procedure orders for recovery times and pain medications as needed. The patient shall receive routine post-procedure care according to the type of sedation used for the procedure.

Angio Suite Requirements

- 1. Consent forms.
- 2. Necessary supplies including catheters, guidewires, introducer sheaths, needles, etc.
- 3. Automatic contrast pressure injector, as needed.
- 4. Sterile field table, all necessary sterile supplies (gloves, gowns, etc.)
- 5. Patient monitoring equipment: pulse oximeter, blood pressure, heart rate, respiration.
- 6. Emergency equipment: defibrillator, oxygen supply, suction, crash cart.
- 7. Support personnel: Radiologist, 2 to 3 Radiologic Technologists and an RN (if any level of sedation is given)
- 8. Red bag containers for appropriate waste.
- 9. Sharps containers.
- 10. Medication waste containers.
- 11. Scrub sink with hot and cold water.

All revision dates:

3/8/2022, 3/21/2019, 10/1/2015, 5/1/2012, 3/2/2009

Attachments

No Attachments

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medicine Committee	Stephanie Denson: Manager, Medical Staff Office	2/27/2025
Imaging Services	Matt McGill: Director, Imaging Services	1/14/2025
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	1/9/2025



PolicyStat ID: 17362589

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Ma Se Policy Area:

6/1/2007 Upon Approval N/A 3/21/2019 3 years after approval Matt McGill: Director, Imaging Services Imaging Services

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

IS.15 Handling of the Critically III Patient by Imaging Services Staff

POLICY:

To provide guidelines for Imaging Services staff when handling critically ill patients at Ventura County Medical Center and Santa Paula Hospital.

PROCEDURE:

- I. CRITICALLY ILL PATIENTS SHALL NOT BE MOVED WITHOUT THE CONSENT OF THE PHYSICIAN.
 - A. Critically ill patients shall not be moved without an Imaging Services study order entered into the electronic health record (EHR) by the patient's physician.
 - B. The x-ray technologist shall speak with patient's physician before moving the patient to find out if there has been any change in his/her condition since the order was placed.
- II. CRITICALLY ILL PATIENTS SHALL BE ACCOMPANIED BY the APPROPRIATE PERSONNEL AT ALL TIMES

Depending on the seriousness of the patient's condition, a Registered Nurse and/or Respiratory Therapist shall accompany the patient.

- III. EQUIPMENT
 - A. The physician shall be contacted to determine whether the patient requires oxygen, special suction equipment, IV medication, etc. when being transported.
 - B. The appropriate medical personnel shall verify that all necessary life support equipment is available during transit and while the patient is in Imaging Services.
 - C. All necessary ancillary equipment, such as weight, neck collars, etc., shall be transported with the patient.
 - D. Nursery patients shall only be moved in an isolette.
- IV. PATIENTS ON POSITIVE OR NEGATIVE ISOLATION: Please refer to infection control and isolation practices.
- V. UNNECESSARY TRANSPORTATION OF THE PATIENT TO IMAGING SERVICES SHALL BE AVOIDED
 - A. Portable studies shall be performed when feasible.

- B. If more than one imaging study is requested, they shall be performed at the same time whenever feasible.
- VI. RETURN TO WARD

Critically ill patients shall be returned to their room as soon as the ordered study is completed.

All revision dates:

3/21/2019, 9/1/2007

Attachments

No Attachments

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medicine Committee	Stephanie Denson: Manager, Medical Staff Office	2/27/2025
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	1/9/2025
Imaging Services	Matt McGill: Director, Imaging Services	1/9/2025



PolicyStat ID: 17362587

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Ma Se Policy Area:

12/1/2006 Upon Approval N/A 3/8/2022 3 years after approval Matt McGill: Director, Imaging Services Imaging Services

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

IS.21 Interventional Radiology Medical Emergency Response

POLICY:

The purpose of this policy is to provide guidelines for the Interventional Radiology (IR) staff to follow in the event of life threatening emergencies such as cardiac arrest or anaphylactic shock.

PROCEDURE:

If a patient has an anaphylactic reaction, experiences respiratory or cardiac arrest, or develops a medical emergency of any kind, the technologist shall call Ext 7-6666 (VCMC) and initiate CPR. See policies <u>100.086</u> <u>Rapid Response Team</u>, <u>106.003 Hospital Emergency Call Codes</u>, <u>100.055 Code Blue - Adult Medical</u> <u>Emergency</u>.

- A. The Interventional Radiology suite unit shall be equipped with the following:
 - 1. Crash cart with Defibrillator
 - 2. Oxygen (masks, tubing, etc.)
 - 3. Suction
 - 4. Anaphylactic drug kit
- B. All IR staff shall complete all CORNERSTONE annual safety classes.
- C. All IR nurses shall complete annual nursing competencies.

All revision dates:

3/8/2022, 3/21/2019, 4/24/2018, 4/1/2015

Attachments

No Attachments

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medicine Committee	Stephanie Denson: Manager, Medical Staff Office	2/27/2025
Imaging Services	Matt McGill: Director, Imaging Services	1/14/2025
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	1/9/2025



PolicyStat ID: 17362607

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: S Policy Area:

3/1/2009 Upon Approval I: N/A 3/8/2022 3 years after approval Matt McGill: Director, Imaging Services Imaging Services

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

IS.29 Imaging Services Medication Administration

POLICY:

To provide for the safe and accurate administration of medications (i.e., imaging media) to patients by Imaging Services staff.

PROCEDURE:

- I. The term "medication" shall refer to media commonly used in medical imaging procedures, including, but not limited to:
 - a. Iodinated contrast media, all modalities (oral or IV)
 - b. Barium-based contrast media (intracavitary)
 - c. Gadolinium-based contrast media (IV)
 - d. Radiopharmaceuticals used in Nuclear Medicine (IV or ventilation)
 - e. Radiopharmaceuticals used in PET and PET/CT (IV)
 - f. Saline solution used to flush IV tubing and/or as a solvent or suspension medium for the above (IV)
 - g. Heparin used in conjunction with Heparin locks (IV)
 - h. Contrast agents used when performing Echocardiology exams.
- II. Before administering medication, Imaging Services staff shall:
 - i. Verify that the medication selected for administration is the correct one based on the exam ordered, exam protocols, and the product label.
 - ii. Verify that the medication is stable based on visual examination for particulates or discoloration and that the medication has not expired.
 - iii. Verify that there is no contraindication for administering the medication, if applicable.
 - iv. Verify that the medication is being administered at the proper time, to the proper individual, in the proper dose, and by the correct route.

Guidelines

- When drawing up medication into a syringe/auto-injector, the syringe/auto-injector must be labeled with beyond use date, name and strength of the medication.
- Discard unused medications immediately after beyond use date is exceeded.

- All medication vials are considered single use vials and are not to be used for multiple doses/patients. See policy <u>PH.79 Multiple Dose Vials</u>.
- All intravenous medication administration shall be performed using aseptic technique.

All revision dates:

3/8/2022, 8/21/2018, 1/1/2013

Attachments

No Attachments

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medicine Committee	Stephanie Denson: Manager, Medical Staff Office	2/27/2025
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	2/7/2025
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	1/9/2025
Imaging Services	Matt McGill: Director, Imaging Services	1/9/2025



PolicyStat ID: 17387568

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Policy Area: A

7/1/2004 Upon Approval N/A 1/24/2025 3 years after approval Sul Jung: Associate Director of Pharmacy Services Administrative - Patient Care

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

PH.79 Multiple Dose Vials

POLICY:

Multiple dose vials (MDVs) are considered single dose vials and shall be used for one patient and discarded immediately after use.

The following MDVs are exceptions to this policy and may be used for multiple use for one patient:

Insulin vials

The following MDVs are exceptions to this policy and may be used for multiple use for more than one patient:

- Tuberculin Purified Protein Derivative (PPD)
- Vaccines

Multiple dose vials used for sterile compounding in the pharmacy department shall be exempt from this policy. See PH.26.04 Sterile Drug Preparation, Labeling, End Product Evaluation and Record Keeping.

Ventura County Medical Center (VCMC), Santa Paula Hospital (SPH), and Ambulatory Care Clinics (AMB) appropriately handles multiple dose and single dose containers of medications, fluids, and vaccines in adherence to the manufacturer's instructions for use and established infection prevention practices.

DEFINITIONS

- A. Beyond use date (BUD) is the date or time beyond which an opened multiple dose container should not be used. The BUD should never exceed the manufacturers expiration date⁴.
- B. Manufacturer's expiration date reflects the time period during which the unopened product is known to remain stable and retains its strength, quality, and purity when it is stored according to its labeled storage conditions¹. For expiration dates that only include the month/year, the unopened product is considered usable until the end of the month unless otherwise stated by the manufacturer³.
- <u>C.</u> <u>Immediate patient care area²</u>. is any setting in which patients are examined, evaluated, or provided care in the inpatient, outpatient, and campus setting. Examples of an immediate patient care area include operating and procedure rooms, anesthesia and procedure carts, and patient rooms or bays.
- D. Parenteral injection containers¹⁻³
 - 1. Single dose injectable container: A container of a sterile medication for parenteral administration (injection or infusion) designed for use with a single patient as a single injection/infusion. Single dose containers typically do not contain an antimicrobial preservative. There have been multiple

outbreaks resulting from health care personnel using singe dose containers for multiple patients. Examples of single dose containers are single-dose vials (SDV), ampules, and pre-filled syringes.

- 2. Multiple dose injectable container: A container of a sterile medication for parenteral administration (injection or infusion) that is intended to contain more than one dose of the drug product. Multiple dose containers typically contain an antimicrobial preservative. The preservative has no effect on viruses and does not protect against contamination when health care personnel fail to follow safe injection practices. Examples of a multiple-dose injectable container is a multi-dose vial (MDV).
- 3. Single patient use injectable container¹: A container of a sterile medication for parenteral administration (injection or infusion) that is intended to be used multiple times for a single patient. Examples of single-patient use containers are patient controlled analgesia cartridges and certain pens for injection.
- E. Non-injection containers
 - <u>Non-injection, multiple use container</u> is a container that allows for multiple doses to be withdrawn from the container without changing the strength, quality, or purity of the remaining product. Examples of non-injection, multiple use containers are bottles of capsules, tablets, oral or topical liquids and semisolids.
 - 2. Non-injection, single use container is a container that is designed to hold a quantity of drug product intended for administration as a single dose and intended for use promptly after the container is opened.

PROCEDURE:

To minimize the use of MDVs, single unit injectable drugs are purchased when possible including ampules, pre-filled syringes, and single dose vials.

For medications that are exempt from this policy, the following shall apply:

Handling of vials

- A. Wash hands thoroughly before handling injectables.
- B. Determine if vial has been stored properly.
- C. Check all multiple dose vials for evidence of contamination and deterioration. Color, clarity, and presence or absence of precipitate should resemble normal state.
- D. Check all multiple dose vials for evidence of particulate matter: coring (residue from rubber diaphragm), floaters, etc.
- E. Use appropriate aseptic technique. Swab with alcohol before puncturing.
- F. Place bevel of needle at appropriate angle to prevent coring.
- G. Use a sterile needle each time a multiple dose vial is entered.
- H. If vial is unopened and if vial requires reconstitution, reconstitute according to manufacturer's guidelines. Determine shelf life date according to section below.
- I. If vial is unopened and vial does not require reconstitution, determine shelf life according to section below.
- J. If vial is opened, determine if it can be reused according to guidelines below.

K. Store properly according to manufacturer's recommendations.

Determining Shelf Life

- A. Multiple dose vials shall be discarded when empty, when suspected or visible contamination is present, when deterioration is suspected, or when particulate matter is present.
- B. Multiple dose vials shall be discarded within 28 days after initial access provided they are stored according to manufacturer's recommendation.
 - 1. Exception: If the manufacturer indicates that the multiple dose vial may be used beyond 28 days, the multiple dose vial may be used for the duration specified by the manufacturer.
- C. When vials have been accessed, the recalculated expiration date shall be placed on the vial as follows: "Exp mm/dd/yy".

Exceptions

A multiple dose vial taken into the room of a patient is not considered to be available to other patients, should be restricted to that patient and discarded after use.

Multi-Dose Dilating and Other Diagnostic Eye Drops

Unit dose bottles are not available for many eye drops. The smallest available volume bottle should be substituted for larger volume bottles. All bottles shall be discarded immediately after use.

VCMC, SPH, and AMB Clinics aim to minimize use of multiple dose/use containers whenever possible. If a single-dose/use container is not available, the smallest available multiple dose/use container should be substituted whenever possible.

Overview

- A. VCMC, SPH, and AMB Clinics complies with the original product Manufacturer's Instructions for Use (MIFU).
- B. Products must be inspected prior to use and discarded if discolored or contaminated or out of date.
- C. VCMC, SPH, and AMB Clinics follows safe injection practices
 - 1. Prepare injections using aseptic technique in a clean area free from contamination or contact with blood, body fluids, or contaminated equipment. See aseptic technique section below.
 - 2. Do not use needles and syringes for more than one patient.
 - 3. Injectable containers are entered with a new needle and new syringe.
 - 4. Single dose and single use containers are not used for more than one patient.
 - 5. Prepare an injection as close as possible to the time of administration to reduce the risk of compromising the medications sterility and physical and chemical stability.
- D. For expiration dates that only include the month/year, the unopened product is considered usable until the end of the month unless otherwise stated by the manufacturer.

Multiple dose injectable containers (e.g., MDVs)

- A. Multiple dose injectable containers shall be used for one patient and discarded immediately after use.
- B. The following multiple dose injectable containers are the exception and **may be used for multiple** doses for one patient

- 1. Insulin vials
- 2. Lidocaine with or without epinephrine vials
 - a. In orthopedic cases, a multiple dose vial shall be used for one, separate joint.
- C. The following multiple dose injectable containers are the exception and may be used for **multiple doses** for more than one patient
 - 1. Allergen extracts
 - 2. Tuberculin Purified Protein Derivative (PPD)
 - 3. Vaccines in a multiple dose vial.
 - 4. Multiple dose vials used in sterile compounding in the pharmacy department. See PH.26.04 Sterile Drug Preparation, Labeling, End Product Evaluation and Record Keeping.
- D. All multiple dose injectable containers must be kept in a clean, uncluttered medication area to avoid contamination and must not enter the immediate patient care area. The manufacturer's storage recommendations must be observed.
- E. If a multiple dose injectable container enters the immediate patient care area, it must be dedicated for single patient use and discarded immediately after use
- F. Storage and Stability of multiple dose injectable containers. See policy PH.46 Storage and Security of Medications
 - 1. Discard the multiple dose injectable container after use.
 - 2. Discard an unopened, multi-dose injectable container according to the manufacturer's expiration date.
 - 3. For those exempt multiple dose injectable containers
 - a. Once a multiple dose injectable container is opened (e.g., needle punctured) the container must be dated and discarded within 28 days unless the manufacturer states another date for that opened container.
 - b. The beyond use date must be labeled on the multiple dose injectable container as "MM/DD/ YY."
 - c. Discard opened multiple dose injectable containers that are missing the BUD label.
 - d. Vaccines from a multiple dose injectable vial (e.g., Polio Virus, Inactivated or IPOL) are exempt from the 28-day requirement and are to be discarded per manufacturer's expiration date.⁶

Single dose injectable containers (e.g., SDVs)

- A. Single dose injectable containers are for a single patient for a single case, procedure, or injection.
 - 1. Discard the single dose injectable container after use. See policy PH.46 Storage and Security of Medications
 - 2. Do not combine or pool leftover contents of single dose containers for later use.
 - 3. Discard an unopened single-dose vial according to the manufacturer's expiration date.
- B. Intravenous (IV) fluid solutions are for one patient only.
 - 1. Do not use intravenous solution bags as a common source of supply for more than one patient.
 - 2. Administration sets including IV tubing, bags, connections, needles, and syringes are single patient

<u>use only.</u>

- 3. Discard all intravenous solutions not immediately administered if the manufacturer's outer wrap has been opened or removed and the bag is not labeled with an appropriate BUD.
- 4. Discard any unopened IV fluid containers according to the manufacturer's expiration date.
- C. Single dose injectable containers used in sterile compounding by the pharmacy department follow USP 797 standards. See policy PH.26.04 Sterile Drug Preparation, Labeling, End Product Evaluation and Record Keeping

Non-injectable containers

- A. All products taken into a direct patient care area must be discarded after use unless it is dispensed and labeled for a specific patient and MIFU indicates it is a multiple use container (e.g., patient specific multidose inhaler or MDI; patient specific eye drop).
- B. Oral solutions shall be dispensed as unit dose products for single patient use.
- C. Opthalmic solutions, suspensions, and ointments
 - 1. Single use containers are often not commercially available for opthalmic medications.
 - 2. The smallest available volume container should be substituted for larger volume containers.
 - 3. Dilating and diagnostic eye drops shall be treated as single patient use only and discarded immediately after use.
 - 4. Opthalmic ointments are single patient use only and discarded after use on one patient.
- D. Aerosols are single patient use only.
- E. Sterile irrigation solutions are single patient use only.
- F. Topical applications (e.g., povidone-iodine solution, hydrogen peroxide, silver sulfadiazine, bacitracin/ neomycin/polymyxin B) are single use only to prevent infection.
- G. Discard any unopened non-injectable container according to the manufacturer's expiration date.

<u>Aseptic technique for single or multi-dose injectable containers⁸</u>

- A. Perform hand hygiene.
- B. Determine if the container has been stored properly.
- C. Check the expiration date on the vial
- D. Visually inspect the medication for particles, discoloration, or other loss of integrity. Do not administer if integrity is compromised.
- E. Remove the vial lid.
- F. Disinfect the vial's rubber stopper with an alcohol pad using friction, and then allow to dry.
- <u>G.</u> Pull the syringe plunger back until the volume of air in the syringe equals the volume of drug you will withdraw from the vial.
- H. Without inverting the vial, insert the needle into the vial.
- I. Inject the air into the vial, invert the vial, and keep the needle's bevel tip below the level of the solution as you withdraw the prescribed amount of medication.
- J. Tap the syringe to clear any air from it.

- K. Remove the needle from the vial.
- L. Cover the needle with a needle sheath.
- M. Change the needle on the dose withdrawn and replace it with a needle appropriate in size and length for patient administration.
- N. Syringes with fixed needles such as insulin and tuberculin (TB) syringes, do not require a needle change.
- O. Discard or store the medication container as noted above.

References:

USP Chapter 797 for Multi-Dose Vials

- Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use FDA. October 2018. Accessed 9/11/2024
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- 3. Code of Federal Regulations. 21CFR211.137 Accessed 9/11/2024
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- 5. Preventing infection from the misuse of vials. Sentinel Event Alert: Issue 52. TJC. Accessed 9/12/2021.
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- 7. United States Pharmacopoeia (USP) 797 Pharmaceutical Compounding Sterile Preparations. 2023.
- 8. Subcutaneous Injection, ambulatory care. Intramuscular injection, ambulatory care. Lippincott Procedures. Accessed 9/12/2024.

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1/24/2025, 12/20/2023, 11/10/2020, 9/17/2019, 5/15/ 2019, 5/1/2016, 3/1/2013, 8/1/2011

Attachments

No Attachments

Approver	Date
Stephanie Denson: Manager, Medical Staff Office	pending
Sul Jung: Associate Director of Pharmacy Services	2/7/2025
Sul Jung: Associate Director of Pharmacy Services	2/7/2025
	Stephanie Denson: Manager, Medical Staff Office Sul Jung: Associate Director of Pharmacy Services



PolicyStat ID: 16959626

Origination: Effective: Last Approved: Last Revised: Next Review: Owner: Policy Area:

10/4/2018 Upon Approval N/A 1/22/2025 3 years after approval Sul Jung: Associate Director of Pharmacy Services Administrative - Patient Care

HEALTH CARE AGENCY Policy Area: References:

VENTURA COUNTY

PH.112 Biotherapy and Chemotherapy Dose Rounding

POLICY:

Recent data reviewed by the Hematology/Oncology Pharmacist Association (HOPA) and endorsed by the National Comprehensive Cancer Network (NCCN) shows evidence to support the rounding of biotherapeutic as well as chemotherapeutic drugs. With the cost of drug prices rising quickly, rounding doses is an important initiative to minimize drug waste, ensure accuracy during drug preparation, and reduce healthcare expenditures.

The purpose of this policy is to maintain a protocol of rounding doses of biotherapy and chemotherapy compounded in the infusion center pharmacy to minimize drug waste and fit with available product sizes. Rounding of doses will be consistent with safe administration and minimal risk, while maintaining optimal therapeutic response.

PROCEDURE:

Dose rounding will be restricted to adult patients receiving biotherapy or chemotherapy drugs compounded by the infusion center pharmacy. This includes both hematology/oncology patients and patients referred by specialty clinics. This policy will extend to doses prescribed for treatment in the infusion center, as well as doses administered in the hospital.

The written dose of **biotherapy** (including monoclonal antibodies and monoclonal antibodies with a cytotoxic component) may be rounded up or down to the nearest vial size if the vial size dose is within 10% of the prescribed order. This <u>policy</u> will <u>extend to biosimilar drugs of reference products in this policy</u>. This will be done by the clinical pharmacist during the order review process without prior authorization of the ordering physician. When applicable, doses will be preferentially rounded down. Therapy written for curative patients may be excluded when it is clearly marked on the order by the physician.

These drugs include but are not limited to:

D	0 11 4 1 1	December (constra)	Q
Drug name (generic)	Smallest vial size	Drug name (generic)	Smallest vial size
Ado-trastuzumab	100 mg vial	Ipilimumab	50 mg vial
emtansine			
Avelumab	200 mg vial	Nivolumab	40 mg vial
Belimumab	120 mg vial	Panitumumab	100 mg vial
Bevacizumab	100 mg vial	Pembrolizumab	100 mg vial
Brentuximab vedotin	50 mg vial	Ramucirumab	100 mg vial
Cetuximab	100 mg vial	Rituximab	100 mg vial
Durvalumab	120 mg vial	Tocilizumab	80 mg vial
Infliximab	100 mg vial	Trastuzumab	150 mg vial
	0 11 1 .		G 11 4 1 1 1
Drug name (generic)	Smallest vial size	Drug name (generic)	Smallest vial size
Drug name (generic) Ado- <u>trastuzumab</u>	Smallest vial size 100 mg vial	Drug name (generic) Ipilimumab	Smallest vial size 50 mg vial
Ado-trastuzumab			
Ado-trastuzumab emtansine	100 mg vial	Ipilimumab	50 mg vial
Ado-trastuzumab emtansine Avelumab	100 mg vial 200 mg vial	Ipilimumab Nivolumab	50 mg vial 40 mg vial
Ado- <u>trastuzumab</u> emtansine <u>Avelumab</u> Belimumab	100 mg vial200 mg vial120 mg vial	Ipilimumab Nivolumab Panitumumab	50 mg vial 40 mg vial 100 mg vial
Ado- <u>trastuzumab</u> emtansine Avelumab Belimumab Bevacizumab	100 mg vial 200 mg vial 120 mg vial 100 mg vial	Ipilimumab Nivolumab Panitumumab Pembrolizumab	50 mg vial 40 mg vial 100 mg vial 100 mg vial
Ado-trastuzumab emtansine Avelumab Belimumab Bevacizumab Brentuximab <u>vedotin</u>	100 mg vial 200 mg vial 120 mg vial 100 mg vial 50 mg vial	Ipilimumab Nivolumab Panitumumab Pembrolizumab Ramucirumab	50 mg vial 40 mg vial 100 mg vial 100 mg vial 100 mg vial 100 mg vial

The written dose of **chemotherapy** may be rounded up or down to the nearest vial size if the vial size dose is within 10% of the prescribed order. This will be done by the clinical pharmacist during the order review process without prior authorization of the ordering physician. When applicable, doses will be preferentially rounded down. Therapy written for curative patients may be excluded when it is clearly marked on the order by the physician.

These drugs include but are not limited to:

Drug name (generic)	Smallest vial size	Drug name (generic)	Smallest vial size
Bleomycin	15 unit vial	Gemcitabine	1000 mg vial
Bortezomib	3.5 mg vial	Ifosfamide	3 gram vial
Cabazitaxel	60 mg vial	Irinotecan	100 mg vial
Carfilzomib	30 mg vial	Ixabepilone	15 mg
Cyclophosphamide	500 mg vial	Liposomal doxorubicin	20 mg vial
Dacarbazine	200 mg vial	Methotrexate	250 mg vial
Decitabine	50 mg vial	Mitomycin	5 mg vial
Doxorubicin	50 mg vial	Oxaliplatin	50 mg vial
Epirubicin	50 mg vial	Paclitaxel Protein-bound	100 mg vial
Eribulin	1 mg vial	Pemetrexed	100 mg vial
Fludarabine	50 mg vial	Topotecan	4 mg vial
Fluorouracil	1000 mg vial	Vinorelbine	50 mg vial

If one of the above biotherapy or chemotherapy agents is ordered for a non-curative patient, the clinical pharmacist will assess the dose for potential dose rounding.

The pharmacist will calculate doses that lie in the approved range of 10% above or below the prescribed dose. If the nearest vial size is within range, the dose may be rounded. If possible, rounding down is preferred.

Example for rounding biotherapy/chemotherapy:

- Cyclophosphamide 600 mg/m2 (BSA = 1.79 m2) = 1075 mg.
- ± 10% of prescribed dose would be between 967.5 mg 1182.5 mg. Using 500 mg vial size, rounding within 10% would result in a new dose of 1000 mg.
- Rituxan 375 mg/m2 (BSA = 1.75) = 656 mg.
- ± 10% of prescribed dose range would be between 590.4 mg 721.6 mg. There is an option to either round down (600 mg) or up (700 mg). Rounding down is preferred, so the new dose would be 600 mg.

Example for when dose rounding is *not* appropriate:

- Trastuzumab 6 mg/kg (Wt = 65 kg) = 390 mg
- ± 10% of prescribed dose would be between 351 mg 429 mg. Vial size is 150 mg which would be either 300 mg or 450 mg. Since the calculated dose range does not overlap with the closest vial size, the dose will remain at 390 mg.

For orders where dose rounding is applied, the clinical pharmacist must document the change on the pharmacy paper chart **as well as** in Cerner.

- Document in pharmacy paper chart: Wording should be as follows:
 "Rounding dose policy: Dose of _____ changed from X (units) to Y (units) per dose rounding policy. Change is within 10% of originally prescribed dose per policy. Sign and date."
- Give a copy of the order to the nursing supervisor so it may be added to the patient's chart.
 Document in Cerner: When entering the dose in MedManager, document dose change by clicking the
- Document in Cerner: when entering the dose in MedManager, document dose change by clicking the "Comments..." button, then entering in the information under the "Special Instructions" field. Wording should be as follows:

"Dose changed from X (units) to Y (units) per dose-rounding policy. Change is within 10%. Initials & Date."

SPECIAL INSTRUCTIONS:

Physician override procedure

- The prescribing physician may notate on the written order that doses are not to be rounded if the physician does not wish for Pharmacy to round any of the prescribed doses (i.e., treatment with curative intent).
- The clinical pharmacist, upon review may decide the patient is not a candidate for dose rounding. This may be clinically significant in patients with major organ dysfunction, poor performance status, an extensive treatment history, enzyme deficiencies or genetic polymorphisms.
- In cases where doses have been reduced due to toxicity, doses should only be rounded down.
- Dose rounding will be restricted to adult patients receiving biotherapy or chemotherapy drugs reviewed and compounded by the infusion center pharmacy. This includes both hematology/oncology patients, as well as specialty patients treated at the infusion center.

REFERENCES:

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- Goldspiel B, Hoffman JM, Griffith NL, et al: ASHP guidelines on preventing medication errors with

chemotherapy and biotherapy. Am J Health Syst Pharm 72(8):e6-e35, 2015.

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Attachments

No Attachments

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	2/7/2025
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	1/22/2025



Ventura County Health Care System Oversight

Compliance Administrative Policies

March 2025

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

- 1. 109.018 Use and Disclosure of Protected Health Information as Authorized by a Personal Representative
- 2. 109.024 Use and Disclosure of Protected Health Information for Public Health Activities
- 3. 109.025 Use and Disclosure of Protected Health Information for Research Activities
- 4. 109.026 Use and Disclosure of Protected Health Information for Specialized Government Functions
- 5. 109.028 Use and Disclosure of Protected Health Information for Workers' Compensation Purposes
- 6. 109.029 Use and Disclosure of Protected Health Information of Deceased Individuals
- 7. 109.031 Use and Disclosure of Protected Health Information to Avert a Serious Threat to Health or Safety
- 8. 109.032 Use and Disclosure of Protected Health Information to Employers (By a Provider)
- 9. 109.033 Use and Disclosure of Protected Health Information to Disaster Relief Organizations
- 10. 109.034 Use and Disclosure of Protected Health Information to Individuals Involved in a Patient's Care
- 11. 109.037 Use and Disclosure of Protected Health Information Within an Organized Care Arrangement
- 12. 109.038 Use and Disclosure of Protected Health Information to Plan Sponsors by Group Health Plans
- 13. 109.041 Verification of Identity and Authority of Persons or Entities Requesting Protected Health Information
- 14. 109.043 Email Communication of PHI



VENTURA COUNTY HEALTH CARE SYSTEM Compliance Committee Policies and Procedures

March 2025

Policies & Procedures / Forms / Orders

The following were reviewed and recommended for approval by the appropriate Departments and Committees. Compliance Committee.

#	Title	Summary	Frequency	Page
1.	109.018 Use and Disclosure of Protected Health Information as Authorized by a Personal Representative	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	4-6
2.	109.024 Use and Disclosure of Protected Health Information <i>for</i> <i>Public Health Activities</i>	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	7-8
3.	109.025 Use and Disclosure of Protected Health Information <i>for</i> <i>Research Activities</i>	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	9-14
4.	109.026 Use and Disclosure of Protected Health Information <i>for</i> <i>Specialized Government Functions</i>	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	15-17
5.	109.028 Use and Disclosure of Protected Health Information <i>for</i> <i>Workers' Compensation Purposes</i>	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	18-19
6.	109.029 Use and Disclosure of Protected Health Information <i>of</i> <i>Deceased Individuals</i>	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	20-21
7.	109.031 Use and Disclosure of Protected Health Information <i>to Avert</i> <i>a Serious Threat to Health or Safety</i>	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	22-24
8.	109.032 Use and Disclosure of Protected Health Information to Employers (By a Provider)	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	25-27
9.	109.033 Use and Disclosure of Protected Health Information to Disaster Relief Organizations	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	28-29
10.	109.034 Use and Disclosure of Protected Health Information to	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	30-32
11.	109.037 Use and Disclosure of Protected Health Information <i>Within</i> <i>an Organized Care Arrangement</i>	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	33-35
12.	109.038 Use and Disclosure of Protected Health Information to Plan Sponsors by Group Health Plans	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	36-39
13.	109.041 Verification of Identity and Authority of Persons or Entities Requesting Protected Health Information	The purpose and policy sections were separated. All other changes were minor formatting and editing changes.	Annual	40-42
14.	109.043 E-Mail Communication of PHI	The changes included substantive, language and formatting changes. Substantive changes included providing methods of secure	Annual	43-47

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		munication, which prefers	
	patie	ents are directed to patient	
	porta	als. The confidentiality notice	
	disc	aimer was added as the	
	sugg	ested email disclaimer for	
	emp	loyee use. The fax disclaimer was	
	remo	oved. Highly confidential	
	infor	mation was revised from never	
	trans	smitted by email to MUST be	
		smitted by encrypted email. The	
		f information deemed highly	
		idential was revised to align with	
		inology currently in use.	
		uage changes were made to	
		ulate the policy and procedure in	
		ar and direct manner understood	
	by al	l users. The formatting changes	
	-	made to categorize general	
		rity of email systems and email	
		ving PHI and organize the content	
		ocess order.	
	iii bi		

Origination	4/1/2003	Owner	Melissa
Last Approved	Last N/A oved		Guevarra: Acting Compliance
VENTURACOUNTY Effective	N/A	Policy Area	Officer Administrative -
HEALTH CARE AGENCY Last Revised	N/A	T oney Area	Compliance
Next Review	N/A		

109.018 Use and Disclosure of Protected Health Information as Authorized by a Personal Representative

PURPOSE

The purpose of this policy is to ensure that VCHCA staff understands and complies with HIPAA requirements regarding personal representatives.

POLICY:

Under HIPAA, VCHCA must recognize certain persons as a "personal representative" of another individual; and treat that personal representative as the individual for purposes of use and disclosedisclosure of the individual's protected health information. The purpose of this policy is to ensureVCHCA shall recognize certain persons as a personal representative of another individual and treat that VCHCApersonal representative as the individual for purposes of use and disclosure of the individual's staff understands and complies with HIPAA's requirements regarding personal representatives protected health information.

VCHCA shall recognize certain persons as a personal representative of another individual, and treat that personal representative as the individual for purposes of use and disclose of the individual's protected health information.

PROCEDURE

- 1. Adults and emancipated minors. If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, VCMC must treat such person as a personal representative under HIPAA with respect to protected health information relevant to such personal representation.
- 2. Deceased individuals. If under applicable law an executor, administrator, or other person has

authority to act on behalf of a deceased individual or of the individual's estate, VCMC must treat such person as a personal representative under HIPAA with respect to protected health information relevant to such personal representation.

Un-emancipated minors.

a. If under applicable law a parent, guardian, or other person acting *in loco parentis* has authority to act on behalf of an individual who is an un-emancipated minor in making decisions related to health care, VCHCA must treat such person as a personal representative under HIPAA, with respect to protected health information relevant to such personal representation.

However, such person may not be a personal representative of an un-emancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

- i. the minor consents to such health care service;
- ii. no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained;
- iii. the minor has not requested that such person be treated as the personal representative; and
- iv. a parent, guardian, or other person acting *in loco parentis* assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care services.
- b. Notwithstanding the provisions above:
 - i. If, and to the extent, permitted or required by an applicable provision of state or other law, including applicable case law, VCHCA may disclose, or provide access to, protected health information about an un-emancipated minor to a parent, guardian, or other person acting *in loco parentis*;
 - ii. If, and to the extent, prohibited by an applicable provision of state or other law, including applicable case law, VCHCA may not disclose, or provide access to, protected health information about an un-emancipated minor to a parent, guardian, or other person acting *in loco parentis*; and
 - iii. Where the parent, guardian, or other person acting *in loco parentis*, is not the personal representative under paragraphs 3.a.(i), (ii), or (iii) of this Policy and Procedure and where there is no applicable access provision under state or other law, including case law, VCHCA may provide or deny access to a parent, guardian, or other person acting *in loco parentis*, if such action is consistent with state or other applicable law, provided that such decision must be made by a licensed health care professional based on a good faith belief that providing or denying access is in the best interest of the individual.
- c. VCHCA must, consistent with state or other applicable law, provide a right of access to either:
 - i. a parent, guardian, or other person acting *in loco parentis*, as the personal representative of the un-emancipated minor,

- ii. the un-emancipated minor, or
- iii. both (i) and (ii).
- 3. Abuse, neglect, endangerment situations. Notwithstanding a state law or any requirement to the contrary, VCHCA may elect not to treat a person as the personal representative of an individual if:
 - a. VCHCA has a reasonable belief that:
 - i. The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or
 - ii. <u>Treating such person as the personal representative could endanger the</u> individual; and
 - b. VCHCA's professional staff, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.
- 4. Authorization by supervisory/management staff. The appropriate supervisory/management staff must authorize disclosures made pursuant to this Policy and Procedure.
- 5. Documentation of disclosures. Health Information Management staff shall document in the individual's medical record any uses or disclosures of protected health information authorized by or made to a personal representative, including a description of the information disclosed, the date of the disclosure, the individual and/or entity to whom/which the disclosure was made, the basis upon which the personal representative was authorized to act on behalf of the individual, and the supervisory/management staff who authorized the disclosure.

Applicable Laws and Regulations:

45 CFR §164.502(g); California Civil Code §56.10(c) (14).

PROCEDURE:

- 1. Adults and emancipated minors. If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, VCMC must treat such person as a personal representative under HIPAA with respect to protected health information relevant to such personal representation.
- 2. Deceased individuals. If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, VCMC must treat such person as a personal representative under HIPAA with respect to protected health information relevant to such personal representation.

Un-emancipated minors.

a. If under applicable law a parent, guardian, or other person acting *in loco parentis* has authority to act on behalf of an individual who is an un-emancipated minor in making decisions related to health care, VCHCA must treat such person as a personal representative under HIPAA, with respect to protected health information relevant to such personal representation. *However,* such person may not be a personal representative of an un-emancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

- i. the minor consents to such health care service;
- ii. no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; *and*
- iii. the minor has not requested that such person be treated as the personal representative.
- b. Notwithstanding the provisions above:
 - i. If, and to the extent, permitted or required by an applicable provision of state or other law, including applicable case law, VCHCA may disclose, or provide access to, protected health information about an un-emancipated minor to a parent, guardian, or other person acting *in loco parentis*;
 - ii. If, and to the extent, prohibited by an applicable provision of state or other law, including applicable case law, VCHCA may not disclose, or provide access to, protected health information about an un-emancipated minor to a parent, guardian, or other person acting *in loco parentis*; and



- iii. Where the parent, guardian, or other person acting in loco parentis, is not the personal representative under paragraphs 3.a.(i), (ii), or (iii) of this Policy and Procedure and where there is no applicable access provision under state or other law, including case law, VCHCA may provide or deny access to a parent, guardian, or other person acting in loco parentis, if such action is consistent with state or other applicable law, provided that such decision must be made by a licensed health care professional, in the exercise of professional judgment.
- c. VCHCA must, consistent with state or other applicable law, provide a right of access to either:
 - i. a parent, guardian, or other person acting *in loco parentis*, as the personal representative of the un-emancipated minor,
 - ii. the un-emancipated minor, or
 - iii. both (i) and (ii).
- 3. Abuse, neglect, endangerment situations. Notwithstanding a state law or any requirement to the contrary, VCHCA may elect not to treat a person as the personal representative of an individual if:
 - a. VCHCA has a reasonable belief that:
 - i. The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or
 - ii. Treating such person as the personal representative could endanger the individual; and
 - b. VCHCA's professional staff, in the exercise of professional judgment, decides that it

is not in the best interest of the individual to treat the person as the individual's personal representative.

- 4. Authorization by supervisory/management staff. The appropriate supervisory/management staff must authorize disclosures made pursuant to this Policy and Procedure.
- 5. Documentation of disclosures. Health Information Management staff shall document in the individual's medical record any uses or disclosures of protected health information authorized by or made to a personal representative, including a description of the information disclosed, the date of the disclosure, the individual and/or entity to whom/which the disclosure was made, the basis upon which the personal representative was authorized to act on behalf of the individual, and the supervisory/management staff who authorized the disclosure.



Origination	4/1/2003	Owner	Melissa
Last Approved	N/A		Guevarra: Acting Compliance
VENTURACOUNTY Effective	N/A	Policy Area	Officer Administrative -
HEALTH CARE AGENCY Last Revised	N/A	T oney Area	Compliance
Next Review	N/A		

109.024 Use and Disclosure of Protected Health Information for Public Health Activities

PURPOSE

The purpose of this policy is to ensure that such disclosures are made in accordance with HIPAA and applicable state laws.

POLICY:

Under HIPAA, VCHCA may, for certain public health activities, use or disclose protected health information without the individual's written authorization or opportunity to agree or object to the use or disclosure. The purpose of this policy is to ensure that such disclosures are made in accordance with HIPAA and applicable state laws. VCHCA may disclose, without patient authorization, protected health information for public health activities and purposes to public health authorities, entities, and persons authorized by law to receive such information.

PROCEDURE

- 1. **Permissible Disclosures**. VCHCA may use or disclose protected health information, without the written authorization of the individual or the opportunity for the individual to agree or object, to any of the following individuals or entities:
 - A public health authority that is explicitly authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to, the reporting of disease, injury vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority.

- A public health authority or other appropriate government authority authorized by law to receive reports of child abuse, neglect, sexual or domestic violence.
- <u>A person subject to the jurisdiction of the FDA with respect to a FDA-regulated</u> product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:</u>
 - i. To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations,
 - ii. To track FDA-regulated products,
 - iii. To enable product recalls, repairs, or replacement, or look back (including locating and notifying individuals who have received products that have been recalled withdrawn, or are the subject of look back), or
 - iv. To conduct post marketing surveillance.
- A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation.
- To an individual's employer, under certain circumstances (see Policy and Procedure on Disclosure of Protected Health Information to Employers).
- 2. Management Approval Process. The disclosures contemplated by this policyare not mandatory. VCHCA shall not disclose the information contemplated by this policy unless and until approved by VCHCA management. In such cases, management shall verify the authority of the entity to receive the requested information and document the verification and other relevant facts of the disclosure in the patient's medical record.

Applicable Laws and Regulations:

- 45 CFR §164.512(b)
- California Civil Code §56.10(c)(14)

PROCEDURE:

- 1. **Permissible Disclosures**. VCHCA may use or disclose protected health information, without the written authorization of the individual or the opportunity for the individual to agree or object, to any of the following individuals or entities:
 - A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to, the reporting of disease, injury vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public

health authority.

- A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect.
- A person subject to the jurisdiction of the FDA with respect to a FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:
 - i. To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations,
 - ii. To track FDA-regulated products,
 - iii. To enable product recalls, repairs, or replacement, or look back (including locating and notifying individuals who have received products that have been recalled withdrawn, or are the subject of look back), or
 - iv. To conduct post marketing surveillance.
- A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation.
- To an individual's employer, under certain circumstances (see Policy and Procedure on Disclosure of Protected Health Information to Employers).
- 2. Management Approval Process. The disclosures contemplated by this policyare not mandatory. VCHCA shall not disclose the information contemplated by this policy unless and until approved by VCHCA management. In such cases, management shall verify the authority of the entity to receive the requested information and document the verification and other relevant facts of the disclosure in the patient's medical record.

Step Description	Approver	Date
Compliance & Privacy Office	Melissa Guevarra: Acting Compliance Officer	Pending

Status	Draft	PolicyStat ID	17803872
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Origination	4/1/2003	Owner	Melissa
Last Approved	N/A		Guevarra: Acting Compliance
VENTURACOUNTY Effective	N/A	Policy Area	Officer Administrative -
HEALTH CARE AGENCY Last Revised	N/A	T oney Area	Compliance
Next Review	N/A		-

109.025 Use and Disclosure of Protected Health Information for Research Activities

PURPOSE

Health care organizations may use and disclose Protected Health Information for research activities. The purpose of this policy is to ensure that such uses and disclosures are made in accordance with the requirements of applicable state and Federal laws and regulations.

POLICY:

<u>VCHCA will use and disclose Protected Health Information for research activities only as permitted by</u> <u>state and Federal laws including HIPAA.</u> Under HIPAA, a health care organization may use and disclose Protected Health Information for research activities, regardless of the source of funding of the research, with or without the individual's authorization or an opportunity to object to the use or disclosure, subject to certain conditions. The purpose of this policy is to ensure that such uses and disclosures are made in accordance with the requirements of applicable State and Federal laws and regulations.

Protected health information shall be used and/or disclosed for research purposes only as permitted under applicable State and Federal laws and regulations as set forth in this policy and procedure.

Applicable Laws and Regulations:

PROCEDURE

1. Use or Disclosure for Research Purposes Absent Patient Authorization - General Rule. VCHCA may only use or disclose Protected Health Information for Research purposes, without the individual's authorization or an opportunity to object to the use or disclosure, under the following circumstances:

- a. The researcher obtains a waiver or alteration of the authorization requirement that has been approved an legally established and compliant Institutional Review Board (IRB) or by a Privacy Board that meets certain legal requirements with respect to its members;
- b. The researcher documents in writing that (i) use or disclosure is sought solely to review Protected Health Information as necessary to prepare a research protocol or for similar purposes preparatory to research (ii) no Protected Health Information is to be removed from the premises by the researcher in the course of the review, and (iii) the Protected Health Information for which use or access is sought is necessary for the research purposes, or
- c. VCHCA obtains from the researcher (i) documentation that the use or disclosure is solely for research on the Protected Health Information of decedents, (ii) documentation of the death of such individuals, and (iii) representation that the Protected Health Information for which use of disclosure is sought is necessary for research purposes.

NOTE: A researcher may *not* request a decedent's medical history to obtain health information about a decedent's living relative. A researcher *may* request a decedent's medical history for an outcomes study relating to treatment previously administered to the decedent.

- 2. Method of IRB/Privacy Board Approval. The approval of the IRB or privacy board described in paragraph 1(a) above must occur in the following manner:
 - a. In the case of an IRB, the IRB must follow the requirements of the Common Rule, including the normal review procedures or the expedited review procedures (see VCHCA Policy and Procedure on Institutional Review Boards);
 - b. In the case of a privacy board, the privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present (including at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities), and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure described below.
 - c. A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the Protected Health Information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair.
 - d. The approval of the IRB or privacy board must be documented in the form attached to this Policy and Procedure as Exhibit "A."
- 3. Effect of Permission for Research Obtained Prior to HIPAA Compliance Date. VCHCA may, to the extent allowed by one of the following permissions, use or disclose, for research, Protected

Health Information that it created or received either before or after the HIPAA compliance date of this subpart, provided that there is no agreed-to restriction on the use or disclosure of the individual Protected Health Information (see Policy and Procedure on Processing Requests for Patient Restrictions on Use and Disclosure of Protected Health Information), and VCHCA has obtained, prior to the compliance date, either:

- a. An authorization or other express legal permission from an individual to use or disclose Protected Health Information for the research;
- b. The informed consent of the individual to participate in the research; or
- c. A waiver, by an IRB, of informed consent for the research, in accordance with federal and state law, provided that VCHCA must obtain authorization (see 109.010 Policy and Procedure on Obtaining Authorization for Use or Disclosure of Protected Health Information) if, after the compliance date, informed consent is sought from the individual participating in the research.
- 4. Suspension of Individual's Right of Access During Research. VCHCA may suspend the individual's access to Protected Health Information created or obtained during the course of research that includes treatment only under the following circumstances:
 - a. The individual has agreed to the denial of access when consenting to participate in the research, and
 - b. The individual has been informed that the right of access will be reinstated upon completion of the research.
 - c. Sample language to be included in the research consent form and which will address items a. and b. above is as follows: "You agree that your right to access your Protected Health Information will be suspended during the course of the research. We will notify you when the research is completed, at which time your right to access will be reinstated."

5. Use or Disclosure for Research Purposes with Authorizations

Compound conditioned and unconditioned authorizations are permitted for most kinds of research, provided that the combined authorization clearly differentiates between the conditioned and unconditioned research components and clearly allows the individual the option to opt in to the unconditioned research activities.

<u>Combined authorizations cannot require individuals to opt-out of unconditioned research</u> activities. Uses involving a decedent's PHI requires authorization from the decedent's personal representative during the 50 years since the date of the death of the deceased.

a. Authorizations for Future Research Uses or Disclosures.

Research authorizations need not be study-specific, provided that they describe future uses or disclosures sufficiently to enable individuals to reasonably expect that their PHI could be used or disclosed for future research, combined authorizations **cannot** require individuals to opt-out of unconditioned research activities

b. Psychotherapy Notes

Whether research-related or not, such authorizations may **only** be combined with another authorization for a use or disclosure of psychotherapy notes. See 78 Fed. Reg. 5566, 5610 (January 25, 2013).

Applicable Laws and Regulations

45 CFR §§ 164.512 (i), 164.524(a)(2)(iii), 164.532(c)45 CFR §§ 164.512 (i), 164.524(a)(2)(iii), 164.532(c)

45 C.F.R. § 164.508(b)(3) 45 C.F.R. § 164.508(b)(3)

California Civil Code § 56.10(c)(7)California Civil Code § 56.10(c)(7)

PROCEDURE:

- Use or Disclosure for Research Purposes Absent Patient Authorization General Rule.
 VCHCA may only use or disclose Protected Health Information for Research purposes, without the individual's authorization or an opportunity to object to the use or disclosure, under the following circumstances:
 - a. VCHCA obtains a waiver or alteration of the authorization requirement that has been approved by an legally established and compliant Institutional Review Board or by a Privacy Board that meets certain legal requirements with respect to its members;
 - b. The researcher documents in writing that (i) use or disclosure is sought solely to review Protected Health Information as necessary to prepare a research protocol or for similar purposes preparatory to research (ii) no Protected Health Information is to be removed from the premises by the researcher in the course of the review, and (iii) the Protected Health Information for which use or access is sought is necessary for the research purposes, or
 - e. VCHCA obtains from the researcher (i) documentation that the use or disclosure is solely for research on the Protected Health Information of decedents, (ii) documentation of the death of such individuals, and (iii) representation that the Protected Health Information for which use of disclosure is sought is necessary for research purposes.

NOTE: A researcher may *not* request a decedent's medical history to obtain health information about a decedent's living relative. A researcher *may* request a decedent's medical history for an outcomes study relating to treatment previously administered to the decedent.

- 2. Method of IRB/Privacy Board Approval. The approval of the IRB or privacy board described in paragraph 1(a) above must occur in the following manner:
 - a. In the case of an IRB, the IRB must follow the requirements of the Common Rule, including the normal review procedures or the expedited review procedures (see VCHCA's Policy and Procedure on Institutional Review Boards);
 - b. In the case of a privacy board, the privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present (including at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities), and the alteration or waiver of authorization must be approved by the majority of the privacy board members

present at the meeting, unless the privacy board elects to use an expedited review procedure described below.

- c. A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the Protected Health Information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair.
- d. The approval of the IRB or privacy board must be documented in the form attached to this Policy and Procedure as Exhibit "A."
- 3. Effect of Permission for Research Obtained Prior to HIPAA Compliance Date. VCHCA may, to the extent allowed by one of the following permissions, use or disclose, for research, Protected Health Information that it created or received either before or after the HIPAA compliance date of this subpart, provided that there is no agreed-to restriction on the use or disclosure of the individual Protected Health Information (see Policy and Procedure on Processing Requests for Patient Restrictions on Use and Disclosure of Protected Health Information), and VCHCA has obtained, prior to the compliance date, either:
 - a. An authorization or other express legal permission from an individual to use or disclose Protected Health Information for the research;
 - b. The informed consent of the individual to participate in the research; or
 - e. A waiver, by an IRB, of informed consent for the research, in accordance with 7 CFR 1 c. 116(d), 10 CFR 745.116(d), 14 CFR 1230.116(d), 15 CFR 27.116(d), 16 CFR 1028.116(d), 21 CFR 50.24, 22 CFR 225.116(d), 24 CFR 60.116(d), 28 CFR 46.116(d), 32 CFR 219.116(d), 34 CFR 97.116(d), 38 CFR 16.116(d), 40 CFR 26.116(d), 45 CFR 46.116(d), 45 CFR 46.116(d), or 49 CFR 11.116(d), provided that VCHCA must obtain authorization (see 109.010 Policy and Procedure on Obtaining Authorization for Use or Disclosure of Protected Health Information) if, after the compliance date, informed consent is sought from the individual participating in the research.
- 4. Suspension of Individual's Right of Access During Research. VCHCA may suspend the individual's access to Protected Health Information created or obtained during the course of research that includes treatment only under the following circumstances:
 - a. The individual has agreed to the denial of access when consenting to participate in the research, and
 - b. The individual has been informed that the right of access will be reinstated upon completion of the research.
 - c. Sample language to be included in the research consent form and which will address items a. and b. above is as follows: "You agree that your right to access your Protected Health Information will be suspended during the course of the research. We will notify you when the research is completed, at which time your right to access will be reinstated."
- 5. Use or Disclosure for Research Purposes with Authorizations

Compound conditioned and unconditioned authorizations are permitted for most kinds of research, provided that the combined authorization clearly differentiates between the conditioned and unconditioned research components and clearly allows the individual the option to opt in to the unconditioned research activities.

Combined authorizations cannot require individuals to opt-out of unconditioned research activities. Uses involving a decedent's PHI requires authorization from the decedent's personal representative during the 50 years since the date of the death of the deceased.

a. Authorizations for Future Research Uses or Disclosures.

Research authorizations need not be study-specific, provided that they describe future uses or disclosures sufficiently to enable individuals to reasonably expect that their PHI could be used or disclosed for future research, combined authorizations **cannot** require individuals to opt-out of unconditioned research activities

b. Psychotherapy Notes

Whether research-related or not, such authorizations may **only** be combined with another authorization for a use or disclosure of psychotherapy notes. See 78 Fed. Reg. 5566, 5610 (January 25, 2013).

Attachments

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A: Documentation of IRB/Privacy Board Approval of Alteration or Waiver of Authorization for Use or Disclosure of Protected Health Information for Research Activities

Approval Signatures

Step Description	Approver	Date
Compliance & Privacy Office	Melissa Guevarra: Acting Compliance Officer	Pending

DOCUMENTATION OF IRB/PRIVACY BOARD APPROVAL OF ALTERATION OR WAIVER OF AUTHORIZATION FOR USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH ACTIVITIES

1.	IRB/Privacy Board Name/Identification:
2.	Name/Identification of Research Study:
3.	Name of Principal Investigator:
4.	Date of Approval of Alteration or Waiver of Authorization:
5.	Describe the Extent of the Alteration or Waiver Approved:

(If alteration, as opposed to waiver, attach copy of altered authorization.)

- 6. **Waiver Criteria**: The IRB/Privacy Board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:
 - (a) The use or disclosure of Protected Health Information involves no more than minimal risk to the privacy of the individuals, based on at least the presence of the following elements:
 - i. An adequate plan to protect the identifiers from improper use and disclosure. Describe:

An adequate plan to destroy the identifiers at the earliest opportunity ii. consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Describe:

iii. Adequate written assurances that the Protected Health Information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of Protected Health Information would be permitted under the law

	Describe:
(b)	The research could not practicably be conducted without the alteration or
	waiver. Describe:
(c)	The research could not practicably be conducted without access to and use of the Protected Health Information. Describe:
Pr	otected health information needed . The following is a brief description of th otected Health Information for which use or access has been determined to b cessary by the IRB/Privacy Board:
Pr	otected Health Information for which use or access has been determined to b
Pr ne 	otected Health Information for which use or access has been determined to b
Pr ne — — — Be as	otected Health Information for which use or access has been determined to b cessary by the IRB/Privacy Board: eview and approval procedures. The alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures
Pr ne Pe as No	eview and approval procedures. The alteration or waiver of authorization haven reviewed and approved under either normal or expedited review procedures described below: prmal Expedited Review
Pr ne — — — Be as No —	eview and approval procedures. The alteration or waiver of authorization haven reviewed and approved under either normal or expedited review procedures described below:

Date

Origination	4/1/2003	Owner	Melissa
Last Approved	N/A		Guevarra: Acting Compliance
VENTURACOUNTY Effective	N/A	Policy Area	Officer Administrative -
HEALTH CARE AGENCY Last Revised	N/A	r oney / red	Compliance
Next Review	N/A		

109.026 Use and Disclosure of Protected Health Information for Specialized Government Functions

PURPOSE

HIPAA allows use and disclosure of protected health information for certain specialized government functions. The purpose of this policy is to ensure disclosures are made in accordance with HIPAA and applicable state laws.

POLICY:

Under HIPAA, VCHCA may, for certain specialized government functions described in the Policy and Procedure, use or disclose protected health information without the individual's written authorization or opportunity to agree or object to the use or disclosure<u>under HIPAA</u>. The purpose of VCHCA shall use or disclose protected health information for specialized government functions described in this policy is to ensure that such disclosures are made in accordance withwithout the individual's written authorization or opportunity to agree or object to the disclosure only as permitted under HIPAA and applicable state laws.

VCHCA shall use or disclose protected health information for specialized government functions described in this policy without the individual's written authorization or opportunity to agree or object to the disclosure only as permitted under HIPAA and applicable state laws.

Applicable Laws and Regulations:

45 CFR §164.512(k); California Civil Code §56.10(c)(14).

PROCEDURE:

- VCHCA may use or disclose protected health information without the written authorization of the individual or the opportunity for the individual to agree or object under the circumstances described below:
 - a. Military and veteransveteran's activities.
 - i. **Armed Forces personnel.** VCHCA may use and disclose the protected health information of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the Federal Register the following information:
 - A. Appropriate military command authorities; and
 - B. The purposes for which the protected health information may be used or disclosed.
 - ii. **Foreign military personnel.** VCHCA may use and disclose the protected health information of individuals who are foreign military personnel to their appropriate foreign military authority for the same purpose for which uses and disclosures are permitted for Armed Forces personnel under the notice published in the Federal Register pursuant to paragraph (1)(a)(i) of this Policy and Procedure.
 - b. **National security and intelligence activities.** VCHCA may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counterintelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, et seq.) and implementing authority (e.g., Executive Order 12333).
 - c. **Protective services for the President and others.** VCHCA may disclose protected health information to authorized federal officials for the provision of protective services to the President or other persons authorized by 18 U.S.C. 3056, or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or to for the conduct of investigations authorized by 18 U.S.C. 871 and 879.
 - d. Correctional institutions and other law enforcement custodial situations.
 - i. **Permitted disclosures.** VCHCA may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual protected health information about such inmate or individual, if the correctional institution or such law enforcement official represents that such protected health information is necessary for:
 - A. The provision of health care to such individuals;
 - B. The health and safety of such individual or other inmates;
 - C. The health and safety of the officers or employees of or others at the correctional institution;
 - D. The health and safety of such individuals and officers or other

persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;

- E. Law enforcement on the premises of the correctional institution; and
- F. The administration and maintenance of the safety, security, and good order of the correctional institution.
- The disclosures contemplated by this policy are not mandatory. VCHCA shall not disclose the information covered by this policy unless and until approved by VCHCA management. In such cases, management shall verify the authority of the entity or individual to receive the requested information and document the verification and other relevant facts of the disclosure in the patient's medical record.

Applicable Laws and Regulations

45 CFR §164.512(k); California Civil Code §56.10(c)(14).



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HEALTH CARE AGENCY Last Revised	N/A	r oncy Area	Compliance
Next Review	N/A		-

109.028 Use and Disclosure of Protected Health Information for Workers' Compensation Purposes

PURPOSE

Under HIPAA protected health information relating to workers' compensation or other similar programs may be used and disclosed subject to certain exceptions. The purpose of this policy is to ensure that disclosures for workers' compensation purpose are made in accordance with the requirements of HIPAA and applicable state laws.

POLICY:

Under HIPAA, VCHCA may use and disclose protected health information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs established by law without obtaining a written authorization from the patient or providing the patient with an opportunity to agree or object <u>under HIPAA</u>. California law expressly exempts from the provisions of the Confidentiality of Medical Information Act certain disclosures of medical information related to worker safety and industrial accidents. The purpose of this policy is to ensure that disclosures for workers' compensation purposes are made in accordance with the requirements of HIPAA and applicable state laws.

VCHCA may disclose, without patient authorization, protected health information as authorized by and to comply with laws relating to workers' compensation or other similar programs established by law, that provide benefits for work-related injuries or illness without regard to fault.

Applicable Laws and Regulations:

- 45 CFR §164.512(1)
- California Civil Code §56.10(b)(8)

- California Civil Code §56.30(e), (f), (h), (k)

PROCEDURE: PROCEDURE

 Permitted uses and disclosures. VCHCA shall make disclosures of protected health information regarding a patient who becomes injured or ill as a result of his or her employment without first obtaining the patient's authorization or providing the patient with an opportunity to agree or object when such disclosures are authorized by and necessary for VCHCA to comply with laws relating to workers' compensation or other similar programs.

For example, Labor Code §6300 requires that every physician who attends <u>to</u> any injured employee to file a report of the injury and illness with the employer, or if insured, with the employer's insurer, on forms prescribed for that purpose by the Division of Labor Statistics and Research. Thereafter, the employer or insurer, as the case may be, is required to file the physician's report with the Department of Industrial Relations within five days of receipt. Neither of these disclosures <u>requires</u> the patient's authorization.

- Minimum necessary standard. The information disclosed for workers' compensation purposes must not exceed the minimum necessary to satisfy with the purposes for which the disclosure is made. (See Administrative Compliance policyipolicy on Minimum Necessary Use and Disclosure of Protected Health Information.)
- 3. Authorization for disclosures in response to request; documentation. Upon receiving a request to disclose protected health information for workers' compensation or related purposes, staff shall consult with the appropriate supervisory/management staff prior to making any such disclosures. Staff shall document all relevant facts of any disclosures of this nature in the patient's medical record, including a description of the information disclosure, and the individual and entity to whom/which the disclosure was made.
- 4. Human Resources staff who work on Workmen's Compensation cases have appropriate access to PHI in order to complete their jobs.

Applicable Laws and Regulations

- 45 CFR §164.512(1)
- · California Civil Code §56.10(b)(8)
- California Civil Code §56.30(e), (f), (h), (k)

Approval Signatures

Step Description	Approver	Date
Compliance & Privacy Office	Melissa Guevarra: Acting Compliance Officer	Pending

Status Draft PolicyStat ID 17804391			
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HEALTH CARE AGENCY Last Revised	N/A	i onoy Area	Compliance
Next Review	N/A		

109.029 Use and Disclosure of Protected Health Information of Deceased Individuals

PURPOSE

The purpose of this policy is to ensure compliance with the applicable provisions of State and Federal laws and regulations concerning protected health information of deceased individuals.

POLICY:

Under HIPAA, VCHCA will use or disclose protected health information concerning deceased individuals may be used or disclosed only as permitted by law. The purpose of Protected health information concerning deceased individuals shall be maintained in a confidential and secure manner as set forth in this policyPolicy and Procedure for as long as the information is to ensure compliance with the applicable provisions of State and Federal laws and regulations concerning protected health information of deceased individuals.retained by VCHCA

Protected health information concerning deceased individuals shall be maintained in a confidential and secure manner as set forth in this Policy and Procedure for as long as the information is retained by VCHCA

Applicable Laws and Regulations:

45 CFR §164.502(f), 164.502(g)(4), 164.510, 164.512(g) California Civil Code §56.10(c)(6), 56.10(14) California Health & Safety Code §1797.188(c)

PROCEDURE:

- Upon death, the medical records clerk shall close the patient's medical record and send it to storage. The medical record shall be protected in the same manner and to the same extent required for the protected health information of living individuals, except for uses and disclosures for research purposes.
- 2. The deceased patient's medical records shall be maintained for the length of time required by applicable federal and state laws.
- 3. The deceased patient's medical records shall be disclosed to coroners and medical examiners for identification of a deceased person or to determine cause of death.
- 4. Staff will release to the funeral director for the deceased any information needed so that the funeral director can carry out duties with respect to the deceased. Such disclosures may occur prior to and in reasonable anticipation of the individual's death.
- 5. Staff will treat any family members or other legal representatives who have authority to act on behalf of the deceased as the deceased with respect to personal health care information.
- 6. If the protected health information about the deceased person is relevant to the treatment of a family member, the family member's health care provider may obtain that information with the appropriate authorization of Use and Disclosure.
- 7. We may disclose a decedent's information to family members and others who were involved in the care or payment for care of the decedent prior to the death, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the VCHCA.
- 8. Any information that would otherwise constitute PHI of a decedent under 45 CFR § 160.201 ceases to be PHI 50 years after the death of the decedent. For any use and disclosure that requires authorization, the Use and Disclosure rules apply.
- 9. If the deceased'sdecedents health care information is being requested for research purposes, and the research standards are met for use and disclosure absent authorization, the Health Information Management Department will ensure that the requested information, will be maintained as any other PHI by the except for research that requires authorization.

Applicable Laws and Regulations

<u>45 CFR § § 160.201,164.502(f), 164.502(g)(4), 164.510, 164.512(g)</u> California Civil Code §56.10(c)(6), 56.10(14) California Health & Safety Code §1797.188(c)

Approval Signatures

Step Description

Approver

Date

Origination	4/1/2003	Owner	Melissa
Last Approved	N/A		Guevarra: Acting Compliance Officer
VENTURACOUNTY Effective	N/A	Policy Area	Administrative -
HEALTH CARE AGENCY Last Revised	N/A	T Olicy Area	Compliance
Next Review	N/A		

109.031 Use and Disclosure of Protected Health Information to Avert a Serious Threat to Health or Safety

<mark>POLICY:</mark> PURPOSE

Under HIPAA, VCHCA may use or disclose protected health information, without the written authorization of the individual or the opportunity for the individual to agree or object, if VCHCA, in good faith, believes the use or disclosure, is necessary to avert a serious threat to health or safety. The purpose of this policy is to ensure that such disclosures are made in accordance with the requirements of HIPAA and applicable state laws.

POLICY

VCHCA shall use or disclose protected health information, without the individual's written authorization or opportunity to agree or object to the disclosure, if VCHCA has a reasonable belief that the use or disclosure is necessary to avert a serious threat to health or safety.

Applicable Laws and Regulations:

45 CFR §164.5120); California Civil Code §56.10(c)(14).

PROCEDURE:

 Permitted uses or disclosures to avert a threat to health or safety. Subject to certain exceptions contained in paragraph 5 below, VCHCA may, without the written authorization of the individual or the opportunity for the individual to agree or object, use or disclose protected health information if VCHCA, inhas a good faith, believes belief* the use or disclosure:

- i. Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; **and**
 - ii. Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or
- b. Is necessary for law enforcement authorities to identify or apprehend an individual:
 - i. Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or
 - ii. Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody.
- 2. Limit on information that may be disclosed. A disclosure made pursuant to paragraph 1 .b.(i) of this policy may contain only the statement described in paragraph 1 .b.(i) and the following protected health information:
 - i. name and address

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- ii. date and place of birth
- iii. social security number
- iv. ABO blood type and rh factor
- v. type of injury
- vi. date and time of treatment
- vii. date and time of death, if applicable
- viii. description of distinguishing physical characteristics
- 3. **Disclosures must be authorized by appropriate staff**. Any disclosures in accordance with this policy must be authorized by the appropriate supervisory/management staff.
- 4. **Documentation of disclosures**. Staff shall document all relevant facts of the disclosure in the patient's medical record, including a description of the information disclosed, the date of the disclosure, the individual and entity to whom/which the disclosure was made, and the name of the supervisory/management staff who authorized the disclosure.
- 5. **Use or disclosure not permitted**. A use or disclosure pursuant to item 1 .b. (i) of this policy may not be made if the information described in paragraph 1.b. (i) of this policy may not be made if the information described in paragraph 1.b. (i) is learned by VCHCA:
 - a. In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph 1 .b. (i), or counseling or therapy; or
 - b. Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy described in paragraph 5.a. above.

SEE ALSO PSYCHIATRIC INPATIENT UNIT (IPU) POLICY "REQUEST FOR CONFIDENTIAL INFORMATION - ASSISTANCE TO LAW ENFORCEMENT AGENCIES."

* Good faith belief presumption. A covered entity that uses or disclosed protected health information

pursuant to this policy is presumed to have acted in good faith with regard to a belief described in paragraph 1 **Presumption of good faith belief.** A covered entity that uses or disclosed protected health information pursuant to this policiyif the belief is presumed to have acted in good faithbased upon actual knowledge or in reliance on a credible representation by a person with regard to a belief described in paragraph 1 if the belief is based upon actualapparent knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.

Applicable Laws and Regulations

<u>45 CFR §164.512(i)</u>

California Civil Code §56.10(c)(14)

Approval Signatures

Step Description	Approver	Date
Compliance & Privacy Office	Melissa Guevarra: Acting Compliance Officer	Pending

Origination	4/1/2003	Owner	Melissa
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VENTURACOUNTY Effective	N/A	Policy Area	Administrative -
HEALTH CARE AGENCY Last Revised	N/A	r oney / red	Compliance
Next Review	N/A		-

109.032 Disclosure of Protected Health Information to Employers (By a Provider)

PURPOSE

The purpose of this policy is to ensure that disclosures of an employee's protected health information (PHI) to employers are in made accordance with the requirements of State and Federal laws and regulations.

POLICY:

Under HIPAA, a health care provider VCHCA may disclose protected health information PHI to an individual's employer, without obtaining authorization from that individual or providing the individual an opportunity to object to the use or disclosure, if the provider furnishes health care to the employee as a member of the employer's workforce or at the request of the employer and the protected health information PHI relates to a work-related illness or injury or a workplace-related medical surveillance as set forth below. The purpose of this policyi is to ensure that disclosures of an employee's protected health information to employers are in accordance with the requirements of State and Federal laws and regulations.

Protected health information<u>PHI</u> will be disclosed to an individual's employer without obtaining authorization from that individual only as permitted under applicable State and Federal laws and regulations as set forth below.

PROCEDURE:

Responding to requests from employers for PHI concerning their employee

VCHCA may disclose PHI to an employer about an individual who is a member of the workforce of the

employer, without obtaining authorization from that individual or providing the individual an opportunity to object to the disclosure, if the individual is a member of the workforce of such employer or provides health care to the individual subject to the following.

- 1. Work-related illness or injury and workplace surveillance. Upon request by the employer, PHI about the employee/individual may be provided:
 - i. To conduct an evaluation relating to medical surveillance of the workplace; or
 - ii. To evaluate whether the individual has a work-related illness or injury
 - iii. If concerning a work-related illness or injury or a workplace-related medical surveillance;
- 2. Compliance with the law. The employer needs such findings as described in order to comply with its obligations under applicable federal (HIPAA and OSHA) and state law, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and
- 3. Notice to Individual. VCHCA will provide the individual with written notice (see Exhibit "A") that PHI relating to the medical surveillance of the workplace and work-related illnesses and injuries are disclosed to employers:
 - i. By giving a copy of the notice to the individual at the time the health care is provided; or
 - ii. If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.

Providing PHI to employers for payment responsibility

VCHCA may disclose PHI to an employer, about an individual who is a member of the workforce of the employer, without obtaining authorization from that individual or providing the individual an opportunity to object to the disclosure, if that information is necessary for the employer to allow responsibility for payment to be determined and payment to be made. (See policy 109.027, Use and Disclosure of Protected Health Information for Treatment, Payment or Health Care Operations.)

Applicable Laws and Regulations:

45 CFR § 164.512(b)(1)(v); California Civil Code §56.10(c)(2); 29 CFR § 1904-1928, 30

Responding to Requests from Employers for Protected Health Information Concerning Their Employees:

VCFICP may disclose protected health information to an employer about an individual who is a member of the workforce of the employer, without obtaining authorization from that individual or providing the individual an opportunity to object to the disclosure, if the individual: is a member of the workforce of such employer or provides health care to the:

- 1. Individual at the request of the employer:
 - i. To conduct an evaluation relating to medical surveillance of the workplace; or

- ii. To evaluate whether the individual has a work-related illness or injury
- iii. The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;
- The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and
- 3. Provides written notice (see Exhibit "A") to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries are disclosed to the employer:
 - i. By giving a copy of the notice to the individual at the time the health care is provided; or
 - ii. If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.

Providing Protected Health Information to Employers to Allow Responsibility for Payment to be Determined and Payment to be Made

VCFICA may disclose protected health information to an employer, about an individual who is a member of the workforce of the employer, without obtaining authorization from that individual or providing the individual an opportunity to object to the disclosure, if that information is necessary for the employer to allow responsibility for payment to be determined and payment to be made. (See policy 109.027, Use and Disclosure of Protected Health Information for Treatment, Payment or Health Care Operations.)

Attachments

Approval Signatures

Step Description	Approver	Date
Compliance & Privacy Office	Melissa Guevarra: Acting Compliance Officer	Pending

EXHIBIT "A"

NOTICE TO EMPLOYEES REGARDING DISCLOSURE OF PROTECTED HEALTH INFORMATION TO EMPLOYER

Dear Employee:

In the course of my duties as a health care provider eng	aged by	, I might have
access to health information regarding your physical or	mental health or condition.	So long as that
health information relates to the medical surveillance of	the	
workplace or work-related illnesses and injuries, please	be informed that I am pern	nitted by law to
provide that information to	without your approval an	d will do so at the
request of [Employer]'s management.		

If you have any questions regarding the release of your health information to your employer, please contact the Ventura County Health Care Agency Privacy Officer.

Sincerely,

[Provider]

Origination	4/1/2003	Owner	Melissa
Last Approved	N/A		Guevarra: Acting Compliance
VENTURACOUNTY Effective	N/A	Policy Area	Officer Administrative -
HEALTH CARE AGENCY Last Revised	N/A	Toncy Area	Compliance
Next Review	N/A		-

109.033 Use and Disclosure of Protected Health Information to Disaster Relief Organizations

PURPOSE

Under HIPAA, protected health information may be disclosed absent the individual's written authorization to a state recognized or federally recognized disaster relief organization for the purpose of responding to disaster welfare inquires. The purpose of this policy is to ensure that such disclosures comply with the requirements of applicable State and Federal laws and regulations.

POLICY:

Under HIPAA, protected health information may be disclosed absent the individual's written authorization to disaster relief organizations for the purpose of coordinating with such entities the notification, or assistance in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition or death. The purpose of this policy is to ensure that such disclosures comply with the requirements of applicable State and Federal laws and regulations.

Protected health information concerning an individual's location, general condition or death shall be disclosed, absent the individual's written authorization or consent, to disaster relief organizations for purposes of notifying a family member, personal representative or other person responsible for the care of the individual only as permitted under applicable State and Federal laws and regulations and set forth below.

When responding to disaster welfare inquiries from state recognized or federally recognized disaster relief organization HCA will comply with applicable HIPAA requirements. Accordingly information may be disclosed without the individual's written authorization or consent, is limited to the patient's name, city of residence, age, sex, and general condition or death.

PROCEDURE:

- 1. Upon request of a disaster relief organization, and **the individual is present** or otherwise available prior to, a use or disclosure described below and has the capacity to make health care decisions, staff may disclose protected health information, absent the individual's written authorization consent, for the purpose of coordinating with such entities the notification, or assistance in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition or death, if the staff does the following:
 - a. Obtains the individual's agreement;
 - b. Provides the individual the opportunity to object to the disclosure, and the individual does not express an objections; or
 - c. Reasonably infers from the circumstances, based on the exercise of professional judgment, which the individual does not object to the disclosures.

The information disclosed shall be limited to the following: the individual's name, city of residence, age, sex, and general condition.

The information disclosed, circumstances concerning the disclosure, and the name of the person to whom the information was disclosed will be recorded in the patient's medical record.

2. If the individual is not present for, or the opportunity to agree or object to the use or disclosure described in item 1 above cannot practicably be provided because of the individual's incapacity or an emergency circumstance, supervisory staff may, in the exercise of professional judgment, determine whether the disclosure is in the best interest of the individual and, if so, disclose only the protected healthbasic information that is directly relevant to, including the patient's name, city of residence, age, sex, and general condition to the disaster relief organization.

<u>The information disclosed, circumstances concerning the disclosure and the name of</u> the person's involvement with the individual's health care.

The to whom the information was disclosed, circumstances concerning the disclosure and the name of the person to whom the information was disclosed will be recorded in the patient's medical record.

3. The requirements in items 1 and 2 above shall apply to such uses and disclosures only to the extent that supervisory staff, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

Applicable Laws and Regulations

45 CFR § 164.510(b)

45 CFR § 164.512(a)(1)

California Civil Code §56.10(c)(15)

Approval Signatures

Step Description	Approver	Date
Compliance & Privacy Office	Melissa Guevarra: Acting Compliance Officer	Pending

DRAFT

Status Draft PolicyStat ID 17802519			
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HEALTH CARE AGENCY Last Revised	N/A		Compliance
Next Review	N/A		

109.034 Use and Disclosure of Protected Health Information to Individuals Involved in a Patient's Care

PURPOSE

Under HIPAA, protected health information may be disclosed, absent the patient's written authorization, to a family member or other relative, close personal friend or any other person identified by the patient, if the protected health information is directly relevant to such person's involvement with the patient's care or payment related to the patient's care. The purpose of this policy is to ensure that such disclosures comply with the applicable provisions of HIPAA.

POLICY:

VCHCA is committed to ensuring the privacy and security of protected health information. Under HIPAA, When the patient is present and competent, the patient must be given an opportunity to agree or disagree to the use or disclosure of protected health information. VCHCA may be disclosed, absentdisclose to a family member, relative, close personal friend, or any other person identified by the patient, protected health information directly relevant to such persons' involvement with the patient's written authorization, tocare or payment related to the patient's care as permitted under applicable State and Federal laws and regulations. When the patient is not present or does not have the opportunity to agree or object, supervisory staff must use professional judgment to determine whether disclosure is in the best interest of the patient. In such instances, VCHCA may also disclose a patient's protected health information is directly relevant to such persons identified by the patient, or other relative, close personal friend or any other person identified by the patient, or other relative, close personal friend or any other person identified by the patient, if the protected health information is directly relevant to such personresponsible for the care of the patient of the patient's involvement with the patient's care or payment related to the patient's care. When the patient is present and competent, the patient must be given an opportunity to agree or disagree to the use or disclosure of such information. The purpose of this policy is to ensure that such disclosures

comply with the applicable provisions of HIPAA.location, general condition or death.

VCHCA may disclose to a family member, relative, close personal friend, or any other person identified by the patient, protected health information directly relevant to such persons involvement with the patient's care or payment related to the patient's care as permitted under applicable State and Federal laws and regulations. VCHCA may also disclose a patient's protected health information to notify, or assist in the notification of a family member, personal representative of the patient, or other person responsible for the care of the patient of the patient's location, general condition or death.

PROCEDURE

- 1. Upon request of a person involved in the care of an individual or payment for the care of the individual, and **the individual is present** or otherwise available prior to a use or disclosure described below and has the capacity to make health care decisions, staff may disclose protected health information directly relevant to the person's involvement, absent a written authorization or consent of the individual, under the following circumstances:
 - a. Staff obtains the individual's agreement upon admission or anytime thereafter;
 - b. Staff provides the individual the opportunity to object to the disclosure, and the individual does not express objections; or
 - c. Supervisory staff reasonably infers from the circumstances, based on the exercise of professional judgment that the individual does not object to the disclosures.

The information disclosed, circumstances concerning the disclosure, and the name of the person to whom the information was disclosed will be recorded in the patient's medical record.

2. If the individual is not present for, or the opportunity to agree or object to the use or disclosure described in item 1 above cannot practicably be provided because of the individual's incapacity or an emergency circumstance, supervisory staff, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care. (For example, it is reasonable to infer that it is in the individual's best interest to allow a person acting on behalf of the individual to pick up medical supplies, x-rays, or other similar forms of protected health information.)

The information disclosed, circumstances concerning the disclosure, and the name of the person to whom the information was disclosed will be recorded in the patient's medical record.

- 3. Upon request of a family member, a personal representative, or another person responsible for the care of an individual, and **the individual is present** or otherwise available prior to, a use or disclosure described below and has the capacity to make health care decisions, staff may disclose protected health information to notify such person, or assist in the notification of, the individual's location, general condition or death, absent a written authorization or consent of the individual, if it does the following:
 - a. Obtains the individual's agreement;
 - b. Provides the individual the opportunity to object to the disclosure, and the individual does not express objections; or

c. <u>Reasonably infers from the circumstances, based on the exercise of professional</u> judgment that the individual does not object to the disclosures.

The information disclosed, circumstances concerning the disclosure, and the name of the person to whom the information was disclosed will be recorded in the patient's medical record.

4. If the individual is not present for, or the opportunity to agree or object to the use or disclosure described in item 3 above cannot practicably be provided because of the individual's incapacity or an emergency circumstance, supervisory staff may, in the exercise of professional judgment, determine whether the disclosure is in the best interest of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care.

The information disclosed circumstances concerning the disclosure and the name of the person to whom the information was disclosed will be recorded in the patient's medical record.

5. Supervisory staff may also make affirmative disclosures (i.e., not in response to a request) under the circumstances described in items 1-4 above, when in the best interests of the individual, so long as the requirements of items 1-4 are met.

Applicable Laws and Regulations:

45 CFR §164.510(b)

PROCEDURE:

- 1. Upon request of a person involved in the care of an individual or payment for the care of the individual, and **the individual is present** or otherwise available prior to a use or disclosure described below and has the capacity to make health care decisions, staff may disclose protected health information directly relevant to the person's involvement, absent a written authorization or consent of the individual, under the following circumstances:
 - a. Staff obtains the individual's agreement upon admission or anytime thereafter;
 - b. Staff provides the individual the opportunity to object to the disclosure, and the individual does not express objections; or
 - c. Supervisory staff reasonably infers from the circumstances, based on the exercise of professional judgment that the individual does not object to the disclosures.

The information disclosed circumstances concerning the disclosure and the name of the person to whom the information was disclosed will be recorded in the patient's medical record.

2. If the individual is not present for, or the opportunity to agree or object to the use or disclosure described in item 1 above cannot practicably be provided because of the individual's incapacity or an emergency circumstance, supervisory staff, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care. (For example, it is reasonable to infer that it is in the individual's best interest to allow a person acting on behalf of the individual to pick up medical supplies, x-rays, or other similar forms of protected health information.)

The information disclosed, circumstances concerning the disclosure and the name of the person to whom the information was disclosed will be recorded in the patient's medical record.

- 3. Upon request of a family member, a personal representative, or another person responsible for the care of an individual, and **the individual is present** or otherwise available prior to, a use or disclosure described below and has the capacity to make health care decisions, staff may disclose protected health information to notify such person, or assist in the notification of, the individual's location, general condition or death, absent a written authorization or consent of the individual, if it does the following:
 - a. Obtains the individual's agreement;
 - b. Provides the individual the opportunity to object to the disclosure, and the individual does not express objections; or
 - c. Reasonably infers from the circumstances, based on the exercise of professional judgment that the individual does not object to the disclosures.

The information disclosed, circumstances concerning the disclosure and the name of the person to whom the information was disclosed will be recorded in the patient's medical record.

4. If the individual is not present for, or the opportunity to agree or object to the use or disclosure described in item 3 above cannot practicably be provided because of the individual's incapacity or an emergency circumstance, supervisory staff may, in the exercise of professional judgment, determine whether the disclosure is in the best interest of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care.

The information disclosed circumstances concerning the disclosure and the name of the person to whom the information was disclosed will be recorded in the patient's medical record.

5. Supervisory staff may also make affirmative disclosures (i.e., not in response to a request) under the circumstances described in items 1-4 above, when in the best interests of the individual, so long as the requirements of items 1-4 are met.

Approval Signatures

Step Description	Approver	Date
Compliance & Privacy Office	Melissa Guevarra: Acting Compliance Officer	Pending

Origination	2/1/2003	Owner	Melissa
Last Approved	N/A		Guevarra: Acting Compliance Officer
VENTURACOUNTY Effective	N/A	Policy Area	Administrative -
HEALTH CARE AGENCY Last Revised	N/A	T Oncy Area	Compliance
Next Review	N/A		

109.037 Use and Disclosure of Protected Information Within an Organized Care Arrangement

PURPOSE

Under HIPAA, a covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to another covered entity that participates in the organized health care arrangement for purposes of health care operations activities of the organized health care arrangement. The purpose of this policy is to ensure that VCHCA discloses protected health information to its counterparts within an organized health care arrangement and uses a joint Notice of Privacy Practices, if applicable, only in accordance with the provisions of HIPAA and in compliance with state law.

POLICY:

Under HIPAA,VCHCA is a covered entity that participates in an-organized health care <u>arrangements and</u> may disclose protected health information about an individual to another covered entity that likewise participates in the organized health care arrangement for purpose of health care operations activities. Such disclosures may disclose protected health information about antake place absent a written authorization or opportunity on the part of the individual to another covered entity that participates in the organized health care arrangement for purposes of health care operations activities of the organized health care arrangement for purposes of health care operations activities of the organized health care arrangement. Such disclosures may take place absent a written authorization or opportunity on the part of the disclosure. Further, covered entities that participate in organized health care arrangements may use a joint Notice of Privacy Practices, under specified circumstances. The purpose of this policy is to ensure that VCHCA discloses protected health information to its counterparts within an organized health care arrangement and uses a joint Notice of Privacy Practices, if applicable, only in accordance with the provisions of HIPAA and in compliance with state law.

VCHCA will use or disclose protected health information within an organized health care arrangement without the individual's written authorization or opportunity to agree or object to the disclosure, and will use a joint Notice of Privacy Practices, only as permitted under HIPAA and applicable state laws.

PROCEDURE

- 1. Determination whether VCHCA participates in one or more organized health care arrangements. The participants in any such organized health care arrangement shall be identified and listed. Staff shall be assigned responsibility for updating the list, as needed.
- 2. Uses and disclosures to counterparts in an organized health care arrangement. Disclosures by VCHCA to other covered entities that are determined to be in the same organized health care arrangement as VCHCA may be made without first obtaining the patient's written authorization or providing the patient with an opportunity to agree or object to the disclosure, so long as the disclosure is in connection with the health care operations activities¹ of the organized health care arrangement.
 - a. Policies and procedures regarding use and disclosure of protected health information shall be footnoted to identify the covered entities within the applicable organized health care arrangement, and the corresponding exemption from the requirement to obtain a patient authorization prior to use or disclosure of protected health information in connection with health care operations activities of the organized health care arrangement.
- 3. Joint Notice of Privacy Practices. Refer to Policy and Procedure on Distribution of Notice of Privacy Practices. If VCHCA is part of an organized health care arrangement, it may use a joint Notice of Privacy Practices, in common with the other covered entities in the organized health care arrangement, under the following circumstances:
 - a. <u>The covered entities participating in the organized health care arrangement agree to</u> <u>abide by the terms of the notice with respect to protected health information created</u> <u>or received by the covered entity as part of its participation in the organized health</u> <u>care arrangement;</u>
 - b. The joint notice meets the requirements for the notice set forth in HIPAA, except that the statements may be altered to reflect the fact that the notice covers more than one covered entity; and
 - i. Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;
 - ii. Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and
 - iii. If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.
 - c. The covered entities included in the joint notice must provide the notice to individuals in accordance with the requirements of HIPAA. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice

will satisfy the requirement to provide the notice with respect to all others covered by the joint notice.

1 "Health care operations" is defined in the HIPAA Glossary.

Applicable Laws and Regulations:

45 CFR §164.501; 45 CFR §164.506 (c)(5); 45 CFR §164.520(d); California Civil Code §56.10(c)(14)

PROCEDURE:

- 1. Determination whether VCHCA participates in one or more organized health care arrangements. The participants in any such organized health care arrangement shall be identified and listed. Staff shall be assigned responsibility for updating the list, as needed.
- 2. Uses and disclosures to counterparts in an organized health care arrangement. Disclosures by VCHCA to other covered entities that are determined to be in the same organized health care arrangement as VCHCA may be made without first obtaining the patient's written authorization or providing the patient with an opportunity to agree or object to the disclosure, so long as the disclosure is in connection with the health care operations activities¹ of the organized health care arrangement.
 - a. Policies and procedures regarding use and disclosure of protected health information shall be footnoted to identify the covered entities within the applicable organized health care arrangement, and the corresponding exemption from the requirement to obtain a patient authorizing prior to use or disclosure of protected health information in connection with health care operations activities of the organized health care arrangement.
- 3. Joint Notice of Privacy Practices. Refer to Policy and Procedure on Distribution of Notice of Privacy Practices. If VCHCA is part of an organized health care arrangement, it may use a joint Notice of Privacy Practices, in common with the other covered entities in the organized health care arrangement, under the following circumstances:
 - a. The covered entities participating in the organized health care arrangement agree to abide by the terms of the notice with respect to protected health information created or received by the covered entity as part of its participation in the organized health care arrangement;
 - b. The joint notice meets the requires for the notice set forth in HIPAA, except that the statements may be altered to reflect the fact that the notice covers more than one covered entity; and
 - i. Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;
 - ii. Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and
 - iii. If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care

operations relating to the organized health care arrangement.

c. The covered entities included in the joint notice must provide the notice to individuals in accordance with the requirements of HIPAA. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the requirement to provide the notice with respect to all others covered by the joint notice.

1 "Health care operations" is defined in the HIPAA Glossary.

Approval Signatures

Step Description	Approver	Date
Compliance & Privacy Office	Melissa Guevarra: Acting Compliance Officer	Pending

Origination	4/1/2003	Owner	Melissa
Last Approved	N/A	Com	Guevarra: Acting Compliance
VENTURACOUNTY Effective	N/A	Policy Area	Officer Administrative -
HEALTH CARE AGENCY Last Revised	N/A	T Olicy Area	Compliance
Next Review	N/A		

109.038 Use and Disclosure of Protected Health Information to Plan Sponsors by Group Health Plans

PURPOSE

Under HIPAA, a Covered Entity may disclose protected health information to a Group Health Plan Sponsor only under certain conditions. The purpose of this policy is to ensure that the disclosure by a Group Health Plan of protected health information to a Plan Sponsor complies with the requirements of HIPAA.

POLICY:

VCHCA is committed to ensuring that use and disclosure of protected health information complies with

HIPAA. Under HIPAA; a Covered Entity includes a Group Health Plan.¹ A Group Health Plan may disclose protected health information to a Plan Sponsor only under certain conditions. The purpose of Disclosure by a Group Health Plan to a Plan Sponsor shall be made only in accordance with the requirements set forth in this policy is to ensure that the disclosure by a Group Health Plan of protected health information to a Plan Sponsor soft and under HIPAA. Disclosure by a Group Health Plan to a Plan Sponsor complies with the requirements of and under HIPAA. Disclosure by a Group Health Plan to a Plan Sponsor shall be made only in accordance with the requirements.

Applicable Laws and Regulations:

45 CFR§ 164.504(f)(1)

PROCEDURE:

PROCEDURE

VCHCA shall consult with legal counsel to determine if it is a Group Health Plan and therefore subject to

the requirements of this policy.

Disclosures by a Group Health Plan to a Plan Sponsor

- 1. **Disclosures Not Permitted Unless Plan Documents Contain Certain Provisions**. Except as permitted under paragraphs 2 and 3 below, or pursuant to a written authorization from the patient (see Policy and Procedure on Obtaining Authorization for Use or Disclosure of Protected Health Information), a Group Health Plan shall not disclose Protected Health Information to the Plan Sponsor, or provide for or permit the disclosure of Protected Health Information to the Plan Sponsor by a health insurance issuer or HMO with respect to the Group Health Plan, unless the Group Health Plan ensures that the plan documents are amended to:
 - Incorporate provisions to establish the permitted and required uses and disclosures
 of such information by the Plan Sponsor, provided that such permitted and required
 uses and disclosures are not otherwise inconsistent with HIPAA;
 - Provide that the Group Health Plan will disclose Protected Health Information to the Plan Sponsor only upon receipt of a certification by the Plan Sponsor that the plan documents have been amended as required; and
 - Provide for adequate separation between the Group Health Plan and the Plan Sponsor.

(See <u>Exhibit "A"</u> the Sample Amendment to Plan Documents and Sample Plan Sponsor Certification attached to this Policy and Procedure as Exhibits "A" and "B," respectively.)

- 2. Exceptions for Disclosure of Summary Information in Certain Cases. The Group Health Plan, or a health insurance issuer or HMO with respect to the Group Health Plan, may disclose Summary Health Information to the Plan Sponsor, if the Plan Sponsor requests the Summary Health Information for the purpose of:
 - Obtaining premium bids from health plans for providing health insurance coverage under the Group Health Plan; or
 - Modifying, amending, or terminating the Group Health Plan.
- 3. **Exceptions for Information Regarding Enrollment or Disenrollment**. The Group Health Plan, or a health insurance issuer or HMO with respect to the Group Health Plan, may disclose to the Plan Sponsor information on whether the individual is participating in the Group Health Plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

Further Restrictions on Uses and Disclosures by a Group Health Plan to a Plan Sponsor

- 4. **Disclosures for Plan Sponsor to Perform Administration Functions**. A Group Health Plan may disclose Protected Health Information to a Plan Sponsor to carry out plan administration functions that the Plan Sponsor performs only if the plan documents have been amended as described in paragraph 1 above and Exhibit "A" attached hereto.
- 5. **Disclosures to Plan Sponsor by Group Health Plan's Health Insurance Issuer or HMO**. A Group Health Plan may not permit a health insurance issuer or HMO with respect to the Group Health Plan to disclose Protected Health Information to the Plan Sponsor unless the plan documents have been amended as described in paragraph 1 above and Exhibit "A" attached hereto, subject to the restrictions contained in paragraphs 5 and 6 below.

- 6. **Disclosures to Plan Sponsors Must be Described in Notice of Privacy Practices**. A Group Health Plan may not disclose, and may not permit a health insurance issuer or HMO to disclose, Protected Health Information to a Plan Sponsor as otherwise permitted by this Policy and Procedure unless a statement concerning the disclosure is included in the applicable Notice of Privacy Practices.
- 7. **Disclosures to Plan Sponsors for Employment-Related Actions are Not Permitted**. A Group Health Plan may not disclose Protected Health Information to the Plan Sponsor for the purpose of employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the Plan Sponsor.

¹ This term and all other capitalized terms in this policy are defined in the HIPAA Glossary.

Applicable Laws and Regulations

- Attachments

 A: Sample Amendment to Plan Documents

 Approval Signatures

 Step Description

 Approver

 Date

 Compliance & Privacy Office
 Melissa Guevarra: Acting Compliance Officer
- 45 CFR § 164.504(f)(1)

EXHIBIT "A"

SAMPLE AMENDMENT TO PLAN DOCUMENTS

<u>Amendment to Plan Documents Regarding Uses and</u> <u>Disclosures of Protected Health Information by Plan Sponsor</u>

- 1. Plan Sponsor shall not use or further disclose Protected Health Information other than as permitted or required by the plan documents or as required by law;
- 2. Plan Sponsor shall ensure that any agents, including a subcontractor, to whom it provides Protected Health Information received from the Group Health Plan agrees to the same restrictions and conditions that apply to Plan Sponsor with respect to such information;
- 3. Plan Sponsor shall not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of Plan Sponsor;
- 4. Plan Sponsor shall report to the Group Health Plan any use or disclosure of the information that is inconsistent with the uses or disclosures provided for of which it becomes aware;
- 5. Plan Sponsor shall make available Protected Health Information in accordance with 45 CFR § 164.524 (which provision addresses the right of the individual to access his or her Protected Health Information);
- 6. Plan Sponsor shall make available Protected Health Information for amendment and incorporate any amendments to Protected Health Information in accordance with 45 CFR §164.526 (which provision address the right of the individual to amend his or her Protected Health Information);
- 7. Plan Sponsor shall make available the information required to provide an accounting of disclosures in accordance with 45 CFR § 164.528 (which provision addresses the right of the individual to obtain an accounting of disclosures of his or her Protected Health Information);
- 8. Plan Sponsor shall make its internal practices, books, and records relating to the use and disclosure of Protected Health Information received from the Group Health Plan available to the Secretary for purposes of determining compliance by the Group Health Plan with HIPAA;
- 9. If feasible, Plan Sponsor shall return or destroy all Protected Health Information received from the Group Health Plan that Plan Sponsor still maintains in any form and retain no copies of such information when no longer needed for the purpose for which disclosure was made, except that, if such return or destruction is not feasible, limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible; and
- 10. Plan Sponsor shall provide for adequate separation between the Group Health Plan and the Plan Sponsor as follows:
 - (a) Only the following employees of Plan Sponsor shall be given access to the Protected Health Information_____
 - (b) Access to and use by such employees described in paragraph (a) shall be restricted to the plan administration functions that Plan Sponsor performs for the Group Health Plan; and
 - (c) The employees of Plan Sponsor described in paragraph (a) shall be subject to discipline, up to and including termination, for failure to comply with the provisions set forth in items 1 through 10 above.

Origination	4/1/2003	Owner	Melissa
Last Approved	N/A	Com	Guevarra: Acting Compliance
VENTURACOUNTY Effective	N/A	Policy Area	Officer Administrative -
HEALTH CARE AGENCY Last Revised	N/A	Toncy Area	Compliance
Next Review	N/A		

109.041 Verification of Identity and Authority of Persons or Entities Requesting Protected Health Information

PURPOSE

The purpose of this policy is to provide a mechanism for identity verification to ensure that proper steps are taken to verify the identity and authority of individuals and entities requesting protected health information.

POLICY:

VCHCA is committed to ensuring the privacy and security of protected health information. Under HIPAA, health care organizations are required to verify the identity and authority of any person or entity requesting protected health information. The purpose of this policy is to provide a mechanism for identity verification to ensure that proper steps are taken to verify the identity and authority of individuals and entities requesting protected health information.

VCHCA staff will take necessary steps to verify the identity and authority of any person or entity requesting access to protected health information if VCHCA staff does not know the identity or any such authority of the person or entity.

Applicable Laws and Regulations: PROCEDURE

1. Verification of the identity and authority. Take reasonable steps to verify the identity and authority of any person or entity requesting protected health information if you do not know the identity or any such authority of the person or entity. No particular identification requirements, such as driver's license or photo ID, are mandated, but in most situations, you

will need to look at a photo ID, such as a driver's license, or receive certain personal information, such as date of birth, mother's maiden name, or last four digits of Social Security number, to verify the identity of the person.

- a. **Requester identity.** There must be knowledge of the identity and authority of the person requesting protected health information may take the form of:
 - i. A known place of business;
 - ii. A known address;
 - iii. A known phone or fax number; or
 - iv. A known human being.
- b. **Document authority.** Where documentation, statements, or representations, whether oral or written, from the person requesting protected health information is a condition of disclosure under HIPAA, verification must involve obtaining such documentation, statement, or representation.
- 2. Verification of public officials. You may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:
 - a. If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;
 - b. If the request is in writing, the request is on the appropriate government letterhead;
 - c. If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that confirms that the person is acting on behalf of the public official; or
 - d. A request that is made pursuant to a warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal that is presumed to constitute legal authority.
- 3. You may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:
 - a. A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority; or
 - b. If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.
- 4. Verification of law enforcement. When protected health information is requested by the Secretary of the U.S. Department of Health and Human Services, you need to verify the same information that is required for any other law enforcement or oversight request for disclosure.
- 5. Verification in Emergency Situations. You may, in good faith, disclose protected health

information to prevent or lessen a serious and imminent threat to the health or safety of a person or the public if the disclosure is made to a person reasonably able to prevent or lessen the threat. If these conditions are met, no further verification is needed. In such emergencies, you do not need to demand written proof that the person requesting the protected health information is legally authorized. Reasonable reliance on verbal representation is appropriate in such emergencies.

- 6. Verification Exception. You do not need to verify the identity of a person assisting in an individual's care or for notification purposes when the individual being cared for is present. If the individual being cared for is not present, you need to take reasonable steps to verify the identity and authority of the person assisting in the individual's care or for notification purposes when you do not know the identity or any such authority of the person.
- 7. Identity of Personal Representative. You need to take reasonable steps to verify the identify and authority of personal representatives who request protected health information if you do not know the identity or any such authority of the personal representatives. For example, you can require a copy of a power of attorney or ask questions to determine that an adult acting for a young child has the requisite relationship to the child.
- 8. Life Insurance and Disability Insurers. If you receive a request for protected health information from life, disability income, or long-term care insurers in the course of underwriting or claims investigation, and the requester is not known to you, you need to make a reasonable effort to determine that the protected health information is being sent to the entity authorized to receive it. This can be achieved by:
 - a. Sending the information to a recognizable organizational address; or
 - b. If faxing or phoning the information, by calling the requester back through the main organization rather than through a direct phone number.
- 9. Failure to verify. In the event that the identity and legal authority of an individual or entity requesting protected health information cannot be verified, personnel will refrain from disclosing the requested information and promptly report the request to the Compliance and Privacy Officer.

Applicable Laws and Regulations

45 CFR §§164.510; 164.512(f), (i), (j); 164.514(h)

PROCEDURE:

- 1. Take reasonable steps to verify the identity and authority of any person or entity requesting protected health information if you do not know the identity or any such authority of the person or entity. No particular identification requirements, such as driver's license or photo ID, are mandated, but in most situations you will need to look at a photo ID, such as a driver's license, or receive certain personal information, such as date of birth, mother's maiden name, or last four digits of Social Security number, to verify the identity of the person.
- 2. Knowledge of the identity and authority of the person requesting protected health information may take the form of:
 - a. A known place of business;

- b. A known address;
- c. A known phone or fax number; or
- d. A known human being.
- 3. Where documentation, statements, or representations, whether oral or written, from the person requesting protected health information is a condition of disclosure under HIPAA, verification must involve obtaining such documentation, statement, or representation.
- 4. You may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:
 - a. If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;
 - b. If the request is in writing, the request is on the appropriate government letterhead;
 - c. If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that confirms that the person is acting on behalf of the public official; or
 - d. A request that is made pursuant to a warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal that is presumed to constitute legal authority.
- 5. You may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:
 - a. A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority; or
 - b. If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.
- 6. When protected health information is requested by the Secretary of the U.S. Department of Health and Human Services, you need to verify the same information that is required for any other law enforcement or oversight request for disclosure.
- 7. You may, in good faith, disclose protected health information to prevent or lessen a serious and imminent threat to the health or safety of a person or the public if the disclosure is made to a person reasonably able to prevent or lessen the threat. If these conditions are met, no further verification is needed. In such emergencies, you do not need to demand written proof that the person requesting the protected health information is legally authorized. Reasonable reliance on verbal representation is appropriate in such emergencies.
- 8. You do not need to verify the identity of a person assisting in an individual's care or for notification purposes when the individual being cared for is present. If the individual being cared for is not present, you need to take reasonable steps to verify the identity and authority

of the person assisting in the individual's care or for notification purposes when you do not know the identity or any such authority of the person.

- 9. You need to take reasonable steps to verify the identify and authority of personal representatives who request protected health information if you do not know the identity or any such authority of the personal representatives. For example, you can require a copy of a power of attorney or ask questions to determine that an adult acting for a young child has the requisite relationship to the child.
- 10. If you receive a request for protected health information from life, disability income, or longterm care insurers in the course of underwriting or claims investigation, and the requester is not known to you, you need to make a reasonable effort to determine that the protected health information is being sent to the entity authorized to receive it. This can be achieved by:
 - a. Sending the information to a recognizable organizational address; or
 - b. If faxing or phoning the information, by calling the requester back through the main organization rather than through a direct phone number.
- 11. In the event that the identity and legal authority of an individual or entity requesting protected health information cannot be verified, personnel will refrain from disclosing the requested information and promptly report the request to the Privacy Officer.

See Administrative Compliance Po	olicy 109.007.	
Approval Signatures		
Step Description	Approver	Date
Compliance & Privacy Office	Melissa Guevarra: Acting Compliance Officer	Pending

Status	Draft	PolicyStat ID (15943059)
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Origination	9/1/2002	Owner	Melissa
Last Approved	N/A		Guevarra: Acting Compliance Officer
VENTURACOUNTY Effective	N/A	Policy Area	Administrative -
HEALTH CARE AGENCY Last Revised	N/A	T oney Area	Compliance
Next Review	N/A		

109.043 Email Communication of PHI

PURPOSE

The purpose of this policy is to ensure that Protected Health Information (PHI) transmitted by email is protected against threats to the security of the PHI and uses and disclosures not permitted by the Privacy and Security rules.

POLICY:

All Ventura County Health Care Agency (VCHCA) departments must adopt this policy to comply with HIPAA's requirement to protect the security of protected health information (PHI), as well as to fulfill our duty to protect the confidentiality and integrity of protected health information.

All individuals who are authorized to use the email system must be familiar with this policy. Personnel may not utilize email to transmit protected health information unless such use complies with the procedures set forth below.

PROCEDURE:

Applicable Laws and Regulations:

- 45 C.F.R. 142.308(d)(1) -- communications and network controls
- 1. **Dissemination of Policy**. All personnel shall be informed of HCA's email policy during orientation and shall be provided with a written copy of such policy. Personnel shall be required to sign a confidentiality agreement that addresses use of e-mail communications.
- 2. No Right to Privacy. HCA encourages the business use of e-mail to increase productivity. The email system and all messages generated by e-mail, including back up copies, are part of the business equipment of HCA, are owned by HCA, and are not the property of the employees or

other users of the systems. Consequently, email users do not have a right to privacy in their use of the computer systems or its email component.

- 3. **Right to Monitor, Audit, Delete, Read**. Health Care Agency (HCA) reserves the right to monitor, audit, delete, and read e-mail messages. The network administrator may override user passwords. HCA may monitor the contents and usage of email messages to support operational, maintenance, auditing, security, and investigative activities.
- 4. **Prohibited Uses**. E-mail users should restrict their use of the e-mail system to proper business purposes relating to the care and treatment of patients and related administrative matters, such as billing. Prohibited uses of e-mail include transmission of:
 - Confidential information without appropriate authorization or in violation of HCA's
 email confidentiality policy as described in paragraphs 5 and 6 below;
 - Obscene, defamatory, offensive, harassing or hostile messages;
 - Information related to a lawsuit or investigation;
 - Messages critical of HCA's management or employees;
 - · Messages involving any illegal or unethical activity; and
 - Solicitations for outside business ventures, organizations, or political, religious or charitable causes.
- 5. The foregoing is not an exhaustive list of prohibited uses and the systems administrator reserves the discretion to ban other uses of email not related to proper business purposes. The systems administrator may in his discretion allow limited personal use of email for transmission of brief messages that do not violate the prohibitions above and that otherwise do not involve significant staff time and do not interfere with a staff member's duties.
- 6. **Confidentiality Policy**. When email is used for communication of confidential or sensitive information, specific measures must be taken to safeguard the confidentiality of the information. These safeguards include:
 - Utilization of encryption, #secure# in the subject line which will ensure that the information is not accessed by any person other than the intended recipient; the following statement must be included in all e-mails that contain minimum necessary PHI:
- 7. NOTICE: The information contained in this facsimile message may be privileged and confidential and is only for the use of the individual or entity named on this cover sheet. If the reader of this message is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, the reader is hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If this communication has been received in error, the reader shall notify [enter appropriate department and telephone number] the [sender-enter sender name] immediately by telephone, calling collect if the reader is located outside the calling area, and shall destroy all information received. Thank you.
- 8. All communications regarding PHI must use the minimum necessary standard in the determination of the information that the email will contain.
 - A prohibition on use of email distribution lists;

- Distribution of confidential information only to those with a legitimate need to know; and
- A ban on distribution of "highly confidential" information by email (see number 15 below).
- 9. Highly Confidential Information. The following information is deemed highly confidential and shall NOT be transmitted by email under any circumstance:
 - HIV or AIDS status
 - Mental illness
 - Chemical dependency
- 10. The systems administrator, in consultation with the medical staff, may revise the list of highly confidential information which cannot be transmitted by email.
- 11. Urgent and Time Sensitive Communications. E-mail should not be used for urgent or time sensitive communications.
- 12. **Patient Consent** Absolutely no patient information may be transmitted by email unless the Medical Records department has obtained the written consent form of the affected patient. The systems administrator, in consultation with the medical staff, shall develop and implement such a consent form. Patient informed consent should address the following, at a minimum:
 - E-mail communication is not appropriate for emergencies or time sensitive issues;
 - Security and privacy of email messages cannot be guaranteed;
 - Employers have a right to access email messages received or sent by a patient at work;
 - Communications guidelines for email messages including: (i) appropriate subject matter; (ii) how often email will be checked by VCHCA's staff; and (iii) instructions on when to escalate to phone calls and office visits;
 - Highly sensitive information should not be communicated via email;
 - · Staff other than the physician may read and process the email;
 - Messages relevant to the patient's treatment will be documented in the patient's medical record;
 - Email message must include: (1) category of the communication in the subject line (e.g., prescription refill, appointment request, etc.); and (2) patient name, telephone number and other relevant identifying information as requested;
 - Indemnification of VCHCA for information loss due to technical failures;
 - Consent to forwarding of patient information to a third party, such as a consultant or insurance company.
- 13. Inclusion of Patient Emails in Patient File. All email messages sent or received that relate to the diagnosis or treatment of a patient shall be printed and placed in the patient file. Such emails shall be treated with the same confidentiality as other information in the patient's file.
- 14. User Security. The systems administrator shall give each staff member a user ID and password to access the County of Ventura's email system. Users must not share passwords or

reveal them to anyone else.

- 15. **Forwarding Email**. Confidential or sensitive information is to be distributed to those only with a legitimate "need to know." Users must never forward to any person outside of HCA any email message containing confidential information without the approval of the user's supervisor. Confidential information may be forwarded to multiple recipients, provided that such forwarding otherwise complies with this Policy on Email Communications. However, a user may not use distribution lists to forward confidential information without approval of the user's supervisor. Automated forwarding of email is prohibited by both VCHCA and County policy.
- 16. **Retention of Email.** Email back-ups are to be performed to support the retention policy noted in the VCHCA email policy.
- 17. **Receipt of non-compliant e-mails that include PHI.** Email with PHI that is not sent in a compliant manner to VCHCA staff is to be deleted by the recipient. The sender is to be notified that their email been deleted because it is out of compliance with our agency policy and asked to either resend after encrypting their message or resend without including the PHI.

Ventura County Health Care Agency (HCA) and its employees have a duty to safeguard PHI and preserve the confidentiality and integrity of patient information including when PHI is communicated through HCA's email system. To safeguard PHI communicated through its email system, HCA requires users who are authorized to use its email system and who transmit PHI through email comply with the procedures set forth below.

PROCEDURE

General Security of Email Systems

- 1. **Dissemination of Policy**. All personnel shall be informed of the HCA email policy during orientation and shall be provided with a written copy of such policy. Personnel shall be required to sign a confidentiality agreement that addresses use of email communications.
- 2. No Right to Privacy. HCA encourages the business use of email to increase productivity. The e-mail system and all messages generated by email, including back up copies, are part of the business equipment of HCA, are owned by HCA, and are not the property of the employee or other users of the system. Consequently, email users do not have a right to privacy in their use of computer systems or email components.
- 3. **Right to Monitor, Audit, Delete, Read**. Health Care Agency (HCA) reserves the right to monitor, audit, delete, and read email messages. The network administrator may override user passwords. HCA may monitor the contents and usage of email messages to support operational, maintenance, auditing, security, and investigative activities.
- <u>4.</u> <u>User Security</u>. The systems administrator shall give each staff member a user ID and password to access the County of Ventura's email system. Users must not share passwords or reveal them to anyone else.
- 5. **Retention of Email.** Email back-ups are to be performed to support the retention policy noted in the VCHCA email policy.
- 6. **Prohibited Uses**. Email users should restrict their use of the e-mail system to proper business purposes relating to the care, treatment, and operations regarding patients and related

administrative matters such as billing. Prohibited uses of e-mail to transmit confidential information without appropriate authorization or in violation of HCA e-mail encryption procedure as described below.

- 7. Urgent and Time Sensitive Communications. Email should not be used for urgent or time sensitive communications.
- 8. **Confidentiality Notice Disclaimer.** Users will add a Confidentiality Notice Disclaimer to their email signature template. A recommended disclaimer is provided below.
 - CONFIDENTIALITY NOTICE: This message including attachments is intended only for the use of the individual or entity to which it is addressed and may contain confidential information protected against unauthorized use or disclosure by applicable federal and state law. If you receive this e-mail message in error, please immediately notify the sender by e-mail, and delete the original message in any electronic or paper form. Dissemination, forwarding, printing, or copying of this e-mail without prior consent of the sender is strictly prohibited. Thank you for your compliance.
- 9. **Encryption**. When email is requested or necessary to communicate and communication includes PHI, individuals should encrypt the email as a safeguard. To encrypt an email;
 - · Verify the intended recipient's email address
 - Include #secure# or #allsecure# in the subject line of the email.
- 10. **Highly Confidential Information**. The following information is deemed highly confidential and MUST be transmitted by encrypted email:
 - HIV or AIDS status
 - Mental illness
 - <u>Substance use disorder</u>
 - <u>Sexual orientation</u>
 - Reproductive health
- 11. **Minimum Necessary Standard.** The minimum necessary standard applies to all communications that include PHI. In addition to including only the minimum information necessary, HCA prohibits communication of PHI using distribution lists. Confidential information should only be sent to those with a legitimate need to know basis. These considerations apply to the communication of highly confidential information.
- 12. **Email Retention**. Email messages sent or received that relate to the diagnosis or treatment of a patient shall be printed and placed in the patient file. Such emails shall be treated with the same confidentiality as other information in the patient's file.
- 13. **Forwarding Email**. Confidential or sensitive information must never be forwarded to any person outside of HCA without first obtaining supervisor approval. Confidential information may be forwarded to multiple recipients, provided that such forwarding otherwise complies with this Policy. Automated forwarding is prohibited by both HCA and County policy.
- 14. **Receipt of Non-Compliant Emails that Include PHI.** When receiving an email communication that includes PHI, that is not sent in a compliant manner, the HCA recipient should 1) contact the Compliance Department to report the non-compliant email, 2) permanently delete the email, 3) call the sender to notify them of the deletion and agency policy, and 4) ask the sender

to recall, encrypt and resend the email or recall an resend without PHI.

Email Communication with Patients

- 1. Methods of secure communication. Individuals should not send external emails to patients via email except according to the standards set forth in this policy. Individuals are encouraged to use other secure means of communication first. Patients should likewise be encouraged to use patient portals provided by HCA for sending secure electronic communications to their providers.
 - https://vchca.ighealth.com/self-enroll/
 - <u>https://vchca.consumeridp.us-1.healtheintent.com/saml2/sso/</u> login?authenticationRequestId=70a88a9c-94cd-421c-ac91-ef5edaffa3e0
- 2. **Patient Consent.** Absolutely NO patient information may be transmitted by email unless the Medical Records department has obtained the written consent form of the affected patient. The systems administrator, in consultation with the medical staff, shall develop and implement such a consent form. Patient informed consent should address the following, at a minimum:
 - E-mail communication is not appropriate for emergencies or time sensitive issues;
 - · Security and privacy of e-mail messages cannot be guaranteed;
 - Employers have a right to access email messages received or sent by a patient at work;
 - <u>Communications guidelines for e-mail messages including: (i) appropriate subject</u> matter; (ii) how often e-mail will be checked by VCHCA's staff; and (iii) instructions on when to escalate to phone calls and office visits;
 - Highly sensitive information should not be communicated via e-mail;
 - Staff other than the physician may read and process the e-mail;
 - Messages relevant to the patient's treatment will be documented in the patient's medical record;
 - E-mail message must include: (1) category of the communication in the subject line (e.g., prescription refill, appointment request, etc.); and (2) patient name, telephone number and other relevant identifying information as requested; Indemnification of VCHCA for information loss due to technical failures;
 - Consent to forwarding of patient information to a third party, such as a consultant or insurance company.
- 3. Patient Initiated Communication. If a patient initiates email correspondence with a health care provider, the health care provider should encourage use of the patient portal provide above. If the patient refuses to use the patient portal, the patient must first confirm patient consent is on file to receive email communication of PHI. If such consent is not on file, the provider will refer the patient to the Medical Records department to obtain consent before proceeding with email communication.

Email Communication with other Providers and

Covered Entities

- 1. All General Security Procedures Apply. All general security procedures listed above apply to email communications between HCA and healthcare providers outside of the HCA email system, including encryption and minimum necessary standards.
- 2. **Permitted communications.** HCA may communicate PHI through email to another provider or covered entity when both HCA and the other provider have a relationship with the patient and the PHI relates to that relationship or when the PHI is needed for health care operations or compliance functions such as auditing and monitoring.
- 3. **Verify appropriate recipient.** Prior to sending email communication containing PHI to another provider or covered entity, the HCA sender should verify correct email address.

Email Communication with Business Associate

- 1. All General Security Procedures apply. All general security procedures listed above apply to email communications involving PHI between HCA and HCA Business Associates, including encryption and minimum necessary standards.
- 2. Business Associate Agreement. A current, fully executed, compliant Business Associate Agreement must be in place prior to sending any PHI. The HCA sender should verify such an agreement is in place and remains current.
- 3. Limitations. Only PHI authorized by the Business Associate Agreement to perform required functions may be sent.

Applicable Laws and Regulations

- 45 C.F.R. 142.308(d)(1)
- 45 C.F.R. 164.306(a); 522
- <u>Ca. Civil Code 1798.140(ae)</u>

Approval Signatures

Step Description

Approver

Date