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

Ventura County Health Care System Oversight Committee
Administrative Policies

April 11, 2024

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

1. 108.006 Nurse Staffing and Scheduling
2. L.BB.69 Thawed Plasma – 5 Day
3. RS.19 Use of Pediatric Equipment

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Ventura County Health Care System Oversight Committee
Administrative Policies - April 11, 2024
Summary of Changes

#	Title	Renewal Period	Summary of Changes
1	108.006 Nurse Staffing and Scheduling	Triennial	Reformating and updates to reflect current practices
2	L.BB.69 Thawed Plasma – 5 Day	Annual	Spelled out "Fresh Frozen Plasma (FFP)" and "C" for Centigrade
3	RS.19 Use of Pediatric Equipment	Triennial	Minor update reflecting current practice

Status **Active** PolicyStat ID **15601184**

Origination	9/1/1985
Last Approved	4/9/2024
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Last Revised	4/9/2024
Next Review	4/9/2027
Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH
Policy Area	Administrative - Nursing

108.006 Nurse Staffing and Scheduling

POLICY:

To recognize the rights and responsibilities of the Department of Nursing Services and Nursing staff in meeting mutual obligations for the care of the patients of Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH). To ensure adequate staffing is available to meet patient care requirements while utilizing staff in an optimal manner. To provide a clearly outlined sequential process for providing necessary nursing staff on all nursing units and allowing requested employee time off, while meeting projected patient care needs. To provide written records of staffing assignments on all units which allow retrospective analysis as necessary and meet external regulatory requirements.

GUIDELINES:

The Department of Nursing Services recognizes its obligation to provide an adequate number of skilled and qualified staff to meet the needs of the patients and scope of services required. It is the policy of the Nursing Department that a variety of nursing staff is used to provide necessary staffing. We believe that Registered Nurses (RN), Licensed Vocational Nurses (LVN), Nursing Assistants and Medical Office Assistants all contribute to safe efficient care when properly trained, supervised and assigned. The hospital is flexible in its staffing in order to respond to day-to-day shifts in census and workload. On low census days, or other periods of low workload, (and the hospital is adequately staffed throughout with qualified staff), employees may voluntarily take off hours of leave without pay in order to appropriately reduce the level of staff. The employee may choose to use accrued paid vacation instead.

If an excess of staff can be anticipated before the beginning of the shift, the Clinical Nurse Manager/ Supervisor may initiate phone calls to employees and offer them the opportunity to take the day off. When necessary, in times of low census, the guidelines described in the California Nurse Association Memorandums of Agreement (CNA MOA) that cover all CNA represented employees will be followed. The employee may also initiate a call to the supervisor prior to the beginning of the shift to see if he/she

is needed for duty. Leaves given in this way will also follow the plan developed by the Manager. Leave will be granted only after the needs of the hospital have been covered. The Supervisor will note on the schedule the number of hours and type of leave used by any employees. Leave With Out Pay (LWOP) may not be used or granted in advance and/or pre-planned. LWOP may be granted, at employee's request, after the Supervisor has reviewed the staffing needs for the shift. VCMC/SPH utilizes an automated scheduling system to create, project, and print long-range schedules. This system automates daily staffing allocation of available staff based on census, patient acuity and budgetary provisions.

Staffing for the nursing units will be reviewed for a 24-hour time frame on a daily basis and adjustments are made prior to the start of each shift as indicated. The Nursing Supervisor/Clinical Nurse Manager assumes this responsibility. Nursing staff may be temporarily reassigned on a shift-by-shift basis when changes occur in either the workload, the staffing requirements and/or availability of assigned staff. In these cases, Nursing Administration has the responsibility and right to assign staff to best meet the determined needs of the patient with the licensure, skill and qualification levels available. Reassignment of nursing staff on a pre-scheduled basis is made through careful consideration of all facts, which include but are not limited to the following:

A. Patient census and acuity
B. Number and classification of staff available, with consideration of floating clusters as outlined in the CNA MOA, affecting all CNA represented employees.
C. Qualifications, experience and competence of staff required and available.
D. Unfilled positions.
E. Daily shift assignments to the unit are finalized and are posted in the Nursing Administration Office at the beginning of the shift.
F. Any changes posted in staff assignments must be verified by the Nursing Supervisor/Clinical Nurse Manager.
G. Nursing staff, i.e. all CNA represented employees are assigned routinely to areas within their clusters as outlined in the CNA MOA, in which they are qualified and have received training and proper orientation. It is the intent of the nursing department that when a temporary and/or immediate assignment must be made, the needs of the patient and the needs of the employee will be considered. If immediate assignment is necessary, a "helping hands" orientation to the unit will be given and a resource person will be available. Employees are encouraged to discuss their assignments with their coordinator or supervisor in the event of concerns or problems.

Holidays: Refer to the appropriate union contract.

Vacation:

A. All employees, full-time, part-time and per diem, will submit vacation requests in writing to the Clinical Nurse Manager for approval (at the latest) prior to finalization of each six-week schedule
B. During the months of June through September, no more than 2 weeks will be granted per employee, without special approval of the Clinical Nurse Manager.
C. During the period between December 1st and January 1st, requests for vacation hours in

excess of 24 hours will require special approval by the Clinical Nurse Manager.

D. Vacation ‘wrap arounds’ will not be approved. The days the employees are requesting off/days needed off due to travel plans, will need to be requested and approved as the schedule allows and vacation hours utilized to cover such.

E. Vacation hours must be banked prior to vacation request being considered for approval.

F. ‘X’s’ on request scheduled are not guaranteed.

Acuity Determination: Staffing considerations include acuity assessments. Acuity is determined using department based tools. See attachments.

PROCEDURE

Schedules are created on 6-week cycles: Schedules will be posted 3 weeks (21 days) prior to the start of the new schedule and contain the following 6 weeks of scheduled work time.

Changes in Schedule/Special Requests: For changes to the final posted schedule or special requests, the employee fills out the "Schedule Change Request" form and obtains signature of approval from the Clinical Nurse Manager before submitting request form to the staffing office.

Schedules:

Prepared on a 6 week basis to provide a method of planning the basic staffing of all nursing units within the Department of Nursing.

Updated every shift to reflect cancellations, illness, special requests and additional alterations or additions to the general staffing.

This record will be maintained for a period of 3 years.

The Clinical Nurse Manager or their designee assists in this responsibility by reviewing the staffing levels and patient care requirements and communicating special needs/problems to the nursing office. The Clinical Nurse Manager assists in this responsibility by monitoring sick calls and unexpected absences and communicating this activity to the nursing office.

Approvals for exchange of days worked are made on the basis that the exchange is made with someone of the same job class and skill level, the exchange is made within the same pay period, and minimum employment agreements are met. Approval for changes is made on the basis that no overtime is incurred and that appropriate staffing and skill mix is accomplished. Any emergency situation which is unexpected in nature will be handled on an individual basis by the Nursing Supervisor if it occurs on weekends, holidays, or after hours.

Daily Staffing:

Clinical Nurse Manager/House Supervisor reviews and makes necessary adjustments to daily staffing.

A. Census activities and acuity determinations will be reported at 4:00 AM, noon, and 8:00 PM. Additional census confirmation may also be done at 4:00 pm. The Inpatient Psychiatric Unit collects census information at 05:00 and 17:00, which is used to make daily staffing plans.

B. Staffing is reviewed and adjustments are made based on staffing guidelines and census/acuity requirements.

C. The Clinical Nurse Manager will be responsible for covering staffing needs. The Clinical Nurse Manager may request assistance to place phone calls from the Staffing Office, Nursing Supervisor and charge nurse (if time permits).

Weekend Commitment:

A. Each full-time or part-time staff member may be scheduled to work a minimum six (6) weekend shifts per 6-week schedule. For the purpose of this policy, a weekend shift is one that is scheduled to begin on or after 6:45pm Friday and scheduled to end on or prior to 7:15am Monday.

B. All Staff: Weekend absences:

1. One weekend absence allowed every calendar year. For the purpose of this policy, a weekend absence is defined as one (1) weekend shift.
2. All others subject to make up, i.e. automatically scheduled by the Clinical Nurse Manager for an extra weekend as needed by unit. This requirement is waived for employees normally scheduled to work a minimum of eight (8) weekend shifts per month.
3. Any make up weekend shift shall not be scheduled, unless by mutual agreement, prior to 21 days from the date of the missed shift. The clinical nurse manager will propose a makeup shift based on operational need. The nursing staff will make a reasonable effort to comply with the makeup shift; if there is a major conflict with identified shift, nursing staff will propose alternative shift.
4. The Clinical Nurse Manager may, by mutual agreement, cancel a make up weekend shift if the employee is not needed.
5. An employee scheduled to make up a weekend shift may request to drop a weekday shift, if operationally feasible, within that same pay period. Such a request shall not be unreasonably denied.

It is the daily responsibility of the Staffing Office, Clinical Nurse Manager and Nursing Supervisor to assign the available staff so that it matches the pattern required by the acuity and census. Skill Mix Substitutions – If insufficient numbers of staff are available in a particular skill level, then substitutions may be made within certain guidelines:

A. A higher skill level may always be substituted for a lower level, e.g., RN for LVN.

B. A lower level may be substituted for a higher level only where there is adequate RN coverage on the unit to assess patients and meet the State Staffing Ratios, to make appropriate assignments, and to carry out complex care.

Clinical Nurse Manager/Nursing Supervisor reviews the census and staffing for all units within the first 2 hours of each shift. Staffing Shortage – When there are insufficient numbers of staff in a given skill level, the Clinical Nurse Manager, Staffing Coordinator, and/or Nursing Supervisor will be responsible for finding adequate coverage by doing one of the following:

A. Assign Alternate assignment for extra personnel on duty.

B. Request regular part-time person to come in.
C. Request per diem person to come in.
D. Request on-duty staff to work overtime.
E. Request off-duty staff to work overtime.
F. Request Registry personnel.
G. Reassign on-duty staff for optimum coverage.
H. Mandate Overtime (Requires Nurse Executive or designee approval).

Supervisor moves staff from low-census to high census areas where possible. Moves are made based upon levels of licensure, training and competency of staff available.

All staff are expected to comply with appropriate requests to change their areas of work on short notice in order to provide for safe patient care throughout the hospital.

Unscheduled Leave: It is the expectation that unscheduled leave will be minimal for a 12-hour shift program. The accepted hospital standard is an average of 2.2 hours of unscheduled leave per pay period for full-time employees. Part-Time employees are assessed on a prorated basis. Consistently exceeding accepted standards may be cause for termination of the employee's 12-hour schedule, and/or disciplinary action. When it is necessary to use unscheduled leave, the 0645 to 1915 shift employee will notify the night shift supervisor by 0500; the 1900 to 0700 shift by 1700.

Scheduled Leave: All requests for scheduled leave (annual leave, educational leave, etc) will be planned in advance and must be submitted in writing at least 14 days prior to the posting of the current four-week master schedule. No more than one employee may be scheduled off, at any one time, unless coverage is available. All requests submitted AFTER the posting of the four-week master schedule may require the employee to arrange his/her own coverage. All scheduled leave requests are subject to the approval of the Clinical Nurse Manager

Overtime:

A. It is the policy of the hospital to avoid the necessity for overtime whenever possible.
B. Overtime work may sometimes be necessary to meet emergency situations, seasonal peak workload requirements or other defined times of need as determined by Nursing Administration.
C. No employee shall work overtime unless authorized to do so by his/her supervisor

Guidelines:

A. Employee anticipated need
    1. Anticipated need for overtime must be communicated to the Clinical Nurse Manager/Nursing Supervisor
    2. If possible with 2 hours notice
    3. If <2 hours before end of shift, ASAP
        a. Clinical Nurse Manager or Nursing Supervisor will decide course of action

b. Authorize overtime
c. Provide assistance to eliminate need for overtime
d. Other action as appropriate

B. Failure to notify in advance may be grounds for disciplinary action
C. Clinical Nurse Manager or Nursing Supervisor will make telephone calls to off-duty staff, Registry, offer overtime, etc to meet patient care needs.

Mandatory Overtime:

In the event that the procedures above fail to provide safe, adequate staffing levels, it may be necessary to institute mandatory overtime. Any need to mandate overtime must be authorized by the Nurse Executive or her immediate designee. All mechanisms to provide safe patient care without mandatory overtime will have been exhausted. At the decision to mandate overtime, employees on duty will be polled to determine ability to stay. Otherwise the Nurse Executive, working with Clinical Nurse Manager or Nursing Supervisor, will make the final staffing decisions.

Mandatory overtime will continue for as short a time as possible, while continuing efforts are made to provide alternate staffing.

Failure to abide by these decisions may result in disciplinary action.

REFERENCES

1. Title 22 Department of Health Services, State of California.
2. United States Department of Health & Human Services.
3. California Department of Public Health.

All Revision Dates

4/9/2024, 3/22/2024, 3/24/2023, 1/30/2023, 1/10/2023, 11/14/2022, 11/14/2022, 8/27/2021, 5/1/2016, 11/1/2013, 12/1/2010, 12/1/2001, 3/1/2000, 1/1/2000, 1/1/1999, 12/1/1992, 9/1/1988, 9/1/1987, 9/1/1986

Attachments

Nurse Acuity MedSurgTele.xlsx

Nurse Acuity NICU

NurseAcuity ICU.docx

NurseAcuity L&D.docx

NurseAcuity Peds.docx

NurseAcuity PICU.docx

NurseAcuity PP.docx

VCMC IPU Patient Acuity.docx

Approval Signatures

Step Description	Approver	Date
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	4/9/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/9/2024
Policy Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/9/2024

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Origination	10/1/2008	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	3/19/2024		
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Last Revised	3/19/2024		
Next Review	3/19/2026		

L.BB.69 Thawed Plasma – 5 Day

PRINCIPLE:

Thawed Plasma is derived from Fresh Frozen Plasma (FFP) and Plasma Frozen Within 24 hours of phlebotomy (PF24) that has been thawed at 30° to 37°C in a closed system and stored at 1° to 6°C for 1 to 5 days. The expiration date is 5 days after thawing of the original component. Thawed Plasma contains somewhat reduced amounts of labile coagulation Factors V and VIII.

SPECIMEN COLLECTION:

1. Pink EDTA blood bank tube.
2. Type and Screen performed.
3. Blood bank band on the blood bank tube and the patient banded with the corresponding Blood Bank wristband.

REAGENTS-SPECIAL SUPPLIES AND EQUIPMENT:

1. Waterbath- 30° to 37° Centigrade.
2. Waterproof plastic Helmer bags.
3. Product code labels.
4. ISBT printer with ISBT label

PROCEDURE:

Selection of Units

1. ABO group specific is preferred. If not available use only the options listed below. The Rh(D) type is not a consideration.

PATIENT TYPE	DONOR TYPE
O	**O, A, B, AB**
A	**A, AB**
B	**B, AB**
AB	**AB**

2. If the patient does not have a current blood bank specimen, provide AB plasma until a blood bank specimen can be drawn and testing completed. Use the "Dispense and Assign Products - emergency dispense mode" to issue the blood product. The attending physician will be asked to sign an emergency waiver for the units(s).
3. **Trauma Protocol**
    a. Thaw 2 - 6 units of AB plasma.
    b. Place thawed units on the trauma/emergency release shelf in the blood bank refrigerator.
    c. May utilize liquid plasma in place of AB plasma in most trauma settings.
4. Perform a modification of the product in the computer prior to putting the plasma in the bath to be thawed.
    a. ***Health-e-Connect: Thaw Product***
        i. Open Modify Products application.
        ii. In modification field select "Thaw Product" from the drop down list.
        iii. Scan the unit Donor Identification number under Product Number in Original Products.
        iv. The new product will appear in the New Product table below.
        v. Edit the volume of the component by entering the volume shown on the component label located on the lower left.
        vi. The product expiration date and time has been updated by the system, and this date and time should be written on the unit label.
        vii. In the New Product table, highlight the new product and click the "assign to person" icon at the top.
        viii. Click <Save>.
    b. ***Health-e-Connect: Extend Product***
        i. Open Modify Products application.
        ii. In modification field select "Extend Product" from the drop down list.
        iii. Scan the unit Donor Identification Number of original product into Product Number field.
        iv. The new product will appear in the New Product table below.

v. Modify the expiration date to a 5-day expiration date from the date of the original thaw. The time of expiration should be the same as the original expiration time.

vi. Edit the volume of the component by entering the volume shown on the component label located on the lower left.

vii. The ISBT label should print when you save your modification. Review the label for completeness (volume and product code not cut off). Affix the ISBT label to the product. **Do not relabel the product with the ISBT unit number label.**

viii. For downtime procedure, re-label the unit by placing the appropriate "Thawed Plasma" product label code label over the current product code label. Line the label up in the lower left of the large label. (see appendix A for correct product code label). Enter the unit volume on the new label. Cross out the component expiration date and manually write the new expiration date and time. Draw a line through the license information on the upper left of the label that identifies the facility name.

ix. Click <Save>.

x. Perform a label verification using the computer label verify application. The printed report, which prints after successful label verification, should be saved.

xi. If the unit is for the trauma protocol, do not assign it to a patient until it is dispensed.

c. **Health-e-connect: 5 Day Plasma:** Plasma can be thawed and directly extend to 5-day expiration. Click 5 Day Plasma option in Modification Products when ISBT printer is in use. Label Verify the thawed product as in previous section.

d. All Thawed Plasma - 5 day is stored at 1 - 6C for up to 5 days.

PROCEDURE NOTES:

- Thawing will take approximately 30 minutes.
- Place appropriate number of units of FFP/Plasma into plastic waterproof bags.
- Place the bag into the 37° Centigrade waterbath.
- Check the plasma at periodic intervals until it is completely defrosted.
- Avoid getting the ports wet.
- Usually only 1 or 2 plasma(s) should be defrosted for a patient at a time.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD. American Association of Blood Banks, Current Edition.
2. Consensus Standards for the Uniform Labeling of Blood and Blood Uniform Labeling Guideline (FDA).

APPENDIX A:

For downtime procedure, the following table is used to look up the appropriate product code label for 5 day thawed plasma products. The left column are frozen and 24 hour thawed product codes and the right column is the corresponding label for all extended 5 day thawed plasma products.

1. Look at the plasma product that requires extending the expiration to 5 days.
2. The frozen or 24 hour thawed product code is in the lower left quadrant of the unit label.
3. Find that product code in the left column of the table below.
4. Follow that line to the left column and that will be the product code to re-label you product with.

FROZEN PRODUCT CODE	5 DAY THAWED PRODUCT CODE
E2555V00	E2684V00
E2619V00	E2720V00
E7646V00	E5548V00
E7648V00	E5549V00
E7650V00	E5550V00
E7607V00	E6396V00

All Revision Dates

3/19/2024, 2/5/2024, 6/5/2020, 12/1/2016, 5/1/2016

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	3/19/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	3/19/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	3/3/2024

Status **Active** PolicyStat ID **14596837**

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Last Revised	3/25/2024
Next Review	3/25/2027
Owner	Marcos Rodriguez: Manager, Rehabilitation Services
Policy Area	Rehab Services

RS.19 Use of Pediatric Equipment

PURPOSE

To provide guidelines for the use of pediatric therapeutic equipment.

POLICY

Rehab staff will ensure proper identification, safety and application of pediatric equipment.

PROCEDURE

A. Pediatric equipment can include but is not limited to splints, walkers, wheelchairs, crutches, canes, bath chairs, commodes and adaptive devices for Activities of Daily Living (ADL's).

B. Recommendations for pediatric therapeutic equipment will be assessed during the initial therapy evaluation with consideration for age, diagnoses and special needs.

C. Explanation of the equipment and review of precautions will be discussed with the patient/ family, nursing staff and others involved with the care of the pediatric patient.

D. Documentation will be made in patient's Electronic Medical Record (EMR) noting Durable Medical Equipment (DME) process, including vendor information, precautions and patient's response to equipment.

E. In active California Children's Services (CCS) Medical Therapy Unit (MTU) clients, the patient will be referred back to the MTU if equipment adjustments and/or repairs are needed to have the primary MTU therapist re-evaluate the equipment. If new equipment is needed prior to leaving the hospital, Ventura County Medical Center (VCMC) therapy services shall consult with the primary CCS MTU therapist as to recommendations.

F. Individual equipment:

1. **Rental wheelchairs** shall be coordinated with social services and a hospital vendor

and assessed for size of patient, need for specific post-surgery requirements, such as elevating leg rests and removable arms, as well as other needs specific to current hospital stay. Review of equipment, transfer training and safety precautions will be reviewed with patient/family and staff prior to discharge.

2. **Ambulating devices:** age, level of function, cognition and home situation will be assessed prior to assigning and ordering walkers, canes and other ambulation devices. Specific needs shall also be considered as to safety and need of family, such as home stairs, need to return to school, etc. in deciding proper ordering of ambulation devices. Safety and precautions will be reviewed with the family/patient and hospital staff prior to discharge.
3. **Bathroom equipment** needs will be discussed with family such as bath chairs and commodes prior to discharge of patient. Equipment will be ordered through hospital vendor with safety and use discussed with patient, prior to discharge.

G. Under Centers for Medicaid and Medicare Services (CMS) quality standards for DME suppliers, the vendor is responsible for providing instructions as related to use, maintenance and potential hazards of equipment. VCMC rehab staff will attempt to coordinate to assure that vendor provides this information to patient and family.

H. Equipment will always be selected with the utmost regard for patient's safety. A second person may be used for assistance in patient/family instruction, such as balance and transfer training.

I. Equipment will be selected as indicated by age, muscular, sensory, developmental and balance impairments. Considerations will also take into account length of need, family's home situation and ease of use of equipment.

All Revision Dates

3/25/2024, 12/1/2020, 12/1/2010, 7/1/2007, 6/1/2006, 3/1/2006

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	3/25/2024
Rehab Services	Marcos Rodriguez: Manager, Rehabilitation Services	3/25/2024

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Ventura County Health Care System Oversight Committee
Administrative Policies
March 14, 2024

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

1. 100.011 Hospital Visitation
2. 107.017 Plan of Internal Control
3. 107.034 Additions to the Charge Master
4. IS.01 Radiation Safety & Protection Program
5. IS.47 MRI Magnet Quench
6. OB.42 OB Urinalysis Dipstick Quality Control
7. PH.100 Kit Check for Pharmacy Boxes, Kits and Anesthesia Medication Trays
8. PH.18.01 340B Drug Pricing Program: Disproportionate Share Hospital
9. R.20 Blood Gas Laboratory RapidPoint 500 Analyzer Quality Control Program
10. R.54 Designees in the Blood Gas Laboratory
11. L.40 Notifiable Laboratory Test Results
12. L.BB.01 Direct Antiglobulin Test
13. L.BB.04 Blood Component Filters
14. L.BB.05 Irradiation of Blood Products
15. L.BB.32 Blood Bank Issue of Blood Products
16. L.BB.33 Sickle Cell Testing - Donor Units

Ventura County Health Care System Oversight Committee
Administrative Policies - March 14, 2024
Summary of Changes

#	Title	Renewal Period	Summary of Changes
1	100.011 Hospital Visitation	Triennial	Added language to policy statement. This change is to comply with new Joint Commision standards.
2	107.017 Plan of Internal Control	Annual	Minor edits to refer to Auditor-Controller rather than Auditor/Controller. Also in 4th paragraph, last sentence of Financial Control, refer to a "financial" audit, not just an audit.
3	107.034 Additions to the Charge Master	Triennial	Modified approvals in procedure section of policy and other edits.
4	IS.01 Radiation Safety & Protection Program	Triennial	Revised policy layout
5	IS.47 MRI Magnet Quench	Triennial	Removed language specific to "life threatening event" and the "cost" if we were to quench the magnet
6	OB.42 OB Urinalysis Dipstick Quality Control	Triennial	Removed keeping logs for 3 years.
7	PH.100 Kit Check for Pharmacy Boxes, Kits and Anesthesia Medication Trays	Triennial	Add location SPH. Reconcile kit check related boxes and kits
8	PH.18.01 340B Drug Pricing Program: Disproportionate Share Hospital	Annual	Updated patient status to include Outpatient in Bed in Definitions section
9	R.20 Blood Gas Laboratory RapidPoint 500 Analyzer Quality Control Program	Biennial	Additional info added per College of American Pathologists
10	R.54 Designees in the Blood Gas Laboratory	Biennial	Changes per College of American Pathologists
11	L.40 Notifiable Laboratory Test Results	Biennial	Description of HIV result reporting was changed to reflect current practices.
12	L.BB.01 Direct Antiglobulin Test	Biennial	Added date of when paper copy of policy and procedure was last reviewed.
13	L.BB.04 Blood Component Filters	Biennial	Revised filter size from 170 to 150 (Technical Manual, 2023). Added paper copy review date.
14	L.BB.05 Irradiation of Blood Products	Biennial	Revised to include requirements for neonates and pediatric patients, added paper copy review date.
15	L.BB.32 Blood Bank Issue of Blood Products	Biennial	Added "Paper copy reviewed on 12/12/2023 by Janette O'Neill." Revised Procedure section.
16	L.BB.33 Sickle Cell Testing - Donor Units	Biennial	Added "Paper copy reviewed on 12/12/2023 by Janette O'Neill." Reference updated.

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Next Review	2/25/2027
Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices
Policy Area	Administrative - Operating Policies

100.011 Hospital Visitation

POLICY:

In order to ensure the safety and security of patients, employees and volunteers of Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH), to maintain an orderly environment and assist patients and visitors with finding their destination, there is controlled access to both facilities. Hospital visitation guidelines are available in English and Spanish in the Patient Information Booklet.

At designated entrances only, all guests will be required to check in as either a visitor or a vendor and will then be issued a wrist band or vendor identification (ID) badge.

Hospital visitation will not be restricted, limited or otherwise denied based on age (with the exception of children <13 year old), race, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, and gender identity and expression.

PROCEDURE:

There are specific designated entrances at both VCMC and SPH available for patients, visitors, vendors and employees. Any person in the hospital without a visitor or vendor wrist band, vendor ID badge or employee badge should be directed to one of the hospital entrances so that they may sign in and be issued a wrist band or vendor ID badge.

HOSPITAL VISITATION GUIDELINES

For the welfare of our patients and to contribute to each patient's recovery, we urge all visitors to observe the following visitation guidelines:

A. Regular visitation hours are from 9:00 a.m. to 9:00 p.m. daily.

B. Patient visits should not exceed two (2) visitors at any given time, unless there is a special circumstance and approved by the Department Manager or House Supervisor.

C. Visitors must be in good health. Visiting is not allowed if the visitor is ill.

D. Visitors are required to comply with all hospital infection control policies.

    1. Visitors of Neonatal Intensive Care Unit (NICU), Pediatrics Unit, Pediatric Intensive Care Unit (PICU), immunocompromised or other high-risk patients may be asked to mask based on community prevalence of respiratory illnesses or at the discretion of the provider or nurse in charge.

E. Service animals will continue to be allowed entrance.

F. No visitors under the age of 13 are permitted in patient care areas unless they are the parents of hospitalized children, the significant other of a laboring person, a brother or sister of a child who is a patient in NICU, Pediatrics Unit, PICU, Obstetrics Unit (OB) or family members of a terminally ill patient. Visitors meeting this criteria may visit under these conditions:

    1. Siblings may visit during regular visitation hours only. They must be accompanied by a responsible adult.
    2. Siblings must be in good health, as determined (when necessary) by a nurse or physician on the unit.

G. Shoes and shirts are required for all visitors.

H. Noise levels should be kept to a minimum in the corridors and while in patient rooms.

I. No food should be brought in from outside the hospital unless approved by physician and/or nursing staff. Visitors should only eat in patient areas after conferring with nursing staff. Visitors may go to the cafeteria to purchase food.

J. Smoking is prohibited anywhere on hospital grounds, including all parking areas. Smoking includes the use of cigarettes, cigars, water pipes, pipes, hookahs, marijuana (including medical marijuana) and electronic smoking devices, such as e-cigarettes and vaping pens. There are no designated smoking areas on Hospital property. See policy *106.004 Smoking Policy* for more information.

K. Fresh or dried flowers, or potted plants, are not allowed in patient-care areas for immunosuppressed patients.

L. Pediatrics Unit and Pediatric Intensive Care Unit (PICU) - We invite parent participation in the Pediatrics and PICU Unit. One parent may stay with the patient at all times as space allows. Grandparents or other significant adult(s) may visit with a parent, unless otherwise specified. Prior to sibling visitation in the PICU, a joint discussion concerning the risks and benefits of visitation will be had with the charge nurse, Child Life Specialist, physician and parents. See policy *P.32 PICU, NICU and PEDS Visiting Policy* for more information.

M. Neonatal Intensive Care Unit (NICU)-We invite parent participation in the NICU Unit. Parents will be required to wear their identification armband when visiting. One parent may stay with the patient at all time as space allows. Grandparents or other significant adult(s) may visit with a parent unless otherwise specified. See policy *P.32 PICU, NICU and PEDS Visiting Policy* for more information.

N. Emergency Department

1. No children under the age of 13 unless they are the patient, the parent of a patient, or the support person of a pregnant person.
2. Children must be accompanied by an adult, when in the ED or the waiting room.
3. In critical situations, family members can stay at bedside at the nurse's discretion.
4. The Quiet Room may be utilized for families in critical situations.
5. To provide a safe environment, visitors are asked to refrain from multiple entries and exits from the patient care area.
6. The ED is not to be used as a thoroughfare to other areas of the hospital. Visitors should use an alternate entrance to gain entry into the hospital, with the exception of off hours when the front lobby is closed.
7. Visitation for ED Hold patients will follow the rules for visitation in the ED.

O. Obstetrics Unit
    1. The support person of the patient may stay in post-partum or ante-partum overnight. A sibling must be accompanied by an adult. The support person will receive an identification bands at the time of delivery.

P. Post Anesthesia Care Unit (PACU) - Visitors will be restricted to the parent(s) of a minor, the parents(s) or caregiver of persons with special needs and under special conditions.

Q. Visitation hours for the Inpatient Psychiatric Unit (IPU) are Monday through Friday, 5:30 p.m. through 7:20 p.m., and on weekends and holidays, 12:30 p.m. to 2:30 p.m. We do attempt to accommodate visits during times other than those posted on an individual basis. It requires a physician's order and should be arranged in advance.

R. Exceptions to the visitation policy may be made in extenuating circumstances. This will be done with collaboration between Medical Staff, Nursing Supervisor, the patient and their family.

S. In the event of an infectious disease outbreak, the visitor policy may be adjusted at the recommendation of the Infection Control Committee, the Medical Director of Infection Control and Prevention, or the Hospital Chief Medical Officer. If adjusted, the policy will be reviewed on a monthly basis.

The VCMC entrance will be open daily from 5:00 am until 9:00 pm. The Customer Service desk at VCMC will be staffed by one to two Security Guards 24 hours a day, 7 days a week, as well as a Customer Service employee from 5:00 am to 9:00 pm. At SPH the entrance will be open from Monday through Friday 6:30 am to 9:00 pm and Saturday through Sunday 8:30 am to 6:30 pm. Entrance can be gained through the Emergency Department when the front lobby is closed.

Upon entering, guests will check in as a visitor or a vendor and be issued either a wrist band or vendor ID badge. Employees entering the facility through the Main Entrance must wear hospital ID badges. Employees without hospital ID badges will be issued a visitor wrist band which must be worn for the duration of their time spent in the Hospital. If a visitor or vendor is noted anywhere in either hospital without an wrist band or vendor ID badge, they will be instructed to obtain a wrist band or vendor ID badge. All vendors shall comply with policy *106.083 Vendor Access and Registration*.

Emergency Department Entrance. The ED at VCMC and SPH will be staffed with a Security Guard 24 hours a day, 7 days a week.

VCMC Hillmont Surgery Entrance. This entrance will be designated for staff and providers only via badge access. No patients, visitors or vendors will be permitted to enter the Hospital through this entrance. Staff and providers may enter through this entrance 24 hours a day, 7 days a week.

VCMC Loma Vista MRI Trailer Entrance. This entrance will be designated for staff and providers only via badge access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff may enter through this entrance 24 hours a day, 7 days a week.

VCMC Radiology Entrance. This entrance is closed to everyone.

VCMC Lab Entrance. This entrance will be designated for staff and providers only via badge access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff and providers may enter through this entrance 24 hours a day, 7 days a week.

VCMC Boardwalk Entrance. This entrance will be designated for staff and providers only via badge access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff and providers may enter through this entrance 24 hours a day, 7 days a week.

SPH Staff Entrance. This entrance will be designated for staff and providers only via badge access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff may enter through this entrance 24 hours a day, 7 days a week.

REFERENCE:

Patient Information Booklet. Ventura County Medical Center and Santa Paula Hospital. [VCHCA-505-050 (01/2020)]

All Revision Dates

2/26/2024, 1/2/2024, 9/18/2023, 7/6/2023, 3/8/2023, 11/22/2017

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH	2/26/2024
Policy Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices	2/23/2024

Status **Active** PolicyStat ID **12335158**

Origination	5/1/1983	Owner	Jill Ward: Chief Financial Officer, VCMC & SPH
Last Approved	2/14/2024	Policy Area	Administrative - Operating Policies
Effective	2/14/2024		
Last Revised	2/14/2024		
Next Review	2/13/2025		

107.017 Plan of Internal Control

POLICY:

The purpose of this policy is to define methods and procedures necessary to safeguard assets, monitor the accuracy and reliability of accounting data, promote managerial efficiency and encourage adherence to managerial policies.

It is not the purpose of this policy to preempt the ultimate role of responsibility that the County of Ventura Board of Supervisors holds for the Ventura County Medical Center (VCMC) /Santa Paula Hospital (SPH). This policy outlines internal mechanisms of control that have been developed by the VCMC/SPH, the Ventura County Health Care Agency, and the County of Ventura Auditor/Controller, in order to ensure fiscal accountability and managerial effectiveness to the Board of Supervisors. The scope of this policy is general, but references are made to specific documents that provide detailed procedures.

PROCEDURE:

Organization

The organization of the areas of responsibilities within the hospital shall be reviewed at least annually and published in an Organization Chart, which shall be maintained in the front of each Departmental Policy and Procedure Manual (see Attachment A, *VCMC/SPH Organizational Chart*).

The Organizational Chart shall define the reporting mechanisms within VCMC/SPH, the Ventura County Health Care Agency, the Oversight Committee and the Board of Supervisors, which has ultimate responsibility.

Policies and Procedures

Each department within VCMC/SPH shall develop and maintain written policies and procedures necessary for the conduct of its activities, to ensure the quality of its services and to conform to licensing and accreditation requirements applicable to that department. These policies and procedures shall be reviewed every three (3) years and approved by Hospital Administration, Medical Staff and the Health Care Agency Director (by authority delegated by the County Board of Supervisors).

Financial Control

The overall responsibility for financial control rests with the Hospital Chief Executive Officer in conjunction with the Health Care Agency Director and Chief Financial Officer. These individuals shall be accountable for financial control to the County Auditor/ Controller, County Executive Officer and the Board of Supervisors.

VCMC/SPH follows financial accounting guidelines established by the Ventura County Auditor/ Controller's Office, the Office of Statewide Health Planning and Development, and generally accepted accounting principles.

A complete schedule of rates and charges shall be maintained by the HCA Revenue Cycle Department. Inquiries should be directed to the HCA Chief Financial Officer or the Revenue Cycle Director.

A monthly VCMC/SPH financial report is prepared by the VCMC Accounting Department and saved on a common directory of the Hospital server for review by hospital leaders. Internal audits are made periodically by the County Auditor-Controller's staff. These are typically focused reviews on topics such as cash and inventory control and record storage. The County Auditor-Controller's Office arranges for an annual County financial audit, which includes the Ventura County Medical Center, conducted by an independent certified public accounting firm.

Human Resources

The Human Resources Department shall ensure that all personnel actions are conducted according to hospital policies and Memorandums of Agreement (MOA) as established in the Ventura County Personnel Rules and Regulations.

PLAN OF INTERNAL CONTROL DOCUMENTATION

DOCUMENT	RESPONSIBLE PARTY	FILE LOCATION	SCHED. REVIEW
BOARD OF SUPERVISORS:			
County Ordinance	County Government	Government Center	Ongoing
State Government Code	Secretary of State	Government Center	Ongoing
Meeting Minutes	County Government	Government Center	Weekly

DOCUMENT	RESPONSIBLE PARTY	FILE LOCATION	SCHED. REVIEW
Membership	County Government	Government Center	4 Years
***COUNTY GOVERNMENT*:**			
County Administration Manual	County Government	Government Center	Ongoing
***MEDICAL STAFF*:**			
Bylaws	Medical Staff Office	Medical Staff Office	Annual
Organization	Medical Staff Office	Medical Staff Office	Annual
Credentials	Medical Staff Office	Medical Staff Office	Biennial
Committee Minutes	Medical Staff Office	Medical Staff Office	Monthly
***HOSPITAL*:**			
Organization Chart	Hospital Admin	Hospital Admin	Annual
Dept. Manager	Hospital Admin	Hospital Admin	Annual
Administrative Policy	Hospital Admin	Hospital Admin	Triennial
Dept. Functions/ Staffing Responsibilities	Hospital Admin	Hospital Admin	Annual
Dept. Manager Meetings	Hospital Admin	Hospital Admin	Monthly
Reports of Inspection by Agencies & Actions Taken	Hospital Admin	Hospital Admin	As necessary
Annual Report to Grand Jury	Hospital Admin	Hospital Admin	Annual
Hospital License	Hospital Admin	Hospital Admin	Annual
FACILITIES:			
Master Plan	Hospital Admin	Hospital Admin	As necessary
Beds (No. & Type)	Hospital Admin	Hospital Admin	Annual
Statement of Conditions	Hospital Admin	Maintenance	Ongoing
Description & Construction Time-frame	Hospital Admin	Hospital Admin	Biennial
Preventative Maintenance Program	Support Services	Support Services	As necessary
PATIENT CARE:			
Performance Improvement Plan	Administrative Policy Manual		Annual
Review & Evaluation	Patient Care Srvcs	Case Management	Monthly
UR Plan	Administrative Policy Manual		Annual
FISCAL/ACCOUNTING:			

DOCUMENT	RESPONSIBLE PARTY	FILE LOCATION	SCHED. REVIEW
Operating Budget/Capital Budget	Hospital Admin	HCA Accounting	Annual
Schedule of Rates & Charges	Hosp Admin/ HCA Bus. Off.	HCA Business Office	Semi-Annual
Financial Reports	HCA Accounting	HCA Accounting	Monthly
Financial Audit Reports	Auditor-Controller	Auditor-Controller	Annual
Fiscal Intermediary Cost Reports	HCA Accounting	HCA Accounting	Annual
Human Resources:			
Employee Records	HCA Human Resources	HCA Human Resources	Annual
Competency Files	Department Management	VCMC/SPH	Annual
Human Resources Policies	HCA Human Resources	HCA Human Resources	Annual
MOU	HCA Human Resources	Hospital Admin	Biennial
Job & Salary Ordinance	County Human Resources	HCA Human Resources	Annual
Employee Health Program	Occupational Health	Employee Health Services	Annual
Job Description	County Human Resources	HCA Human Resources	Annual
SAFETY/DISASTER:			
Safety Plan	Safety Officer	Hosp. Admin.	Annual
Fire Plan	Fire Safety Chairman	Hosp. Admin.	Annual
Emergency Mangement Plan	Emergency Mgmt Chairman	Hosp. Admin.	Annual
Fire Drills	Fire Safety Committee	EOC Minutes	Quarterly
Disaster Drills	Emergency Mgmt Committee	EOC Minutes	Semi-Annual
Security Management Plan	Security Committee	Security Office	Annual
AUXILIARY:			
Bylaws	Auxiliary	Auxiliary	Annual
Member & Organization	Auxiliary	Auxiliary	Annual
Services	Auxiliary	Auxiliary	Annual
INSURANCE PROGRAM:			

DOCUMENT	RESPONSIBLE PARTY	FILE LOCATION	SCHED. REVIEW
Type Coverage, Exp. Date, Insurer, Policy Co.	County Risk Management	Hosp Admin/ County Risk Mgmt.	Annual
Premium, Payments	County Risk Management	Hosp Admin/HCA Accounting	Annual
DISCHARGE PLANNING/SOCIAL SERVICES:			
Transfer Agreements	Discharge Planning	Hospital Admin	Annual
Home Health Agreements	Case Management	Hospital Admin	Annual
Patients Rights' Policy	Hospital Admin	Admin Manual	Annual
COMMUNITY RELATIONS:			
Media & Press Relations	Hospital Admin	Hospital Admin	Annual
Community Service Programs	Hospital Admin	Hospital Admin	Annual
CONTRACTS:			
Physicians	Hospital Admin	Hospital Admin	Annual
Health Professionals	Hospital Admin	Hospital Admin	Annual
Vendors	County Purchasing	County Purchasing	Annual
Service Contracts	HCA Support Services	Support Services	Annual
Educational Training	Hospital Admin	Hospital Admin	Annual
Third Party Payors	Hospital Admin/HCA Admin	HCA Admin	Annual

All Revision Dates

2/14/2024, 11/16/2021, 9/1/2016, 10/1/2011, 5/1/2006, 12/1/2004, 10/1/1998, 8/1/1992, 8/1/1991, 12/1/1989, 10/1/1986

Attachments

Attachment A: VCMC/SPH Organizational Chart

Approval Signatures

Step Description	Approver	Date

Hospital Administration	John Fankhauser, MD: Chief Executive Officer, VCMC & SPH	2/14/2024
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH	4/24/2023
Finance	Jill Ward: Chief Financial Officer, VCMC & SPH	4/14/2023
Policy Owner	Jill Ward: Chief Financial Officer, VCMC & SPH	4/14/2023

Status **Active** PolicyStat ID **12274057**

Origination	3/1/1985	Owner	Michael Taylor: Chief Financial Officer, Health Care Agency
Last Approved	2/15/2024		
Effective	2/15/2024	Policy Area	Administrative - Operating Policies
Last Revised	2/15/2024		
Next Review	2/14/2027		

107.034 Additions to the Charge Master

POLICY:

As new medical technology is implemented, it is important to establish appropriate patient charges. Patient charges are listed in the Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) Charge Master which is maintained by the VCMC Business Office.

PROCEDURE:

In order to add a charge to the VCMC Charge Master, the approval of the following are required:

1. Hospital Chief Financial Officer (CFO) for Hospital charges OR Ambulatory Care CFO for Ambulatory Care charges
2. Health Care Agency Director (HCA) OR HCA CFO

A memorandum seeking such approval should be addressed to the above individuals allowing sufficient lead time, prior to introduction of the new service.

Information Needed to Add a Charge to the VCMC Charge Master:

1. Proposed date for initiation of charge;
2. Short descriptive (unique) name of charge;
3. Department(s) in which charge will be generated;
4. Expected annual volume;
5. Current Procedural Terminology code, RVS code, unit values (if known);
6. Proposed price;

7. Narrative justification.

While all VCMC rates are ultimately under the purview of the Board of Supervisors (BOS) and subject to public hearing, the power of approval to change, add, or delete charge master items has been delegated to the HCA Director. However, the complete set of charge master items and rates for any new fiscal year budget is to be included in the BOS budget packet and requires the BOS approval. BOS has delegated such approval power to change, add or delete charge master items throughout the year, to the HCA Director.

All Revision Dates

2/15/2024, 11/1/2019, 7/1/2016, 5/1/2006, 11/1/1998, 8/1/1992, 12/1/1989

Approval Signatures

Step Description	Approver	Date
Finance	Jill Ward: Chief Financial Officer, VCMC & SPH	2/15/2024
Finance	Ursula Sutherland: Assistant CFO	11/28/2022
Finance	Michael Taylor: Chief Financial Officer, Health Care Agency	11/8/2022
Policy Owner	Michael Taylor: Chief Financial Officer, Health Care Agency	11/8/2022

Status **Active** PolicyStat ID **15338929**

Origination	1/26/2023
Last Approved	3/4/2024
Effective	3/4/2024
Last Revised	3/4/2024
Next Review	3/4/2027
Owner	Matt McGill: Director, Imaging Services
Policy Area	Imaging Services

IS.01 Radiation Safety & Protection Program

POLICY:

In California, all radiation sources, either radiation (X-ray) machines or radioactive material, are subject to State laws and regulations. The statutes are found in the Health and Safety Code, Division 104-Environmental Health. The regulations are found in the California Code of Regulations (CCR), Title 17, Div. 1, Chapter 5, Subchapters 4, 4.5, and 4.7. Title 17 CCR 30253 incorporates by reference the federal regulations specified in Title 10, Code of Federal Regulations (CFR), Part 20. Requirements in 10 CFR 20 apply to all registrants.

This medical imaging facility is required to develop, document, and implement a radiation protection program commensurate with the scope and extent of use of X-ray machines and sufficient to ensure compliance with the above regulations. Additionally, the medical imaging facility shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are **a**s **l**ow **a**s **r**easonably **a**chievable (ALARA). The Radiation Safety Officer will audit the radiation protection program on an annual basis to ensure it remains within the scope and extent of activities required to ensure compliance with the said regulations.

All components of the Radiation Safety and Protection Program do not have to be contained in one consolidated document. However, all components do have to be documented and identified as being part of the Radiation Protection Program and will be duly listed and described. Records of the Radiation Safety and Protection Program content, implementation and audits must be maintained for inspection by the Department.

The regulatory agency for radiation safety is the Radiologic Health Branch of the Department of Public Health and can be contacted at the following addresses and phone number:

Department of Public Health

Radiologic Health Branch
P.O. Box 997414, MS-7610
Sacramento, CA 95899-7414
Email: RHBInfo@cdph.ca.gov
(916) 327-5106
www.cdph.ca.gov

Access to Title 17 is available for all staff through PolicyStat and can be found within the Imaging Services policy section or directly as policy *IS.17 Title 17 California Code of Regulations*.

PROCEDURE:

Organization and Administration

The delegation and responsibility for each aspect of the radiation program and provisions for ensuring enforcement of radiation safety policies and procedures are as follows:

A. **Facility Radiation Safety Officer, qualifications and responsibilities.**

1. VCMC/SPH's designated Radiation Safety Officer is Miguel Jimenez in partnership with our medical physicist, Therapy Physics Inc.
2. The primary responsibility of the Radiation Safety Officer's (RSO) is implementing the Radiation Safety Program. The RSO shall ensure that radiation safety activities are performed with approved procedures, meeting all regulatory requirements in the daily operation of the licensee's radioactive materials program.
3. The Radiation Safety Officer shall promptly investigate and implement corrective actions as necessary regarding:
    a. Overexposures
    b. Use of ionizing radiation as defined by State and Federal guidelines
    c. Accidents
    d. Spills
    e. Losses
    f. Thefts
    g. Unauthorized receipts, uses, transfers, and disposals; and
    h. Other deviations from approved radiation safety practice. A written report of these investigations and the corrective actions taken shall be given to management.
4. The Radiation Safety Officer shall implement written policies and procedures to:
    a. Authorize the purchase of radioactive material
    b. Use of ionizing radiation as defined by State and Federal guidelines
    c. Receive and open packages of radioactive material
    d. Store radioactive material

e. Keep an inventory record of radioactive material
f. Use radioactive material safely
g. Take emergency action if control of radioactive material is lost
h. Perform periodic radiation surveys
i. Perform checks of survey instruments and other safety equipment
j. Dispose of radioactive material
k. Train personnel who work in or frequent areas where radioactive material is used or stored; and
l. Keep a copy of all records and reports required by department regulations, a copy of these regulations, a copy of each licensing request and license including amendments, and the written policies and procedures required by the regulations.

5. The Radiation Safety Officer shall:
    a. Approve radiation safety program changes for medical use not at a medical institution with the consent of management prior to sending to the department for licensing action. assist the radiation safety committee for medical use at a medical institution.
    b. review, sign and date, at least every 3 months the occupational radiation exposure records of all personnel working with radioactive material.

ALARA Program

VCMC/SPH uses, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA) and documents procedures addressing this requirement. Staff resources and educational materials are available within PolicyStat and through annual education.

Dosimetry Program

All registrants are responsible for the protection of individuals that enter the registrants' controlled areas. The registrant is also responsible for ensuring that the public is protected and that the public dose does not exceed the limits found in 10 CFR 20.

A. Each facility must evaluate whether or not personnel monitoring for occupational exposures is required. If a facility chooses to or is required to monitor, then those who are occupationally exposed to radiation should be instructed in the following:
    1. Types of individual monitoring devices used and exchange frequency.
        - Landauer Film badges (and TLD finger rings for Nuclear Medicine): Monthly
    2. Use of control badges.
        - The use of the control badge is used to maintain a base reading of non-occupational exposure. Control badges are kept in the respective

departments until ready to be sent back with appropriate dosimetry badges for reading.

3. Instructions to employees on proper use of individual monitoring devices, including consequences of deceptive exposure of the device.
    - See Radiation Safety Policy "IS.19 Staff Radiation Safety and Dosimetry Monitoring"

4. Procedures for ensuring that the combined occupational total effective dose equivalent (TEDE) to any employees receiving occupational exposure at this facility and at other facilities does not exceed 5 rem per year.
    - Employee dosimetry reports are monitored at specified intervals (see #1 above) to ensure their combined occupational total effective dose equivalent does not exceed 5 rem per year. An employee's exposure is investigated further if his/her monthly deep dose equivalent is greater than 125 mrem (ALARA Level 1) or quarterly deep dose equivalent is greater than 375 mrem (ALARA Level 2) in a quarter.

5. Procedures for obtaining and maintaining employees' concurrent occupational doses during that year.

    Employees are required to self-disclose any and all concurrent occupational doses received during the previous year in January of the subsequent year or upon being employed. Their doses will be sent to Landauer for inclusion in their dose record. The RSO and designate will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigation Level II and, if warranted, will take action. A notice of exposure and a questionnaire will be sent to the affected staff to determine the source of exposure. An acknowledgement letter will be obtained from the affected staff. A report of the investigation and actions taken will be presented to the Radiation Safety Committee at the first Radiation Safety Committee meeting following completion of the investigation. The details of these reports will be recorded in the Radiation Safety Committee minutes.

6. Procedures for ensuring that if minors are employed, their occupational TEDE does not exceed 500 millirem per year
    - N/A. We don't employ nor have any intentions of employing minors.

7. Procedures for addressing a declaration of pregnancy.
    - See policy *IS.56 Radiation Protection*. Declaration by employees and withdrawal is a voluntary process.

8. Procedures for maintaining documentation of dose to the embryo/fetus and associated documentation for the declared pregnant worker.
    - If an employee declares a pregnancy, she will be required to wear a fetal badge at the waist level and her dosimetry badge at the collar level. The fetal badge will be submitted and processed once a month to ensure fetal readings do not exceed the set dose limits. The employee's occupational dosimetry badges will be submitted monthly or quarterly based on the

department (see item #1). All dosimetry reports are evaluated by the RSO and/or designate to ensure compliance with state/federal regulations concerning dose limits.

Area Monitoring and Control

A. **Radiation Area Monitoring**

The need for area monitoring shall be evaluated and documented.

- Any area regulated through protective measures and safety provisions is considered a "Controlled Area". Access is restricted to controlled areas with warning signs specified in 17 CCR and incorporated sections of 10 CFR 20.
- Any area accessible to personnel in which there exists radiation at such levels that a major portion of the body (whole body, head and trunk, active blood-forming organs, gonads, or lenses of the eye) could receive in any one hour a dose equivalent in excess of 5 mrem or in 5 consecutive days a dose equivalent in excess of 100 mrem is considered a "Radiation Area"

B. **Instrument Calibration and Maintenance**

Instruments used to verify compliance with regulatory requirements must be appropriate for use and calibrated at required frequencies.

Maintenance of the machine should be addressed. This may be addressed in part by the operator's manual from the manufacturer.

All maintenance and calibration is completed by:

- G.E. Healthcare
- Phillips Healthcare
- Konica
- Siemens Medical
- Hologic
- Varian
- In-house Biomedical Engineering: Contracted to the above vendors for all radiation producing and radiation detection instrumentation on campus. All non-PM based services are coordinated with above vendors and completed by qualified field service engineers to meet current regulatory and manufacturer recommendations.

Radiological Controls

A. **Entry and Exit Controls**

Entry and exit from controlled areas must be adequate to ensure radiation safety. Design of emergency escape routes shall comply with applicable building codes. Document procedures

addressing this requirement.

- All applicable building codes were followed in the design of emergency escape routes of our facility.

B. **Posting**

1. Areas that are required to be posted should be identified in the Radiation Protection Program, in addition to procedures for ensuring that such areas are properly posted. Also, include procedures for ensuring that areas or rooms containing as the only source of radiation are posted with a sign or signs that read "CAUTION X-RAY". Identify who is responsible for maintaining those signs and/or labels. In addition, certain documents must be posted. This requirement is found in 17 CCR 30255(b).
    a. Entrances to X-ray suites are posted with signs that read "CAUTION X-RAY".

2. Conspicuously post:
    a. A current copy of the 17 CCR, incorporated sections of 10 CFR 20, and a copy of operating and emergency procedures applicable to work with sources of radiation (If posting of documents specified above is not practicable, the registrant may post a notice which describes the document and states where it may be examined.)
        - A current copy of 17 CCR and incorporated sections of 10 CFR 20 can be found on PolicyStat within policy "IS.17 Title 17 California Code of Regulations"

    b. A current copy of Department Form RH-2364 (Notice to Employees) in a sufficient number of places to permit individuals working in or frequenting any portion of a restricted area to observe a copy on the way to or from such area.
        - A current copy of RH-2364 (Notice to Employees) is posted in each department where ionizing radiation is utilized.

    c. Any notice of violation involving radiological working conditions, or any order issued pursuant to the Radiation Control Law and any required response from the registrant.
        - Notice of violation and any response will be posted in the cited department.

C. **Disposal of Equipment**

Registrants shall report in writing to the Department the sale, transfer, or discontinuance of use of any reportable source of radiation. See the Guidance for Disposal of X-ray Machines available http://www.cdph.ca.gov/programs/Pages/RadiologicHealthBranch.aspx.

D. **Other Controls**

The registrant should evaluate the need for other controls in addition to those mentioned above.

1. The following items should be considered :
    a. Types of controls used to reduce or control exposure to radiation, such as positioning aids, gonadal shielding, protective aprons, protective gloves, mobile shields, etc.
        - Refer to the "Apron Inventory" listing all of the above in each department utilizing radiation or radiation-producing devices.
    b. Procedures for routine inspection/maintenance of such controls.
        - Refer to the policy "IS.24 Lead Apron and Glove Survey" on PolicyStat

Emergency Exposure Situations and Radiation Accident Dosimetry

Identify any possible emergency exposure situations or radiation accidents and document procedures to address such, to include dose assessment.

- An established process to address and manage high radiation dose fluoroscopically guided procedures to ensure proper patient follow-up and follow-ups on suspicious readings has been developed and is followed.
- All exposure situations or radiation accidents that have occurred are reported immediately to the RSO and reviewed quarterly by the Radiation Safety Committee for trends and performance improvement.

Record Keeping and Reporting

All record keeping and reporting requirements are specified in regulations. Document the applicable requirements and commitments to compliance. The facility must also maintain all records of the Radiation Protection Program, including annual program audits and program content review. The following items should also be identified:

The person responsible for maintaining all required records.

- The RSO and/or delegate are responsible for maintaining all required records.

Where the records will be maintained.

- For the most part, all records will be located in Radiology or online.

The format for maintenance of records and documentation.

- Documentation of policies and procedures are online, with a hard copy for specific departments. Film Badge reports are located in their respective departments, and online with Landauer.

Procedures for record keeping regarding additional authorized sites (mobile providers).

- N/A

Reports to Individuals

The Registrant shall provide reports of individual exposure when requested in accordance with 17 CCR 30255. Document procedures addressing this requirement.

- Employees are provided, free of charge, dosimetry badges throughout the duration of their employment. Dosimetry badges must be submitted on a department specific basis. Monthly badges are available on the first of each month, quarterly badges are due on the 15th of each quarter. The dosimetry pick-up/drop-off container is located in each department utilizing badges. The most current dosimetry report is available through the "myLDR.com" web portal.
- User: VCMCDOSEREPORTS
- Pass: Radiation1
- The RSO or delegate reports Level 1 or higher exposure levels to the Radiation Safety Committee. A termination radiation dosimetry summary report is available to each employee once their employment has ended. Annual summary reports are kept indefinitely, available on-line from Landauer Inc.

Radiation Safety Training

A. **Operating and Safety Procedures**

1. All registrants are required to have a written operating and safety procedure manual. This may be the operating manual that comes with a radiation unit which may include safety procedures. However, if safety procedures are not included in the manual they must be developed. These safety procedures must be posted on the machine or where the operator can observe them while using the machine.
2. Document all training your employees, both occupationally exposed and non-occupationally exposed workers, are required to have before using radiation machines including continuing education. Also, document other training you provide to your employees or visitors such as radiation safety and protection program review, safety meetings, formal classroom training, etc.
3. Some of these requirements are found in the 17 CCR 30255(b) (1). Specifically, each registrant shall:
    a. Inform all individuals working in or frequenting any portion of a controlled area of the use of radiation in such portions of the controlled area.
    b. All new employees are required to attend a departmental orientation where he/she is orientated to the various components (policies & procedures) of our radiation protection plan.
    c. Instruct such individuals in the health protection problems associated with exposure to radiation, in precautions or procedures to minimize exposure, instruct such individuals in, and instruct them to observe, to the extent within their control, the applicable provisions of Department regulations for the protection of personnel from exposures to radiation occurring in such areas.

i. This facility has adopted the Radiation Right policies as a guide to effective Radiation Safety.

ii. Annual Radiation Safety review is mandated for all staff dealing with radiation and/or radiation producing devices.

iii. Staff meetings are held routinely, and Radiation Safety incidents are reviewed for best practice.

d. Instruct such individuals of their responsibility to report promptly to the registrant any condition which may lead to or cause a violation of department regulations or unnecessary exposure to radiation, and of the inspection provisions of 17 CCR 30254.

i. Staff are encouraged to report any causes for concern promptly as it relates to department regulation violations or unnecessary radiation exposure. Excessive Fluoroscopy is reported and documented per policy and procedures.

4. Instruct such individuals in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and advise such individuals as to the radiation exposure reports which they may request pursuant to 17 CCR 30255.

5. Any unusual occurrence or malfunction involving exposure to radiation will be promptly reported to the Equipment Service Coordinator who notifies the vendor and administration. Excessive radiation exposure reports will be documented and presented to the Radiation Safety Committee.

Quality Assurance Programs

Quality assurance program testing and frequency will conform with CCR Title 17 and accreditation requirements. Examples include but are not limited to:

Radiographic QC Tests

Factor	Monitoring Frequency	Responsible Party	Limits	Test Tool
AEC	**Annual**		**None**	**Exposure meter**
Collimation	**Annual**		**<2% SID**	**IR + metal markers**
Exposure Linearity	**Annual**		**Greater or less than 10%**	**Exposure meter or ion chamber**
Exposure Reproducibility	**Annual**		**Greater or less than 5%**	**Exposure meter or ion chamber**
Exposure time	**Annual**		**<10 ms, greater or less than 20%**	**Exposure meter**
			>10 ms, greater or less than 5%	
Filtration	**Annual**		**>2.5 mm Al**	**Aluminum sheets**

Focal Spot Size or Spatial Resolution	**Annual**		**± 50% stated FSS - <0.8 mm 40% larger – 0.8 mm – 1.5 mm 30% larger – >1.5mm**	**Slit/pinhole camera or star pattern phantom**
kVp	**Annual**		**Greater or less than 10%kVp**	**kVp meter**

Fluoroscopic QC Tests

Factor	Monitoring Frequency	Responsible Party	Limits	Test Tool
ABC	**Annual**		**None**	**Exposure meter**
Exposure rate	**Annual**		**<10 rad/min**	**Exposure meter**
Protective apparel	**Annual**		**No cracks or gaps**	**Fluoroscope, IR**
Resolution	**Annual**		**None**	**Resolution phantom**

CT Scanner QC Tests

Factor	Monitoring Frequency	Responsible Party	Limits
Contrast resolution	**Semiannual**		**Resolve 5mm objects at 0.5% contrast**
Linearity	**Annually**		**coefficient correlation between the densities & HU should equal or exceed 0.96%**
CT number Accuracy, Noise	**Daily**	**CT Technologist**	**0 +/- 5HU for CT number of water, Noise is dependent on scan parameter (mAs)**
Slice thickness <5mm	**Semiannual**		**0.5 mm**
Slice thickness >5mm	**Semiannual**		**±1.0 mm**
Spatial resolution	**Annual**		**greater or less than 20%**
Table increment accuracy	**Annually**	**Field Service Engineer (PM)**	**Expected table movement should be within ±2 mm**
Uniformity	**Daily**	**CT Technologist**	**<±10 HU across the image**

Regulations

Maintenance of all applicable regulations is required.

Acceptance testing performed on all newly acquired equipment prior to usage. Acceptance testing performed by qualified medical physicist. All acceptance testing procedures are to meet ACR, TJC, IAC, CDPH and Federal Requirements (i.e. MQSA).

Internal Audit Procedures

The Registrant must audit the Radiation Protection Program on an annual basis. Documentation of the annual audits may be requested during inspection. The following items should be addressed depending on the scope of the radiologic health protection problems:

A. Identification of inspection types and program audits conducted, to include radiation machines, personnel and procedures.
    1. Each piece of radiation producing and or radiation detecting device shall be inspected by a qualified medical physicist on an annual basis. All annual testing shall be performed within the confines of current state regulations.
    2. Notification of failure to pass performance-based testing shall be documented and remedied within the allowable time period as dictated by current state regulations.
    3. In certain circumstances equipment must be retested by a qualified medical physicist. Vendor qualified field service engineers shall remedy all deficiencies noted in testing results, and their remedies shall be communicated to the qualified medical physicist.

B. Identification of the individual(s) who are responsible for performing inspections and/or audits.
    1. Only qualified medical physicists shall perform inspections/audits. These individuals must meet requirements as outline by the accreditation body (The Joint Commission diagnostic imaging requirements) and be authorized by the State of CA to provide mammography services.
    2. As a Technologist:
        a. If the test indicates that the x-ray equipment is not functioning within specified standards, I will contact the department Director, equipment vendor, or in-house biomedical engineering to ensure that the equipment is repaired as soon as possible.
        b. If other image quality is not satisfactory, I will contact Therapy Physics, Inc (the medical physicist) to evaluate the system and correct the problem as soon as possible.
        c. All corrective actions will be carried out as soon as possible (within regulatory limits).

C. Identification of where and at what intervals the inspections and/or audits are conducted.
    1. The program is to be valid for VCMC/SPH
    2. Intervals of testing are to be annual. Testing in between annual periods will be dictated by equipment purchases, major component changes in particular systems or the movement of fixed equipment into areas that they do not normally occupy.

Acceptance testing will be conducted at purchase and prior to clinical use for newly acquired equipment. All acceptance testing is designed to satisfy current CDPH, Federal, TJC, ACR, IAC standards.

D. Procedures for conducting the inspections and/or audits.
    1. We are contracted with qualified field service engineers as well as qualified medical physicists. Their contractual obligations are such that they are to make certain that all equipment is compliant with current state and OEM standards and specifications.
    2. The compliance is dictated by the frequency of visits and the legal mandate for frequency of testing. Deficiencies or fail items resulting from testing are remedied within the time confines of current state regulations.

E. Instructions on identification of proper use of instrumentation if staff performs machine maintenance or fluoroscopic monitoring.
    1. The quality control (QC) technologist is responsible for all quality assurance duties not assigned to the lead interpreting physician or the medical physicist. Normally, he or she is expected to perform these duties, but may also assign other qualified personnel or may train and qualify others to do some or all of the tests. When these duties are assigned to others, the QC technologist retains the responsibility to ensure they are performed in accordance with the regulations.
    2. "Other personnel qualified" means persons with technical training appropriate for the task(s) assigned to them. Examples include a radiological technologist qualified under state regulations with appropriate training, a technologist who is trained to do the QC test(s) by the QC Technologist, or other persons appropriately trained to do the task(s) and supervised by the QC technologist. A receptionist or a secretary whose sole qualification is to copy documents, type, or answer the phone is not included under "other" qualified personnel.

All Revision Dates

3/4/2024, 1/23/2024, 5/12/2023, 1/26/2023

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	3/4/2024
Imaging Services	Matt McGill: Director, Imaging Services	3/4/2024

Imaging Services	Michael Hepfer: Medical Director, Imaging Services	2/29/2024

Status **Active** PolicyStat ID **14255759**

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Last Approved	2/6/2024
Effective	2/6/2024
Last Revised	2/6/2024
Next Review	2/5/2027
Owner	Matt McGill: Director, Imaging Services
Policy Area	Imaging Services

IS.47 MRI Magnet Quench

POLICY:

It is the policy of the Imaging Services Department that the MRI magnet will only be quenched in response to a serious safety event impacting a patient, staff, or first responders.

PROCEDURE:

Quenching the magnet is deactivating the magnetic field of the unit.

A magnet quench shall only be initiated if there is a serious safety event which is directly threatening the condition of a patient, staff member, or first responder and there is no other option available due to the impact of the magnetic field on a ferromagnetic object within the scan environment.

The emergency magnet quench button is located in the MRI computer control room. There is a plastic cover over the quench button to prevent accidental activation of the quench.

If you have to quench the magnet due to a serious safety event, lift the plastic cover and push down on the red button. This will initiate the magnet quench.

Remove any patients from the MRI room immediately.

Evacuate any personnel or patients from the MRI area and do not allow anyone to enter the MRI magnet room.

Contact service engineers immediately.

All Revision Dates

2/6/2024, 10/26/2020, 11/17/2017, 4/1/2015

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	2/6/2024
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	2/5/2024
Imaging Services	Matt McGill: Director, Imaging Services	1/23/2024

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VENTURA COUNTY HEALTH CARE AGENCY

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Owner	Kristina Swaim: Clinical Nurse Manager, OB
Policy Area	OB Nursing

OB.42 OB Urinalysis Dipstick Quality Control

POLICY:

To ensure Quality Control (QC) and accuracy of the urinalysis dipstick procedure in the OB Department.

PROCEDURE:

A. QC is performed daily on the day shift using the urinalysis dipstick control kit called "The Dipper," which includes the urine dipstick control vials for high and low QC. This kit is obtained from Central Supply and is kept refrigerated in the dirty utility rooms in the OB Department at Ventura County Medical Center/Santa Paula Hospital.

B. QC results are recorded on the daily log and must fall within the acceptable high and low ranges.

C. For remedial actions, please refer to the "Remedial Actions" section below.

EQUIPMENT NEEDED:

A. Timing device that measures seconds, i.e. clock, watch, timer.

B. QC testing kit.

C. Gloves.

D. Bayer MULTISTIX 10 SG Reagent Strips for urinalysis.

E. QC log.

QUALITY CONTROL:

A. QC testing kit:

1. "The Dipper" urine dipstick control vials are stored in the specimen refrigerator in OB

at 35.6 - 46°F (2 - 8°C) when not in use. Do not freeze.

2. Must be brought to room temperature for testing QC. 68 - 77°F (20 - 25°C) for at least fifteen (15) minutes.

B. Procedure for QC:
NOTE: Each vial of the **Low Level 1** Control is to be used as a **normal** control for dipsticks. Each vial of the **High Level 2** Control is to be used as an **abnormal** control for dipsticks.

1. Remove the control vials from the refrigerator and allow them to come to room temperature.
2. Immerse the dipstick in the control vial as if it were a patient specimen.
3. Read the dipsticks, visually in accordance with manufacturer's instructions.
4. Record the dipsticks results in the Log, low and high levels.
5. Immediately recap the control vials and return them to 35.6 - 46°F (2 - 8°C) when not in use.
6. QC log documents lot #'s and expiration dates of reagent strips and control vial solutions.

POTENTIAL BIOHAZARDOUS MATERIAL:

1. The QC vial solutions contain human urine. Utilize universal precautions.
2. Dispose of QC vials in the Biohazardous Material Container. The chemical in the solution may form metal azides in plumbing and pose a threat of explosion.

STORAGE AND STABILITY OF CONTROL VIALS:

1. Discard the control if turbid or any evidence of microbial contamination is present.
2. When stored at 35.6 - 46°F (2 - 8°C), the controls are stable until the expiration date stated on the label.
3. After initial use, each vial of control is stable for twenty (20) dipstick immersions or three (3) months, whichever occurs first.

REMEDIAL ACTIONS:

1. If results are not within the acceptable range, then the test should be repeated. Document remedial action on the daily log sheet.
2. If results are still not within the acceptable range after being repeated, then repeat the test using a new bottle of strips and a new vial of controls. The bottle of strips and the control vial not within acceptable range should be discarded.
3. If results are still outside the limits, then notify your supervisor and DO NOT REPORT ANY PATIENT RESULTS UNTIL THE PROBLEM IS RESOLVED.

DOCUMENTATION:

QC Log.

REFERENCES:

Bayer Multistix 10 SG. Product Package. Elkhart, Indiana.

All Revision Dates

2/4/2024, 1/1/2016, 9/1/2006, 2/1/2005

Approval Signatures

Step Description	Approver	Date
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	2/4/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	2/4/2024
Laboratory Services	Erlinda Roxas: Director, Laboratory Services	2/4/2024
Laboratory Services	Brad Adler, MD: Medical Director, Laboratory Services	12/2/2022
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	11/2/2022

Status **Active** PolicyStat ID **15262096**

Origination	9/2/2020	Owner	Sul Jung: Associate Director of Pharmacy Services
Last Approved	2/20/2024		
Effective	2/20/2024	Policy Area	Pharmacy Services
Last Revised	2/20/2024		
Next Review	2/19/2027		

PH.100 Kit Check 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 Kit Check 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 Kit Check.
    2. Training consists of the following:
        a. On line training and competency assessment provided by Kit Check.
        b. Live training of Kit Check with a Kit Check certified trainer/super user.

C. Responsibility
    1. Pharmacy technician

a. Affix the RFID labels to the medications and maintain adequate inventory levels.

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.
    d. Assign the location of the boxes, kits, and trays when it leaves the pharmacy.

D. Kit Check medication storage
    1. Medications with the RFID labels attached are kept separately in a designated area to be used exclusively with Kit Check technology.

E. List of Kit Check boxes, kits and trays
    1. Adults crash cart tray
    2. Anaphylaxis kit
    3. Anesthesia emergency kit
    4. Anesthesia Pyxis tray
    5. Anesthesiologist medication box (VCMC only)
    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
    12. OB Epidural kit (SPH only)

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 100.113 Crash Cart Checks and Restocking Process.

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. Kit Check 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 Kit Check and will be routinely checked at least once monthly.
2. Kit Check support shall be called when Kit Check technology complications/ problems cannot be resolved by staff or Kit Check superuser.
    a. Website: http://app.kitcheck.com
    b. Email: help@kitcheck.com
    c. Phone number: 786-548-2432 ext 2

All Revision Dates

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

Attachments

Attachment A: Kit Check Procedure Manual

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	2/20/2024

Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	2/16/2024

Status **Active** PolicyStat ID **14894638**

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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), *(See Reference I)*, 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 "340B Program Compliance, Monitoring and Reporting")*

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. Child Site: 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. Covered Entity: 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. Covered Outpatient Drug: 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. Disproportionate Share Hospital (DSH): 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. Duplicate Discount: 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. Eligible Patient Definition: 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. Parent Site: The main facility of the Covered Entity that becomes eligible to use 340B drugs by virtue of the entity's enrollment in the 340B Program. 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. Mixed-use setting: 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
l. 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 Reference V*)

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")*
6. 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*.
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**

1. 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 340b.recertification@hrsa.gov.

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: http://www.hrsa.gov/opa/eligibilityandregistration/hospitals/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**
    1. 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:
    a. 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**

1. 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*".)
2. 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**

1. 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

   a. 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 *PH.16 Pharmaceutical Borrowing and Loaning*.

   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**

1. 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**

1. 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**

1. The CE's established threshold of what constitutes a material breach of 340B Program compliance is any error that includes 10% 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.
    a. 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) http://www.hrsa.gov/opa/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

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

Attachment A: List of Non-Covered Outpatient Drugs

Approval Signatures

Step Description	Approver	Date
Authorizing Official	John Fankhauser, MD: Chief Executive Officer, VCMC & SPH	1/30/2024
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/30/2024
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	1/29/2024
Pharmacy Services	Beatriz Cachu: 340B Program Administrator	12/15/2023

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Owner	Jessica Rodriguez: Manager, Cardiopulmonary Services
Policy Area	Respiratory Care

R.20 Blood Gas Laboratory RapidPoint 500 Analyzer Quality Control Program

POLICY:

To establish the procedures for the Blood Gas Laboratory RapidPoint 500 Analyzer Quality Control program at Ventura County Medical Center and Santa Paula Hospital.

PROCEDURE:

A. It will be the policy to run a Quality Control program for the RapidPoint 500 analyzers. Much of this program will be in fully computerized and computer managed mode.

1. The RapidPoint 500 analyzers will utilize the Siemens Diagnostics' Automatic Quality Control (AQC) system. This system consists of three (3) replaceable cartridges, one of which is the AQC. The AQC will need to be replaced every 28 days.
2. The AQC system will be set to run all three (3) levels of quality control every eight (8) hours.
3. All staff will have the ability to manually program the analyzer for the QC cycle.
4. New reagent lot/Shipment confirmation of Measurement/Automatic Quality Control Cartridge cartridges: When a new reagent lot or an existing lot from a different shipment is placed into service, that reagent must be compared to the prior lot that is being removed. The new reagent will be compared to the old reagant by using ranges provided by the manufacture. Those ranges will be listed on the report in the Quality Control Corrective Action Log book and can also be located in RapidComm. If the new reagent is within the ranges described, the machine will be ready for use.
5. The Rapidpoint 500 has a measurement cartridge which has a 28 day or set number of sample life span, whichever comes first. Once the measurement cartridge has been replaced and the internal quality control completed, 3 level external Quality

Control testing (using Siemens Rapid QC Complete level 1, 2, and 3) must be performed prior to specimen processing. All printed Quality Control results will be placed into the external Quality Control log book and reviewed and signed off by the Blood Gas Lab Director or designee. External Quality Control results will be uploaded into the RapidComm data management system. The testing material is Siemens Rapid QC Complete level 1, 2, and 3. All internal and external Quality Control test results must be within ranges. Any analyte that fails to fall within Siemens Rapid QC Complete established range is considered out of control and the instrument cannot be utilized for specimen processing. Corrective action must be initiated based upon manufacturer's guidelines found in the Rapidpoint 500 operator's manual. The above outline task for the Rapidpoint 500 measurement cartridge will apply for the Auto Quality Control cartridge as well. All test parameters of the external testing program must pass in order to process blood gas specimens. In the event of a failure immediate on site remedial action must be taken or Siemens Tech-support must be contacted (800-229-3711) to correct the deficiency. All corrective actions taken must be documented in the Quality Control Corrective Action Log book.

B. **AQC Values and Assessments:** Acceptable ranges and means for each analyte on each level will be established and statistical analysis performed, including standard deviations, etc.

1. **Establishing Initial Values:** AQC values were set during installation of the instruments. The Rapidcomm information system has its evaluation system to set "Target Value and Absolute Limits." Siemens Diagnostic has designed the system so that periodic lot changes will not occur. Therefore, the initial values should not require changes over the life of the instruments.
2. **Monitoring and Reassesment of QC Values:** Any AQC failure will be flagged on the display panel of the instrument, and will not allow reporting of results for any analyte (or calculated value based on that analyte) that has sustained AQC failure. In the event of an AQC failure, staff has the ability to manually cycle calibrations. If after repeated calibrations there are still AQC failures, staff should notify a key operator or Siemens Diagnostics technical support.
    a. **Weekly Evaluations:** Key operator staff will review QC data on a weekly basis. This should generally be done on Monday.
    b. **Overriding AQC failures:** It will not be the policy of this Laboratory to allow any AQC failure to be overridden by any operator. The ability to override is inherent in the analyzer software, but is only granted to Level One operators (top level). Level One operations will be assigned to "Key" operators, with the majority of staff assigned as Level Three operators.
3. **DOCUMENTATION**
    A. **Quality Control Logs:**
        1. **Computer records:** Shall be maintained in the Rapidcomm stand-alone computer. All individual data points will be retained by the Rapidcomm information manager.
        2. **Communication Log:** There is a daily report sheet for each shift in the department report room for staff to log procedures that are not covered by the normal Rapidcomm maintenance logs or

to communicate other issues to staff.

All Revision Dates

1/26/2024, 1/18/2024, 8/26/2016, 4/25/2016, 2/10/2016

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/26/2024
Laboratory Services	Brad Adler, MD: Medical Director, Laboratory Services	1/26/2024
Respiratory Care	Jessica Rodriguez: Manager, Cardiopulmonary Services	1/25/2024

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Owner	Jessica Rodriguez: Manager, Cardiopulmonary Services
Policy Area	Respiratory Care

R.54 Designees in the Blood Gas Laboratory

POLICY:

To establish the duties and responsibilities of the Blood Gas Laboratory designees.

PROCEDURE:

I. **DESIGNEES:**

A. **Includes:** The Department Manager and Laboratory Medical Director may assign a qualified Respiratory Therapist to act as Blood Gas Designee. (See attachment of Respiratory Care Blood Gas Designees.)

B. **Examples of Designee Responsibilities:** Designees may, at the Manager's discretion, assume any of the following duties:

1. Management and oversight of Blood Gas Laboratory operations.
2. Development of policies and procedures relevant to Laboratory operations.
3. Oversight of staff activity in the Laboratory, including safe practices.
4. Supervision of Quality Control activities, including Proficiency Studies and Calibration Verification activities.
5. Lead role in the Quality Assessment process.
6. Review of documents produced in the course of Laboratory operations, such as canceled specimen lists, proficiency and Calibration Verification Material (CVM) documents.
7. Review all Blood Gas analysis daily, weekly and monthly reports as required and take any correction actions as may be deemed necessary.
8. Conduct inservice education for staff as may be required.

9. Review maintenance/correction logs maintained for the Blood Gas Laboratory and take corrective action as needed.
10. If the Medical Director is unavailable, the designee is authorized to sign documents for the purpose of timely.

C. The Medical Director will personally document via memo his/her personal, on-site assessment of the adequacy of physical and environmental conditions as well as the adequacy of staffing for Laboratory operations, return of CAP surveys, etc.

D. The Medical Director will evaluate the performance of the technical consultants and designees on a yearly basis.

E. Please see attachment A

All Revision Dates

2/12/2024, 1/9/2024, 12/12/2023, 7/27/2022, 2/13/2019, 10/24/2013

Attachments

R.54 Org Chart 2024.xlsx

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	2/12/2024
Laboratory Services	Brad Adler, MD: Medical Director, Laboratory Services	2/9/2024
Respiratory Care	Jessica Rodriguez: Manager, Cardiopulmonary Services	2/9/2024

Status **Active** PolicyStat ID **14649253**

Origination	3/25/2007	Owner	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services
Last Approved	2/5/2024		
Effective	2/5/2024	Policy Area	Laboratory Services
Last Revised	2/5/2024		
Next Review	2/4/2026		

L.40 Notifiable Laboratory Test Results

POLICY:

The Ventura County Medical Center (VCMC) Laboratory will notify the appropriate physician and/or other authorities of infectious diseases and other reportable test results and will document the notification. The Laboratory Manager will review the state and local regulations and revisions as received.

PROCEDURE:

The State of California lists the reportable disease requirements in Title 17 California Code of Regulations Section 2505 (see attached.) The County of Ventura Public Health Department (VCPHD) has provided a list of the reportable tests and a form on which to report them (see attached). The test results are reported to the VCPHD, the attending physician and the VCMC Infection Control Officer. In most cases, the Public Health Laboratory performs HIV testing, and reports results to the attending physician. In the event that an HIV test is requested by an Emergency Department RN, a rapid assay is performed by Blood Bank personnel and the results are reported to the RN who requested it. Records are maintained in Cerner and in a notebook in the Laboratory's Serology Department.

All Revision Dates

2/5/2024, 11/1/2016

Attachments

A: Confidential Morbidity Report

Title-17-CCR-Section-2505-LabReportableDiseases-Aug-2022.pdf

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	2/5/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/4/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	12/12/2023
Laboratory Services Department	Gayle Haider: Quality Assurance Supervisor, Laboratory Services	11/2/2023

Status **Active** PolicyStat ID **15265049**

Origination	7/20/1991
Last Approved	2/27/2024
Effective	2/27/2024
Last Revised	2/27/2024
Next Review	2/26/2026
Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.01 Direct Antiglobulin Test

PRINCIPLE:

The Direct Antiglobulin Test (DAT) is used to detect "in vivo" red blood sensitization. Red blood cell (RBC) sensitization may be due to adsorbed immunoglobulins or complement. Washed red blood cells from the patient are directly tested with antiglobulin.

The Direct Antiglobulin Test (DAT) is used to:

1. Diagnose hemolytic disease of the newborn.
2. Investigate transfusion reactions.
3. Investigate red blood cell sensitization caused by drugs.
4. Diagnose autoimmune hemolytic anemia.

SPECIMEN:

No special preparation of the patient is required prior to specimen collection.,

RBCs from an EDTA-anticoagulated blood sample.

Recommended to be tested within 48 hours of collection. Sample can be stored 1º 10ºC if there is a delay in testing.

REAGENTS:

1. Normal saline.
2. 12 x 75 mm test tubes.
3. Antihuman globulin (AHG) reagents: Polyspecific antiglobulin reagent, anti-IgG, and anti-C3b,C3d.

4. Control reagent (phosphate-buffered saline)
5. Coombs Control cells.
6. Complement Coombs Control cells.

PROCEDURE:

1. Prepare a 3-5% saline cell suspension of the EDTA cells to be tested.
2. Label four (4) tubes with the first 3 letters of the patient's last name and either Poly, IgG, C3 and Ctr.
3. Place one drop of the cell suspension into each of the four-labeled tubes.
4. Wash each of the tubes four times with saline.
5. Add two drops of polyspecific AHG, anti-IgG or anti-C3b,C3d and Control (saline) to the appropriate tubes.
6. Centrifuge for the calibrated time.
7. Re-suspend the cells with gentle agitation and examine for agglutination. Verify negative tests microscopically. Record results.
8. Incubate all the tubes (Poly, IgG, C3, Control) at room temperature for 5 minutes.
9. Centrifuge for the calibrated time.
10. Re-suspend the cells with gentle agitation and examine for agglutination. Verify negative tests microscopically. Record results.
11. To all negative Poly, IgG, Control tubes, add one drop of IgG Coombs Control Cells.
12. To negative C3 tube(s), add one drop of Complement Coombs Control cells. (**NOTE**: The C3 tube must be allowed to sit for five (5) minutes after the control cells are added before it is centrifuged and read)
13. Centrifuge the Poly, IgG and control tubes and examine for agglutination. Record results.
14. At the end of the five (5) minute incubation time in step 12, centrifuge the C3 tube and examine for agglutination. Record results.

RESULTS/INTERPRETATION:

1. The first centrifugation primarily detects IgG antibodies, which may have coated the cells. The second centrifugation has been found to detect Complement and IgA sensitization. Positive reactions due to coating by IgG antibodies will usually become weaker after standing. Therefore, **do not substitute the second reading for the immediate spin reading.**

2. If the direct antiglobulin test (DAT) is negative the testing is complete.

(NOTE: a negative DAT does not necessarily mean that the red cells have no attached globulin molecules. Polyspecific and anti-IgG reagents detect 150 - 500 molecules of IgG per cell, but patients may still experience autoimmune hemolytic anemia when IgG coating is below this level),

3. <u>If the DAT is positive and the saline control is negative,</u> further testing is indicated and the steps in

the Positive DAT Investigation procedure should be followed. Refer to the section on Cord Blood Testing for the uses of the DAT in diagnosis of Hemolytic Disease of the Newborn.

4. **If the DAT and the saline control is positive,** and the presence of a strong cold agglutinin is suspected, manual washing with warm (37oC) saline should resolve reactivity due to cold agglutinin.

PROCEDURE NOTES:

Steps 1 - 14 should be performed without interruption.

Additional washes may be needed when testing cord blood samples contaminated with Wharton's Jelly.

1. Clinically Insignificant Direct Antiglobulin Test
    a. Clotted blood samples coated with anti-C3.
    b. Silicon gel vacutainer – collected red cells with anti-C3.
    c. Samples from IV lines used for infusion of dextrose-water solutions.
    d. Unwanted agglutinins in the antiglobulin reagent.
    e. Patient with pernicious or megaloblastic anemia.
2. False negative Direct Antiglobulin Test
    a. Inadequate washing of serum/plasma from the test red cells.
    b. Failure to add antiglobulin serum.
    c. Failure to do the five (5) minute room temperature incubation after the immediate spin negative DAT.
    d. RBC's coated with antibody or complement below the limit of detection in manual DAT testing (100-500 molecules per cell).

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, Current Edition.
2. Fung, Mark K MD, PhD. Technical Manual. Bethesda, MD: American Association of Blood Banks, Current Edition.
3. Current manufacturer's package inserts.

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Paper copy reviewed 12/12/2023
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All Revision Dates

2/27/2024, 9/29/2023, 6/5/2020, 10/3/2017, 3/1/2017, 12/1/2016, 12/1/2013, 10/1/1995

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	2/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	2/27/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/17/2024

Status **Active** PolicyStat ID **15265063**

Origination	12/10/1993	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	2/27/2024		
Effective	2/27/2024	Policy Area	Laboratory Services - Blood Bank
Last Revised	2/27/2024		
Next Review	2/26/2026		

L.BB.04 Blood Component Filters

PRINCIPLE:

Components must be administered through special IV tubing with a filter designed to remove blood clots and particles potentially harmful to the patient. Standard blood administration tubing has a 150- to 260-micron filter.

All blood and blood components are leukocyte-reduced during production at the blood center therefore not requiring bedside leukocyte reduction.

MATERIALS:

Blood administration sets for the administration of blood and blood components are supplied by Central Supply.

Central supply has two blood administration sets:

- Baxter 4C8723 is a gravity set with a hand pump with a 170 to 260 micro filter.
- Carefusion 72980E is for the Alaris pumps and has a 180 micron filter.

Blood bank supplies a platelet filter for the administration of platelets to pediatric and adult patients.

Platelet filters are not provided for the transfusion of platelets to the neonates. The NICU uses a small filter routinely and should use the same one for platelets.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, 2022. 33rd Edition.
2. Cohn et.al. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2023.

21st Edition.

Paper copy reviewed 12/12/2023 by Janette O'Neill, CLS

All Revision Dates

2/27/2024, 8/8/2022, 12/1/2016, 2/1/2012

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	2/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	2/27/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/18/2024

Status **Active** PolicyStat ID **15265073**

Origination	3/11/1993	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	2/27/2024	Policy Area	Laboratory Services - Blood Bank
Effective	2/27/2024		
Last Revised	2/27/2024		
Next Review	2/26/2026		

L.BB.05 Irradiation of Blood Products

PRINCIPLE:

Cellular components are required to be irradiated for certain patient populations to prevent transfusion-associated graft-vs-host disease.

The current gamma irradiation dose recommended to prevent proliferation of donor T lymphocytes in the recipient is a minimum of 25 Gy (2500 cGy/rads) to the central point of the blood container and 15 Gy (1500 cGy/rads) to any other part of the container.

The expiration date of irradiated RBCs is 28 days after irradiation or the original expiration date, whichever date is earliest.

SPECIMEN COLLECTION:

N/A

MATERIALS:

N/A

PROCEDURE:

1. All requests for irradiated blood products must be approved by the pathologist (first request only).
2. Add attribute to patient's "transfusion requirements" and document date and ordering physician in BB comment.
3. Charge "IRR" fee for each irradiated unit ordered.
4. Patients in the following categories should receive irradiated blood products:

a. Patients at risk for graft-versus-host disease (GVHD).
b. Premature neonates weighing less than 1200 g at birth.
c. Recipients of intrauterine transfusions.
d. All neonates.
e. Pediatric patients actively receiving chemotherapy
f. Any patient with:
    - Known or suspected cellular immune deficiency
    - Significant immunosuppression related to chemotherapy or radiation treatment.
g. Any patient receiving:
    - Directed donations from blood relatives
    - HLA-Matched or -crossmatched platelet components
    - Granulocyte transfusion.
h. Patients who are immunodeficient
i. Patients who have bone marrow failure or are status post bone marrow or solid organ transplant.
j. At the discretion of the Attending Physician.
k. All irradiated blood and blood components are special ordered from the blood supplier.

CALIBRATION:

N/A

CALCULATIONS:

N/A

RESULTS:

N/A

LIMITATIONS:

N/A

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, Current Edition.

2. Cohn, C., et. al. Technical, Manual. Bethesda, MD: American Association of Blood Banks, Current

Edition.

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Paper copy reviewed 12/12/2023 by Janette O'Neill, CLS
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All Revision Dates

2/27/2024, 4/24/2023, 6/5/2020, 12/1/2016, 12/1/2011

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	2/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	2/27/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/18/2024

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Origination	5/1/1996	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	2/27/2024		
Effective	2/27/2024	Policy Area	Laboratory Services - Blood Bank
Last Revised	2/27/2024		
Next Review	2/26/2026		

L.BB.32 Blood Bank Issue of Blood Products

POLICY:

Anyone who delivers blood or blood products to patient locations at Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) must be a member of VCMC/SPH nursing or Medical Staff (i.e., a physician, Nursing Assistant, Medical Office Assistant, Registered Nurse or Licensed Vocational Nurse).

PROCEDURE:

The individual who delivers blood or blood products must present the following to the Blood Bank:

- Patient Identification
- A Blood Pickup Request Form with the patient's name, medical record number, and current vitals.
- Documentation of informed consent

Note: A patient registration label can be presented to the Blood Bank if the Blood Pickup Request Form cannot be printed due to computer down procedure or during an emergency where the patient's treatment would be delayed.

SPECIMEN COLLECTION:

N/A

MATERIALS:

1. Blood Pickup Request Form.
2. Patient registration label (used during computer down time procedures and during emergency dispensing of blood products).

3. Printed Blood Component Tag.

PROCEDURE:

1. The individual (transporter), who will deliver the blood product to the patient location, must present a ***Blood Pick up Request Form*** with the intended recipient's full name and medical record number to the Blood Bank Technologist. This form should also document the current vitals and the documentation of consent forms having been signed.
    a. A patient registration label may be presented during computer down time procedures or during emergency dispensing of blood products.
2. A Blood Bank Technologist will retrieve the proper product for issue by verifying the patient identification on the unit with the identification provided by the transporter.
    a. When multiple units are available for issue, the shortest dated unit will be issued first.
    b. Only one unit of blood will be issued at a time except in an extreme emergency. When more than one unit is issued, it will be transported in a blood transport cooler to the patient's location. (See policy *Supplying Blood in Blood Transport Coolers).*
    c. A transporter can only pick up blood products for one patient recipient at a time.
3. The Blood Bank Technologist will dispense the unit in the Laboratory Information System as follows:

    Health-*e*-Connect:
    a. Open Dispense and Assign Products application.
    b. Choose a location and click <OK>.
    c. Receive the blood pickup request &/or patient registration label from the courier.
    d. Locate the patient's medical record number on the submitted identification form. Enter this medical record number into the medical record number field in the dispense application.
    e. Press the enter/return key.
    f. The patient's demographic information will load. Compare and verify the loaded information is the same as the submitted identification.
    g. Retrieve the appropriate blood product from storage.
    h. Scan the unit Donor Identification Number under product number in product list below.
    i. Press the enter/return key. The product demographics will load.
    j. Click <Save>.
    k. A dispense dialog box will pop up. Enter the following:
        - Physician
        - Patient Location

- Visual Inspection
- Reason for Transfusion
- Courier's user name
- Blood Cooler (if appropriate)
- Blood Recipient wristband number.

l. Click <OK>.

m. An output destination box will appear for printing the Dispense packing form and the Blood Component/Crossmatch/Emergency Tag. Print to default printer for both forms.

4. A visual inspection of the retrieved blood component will be performed as outlined in the policy, *Visual Inspection of Blood Components*.
5. The Blood Bank Technologist, issuing the blood product, will ask the transporter if he/she has performed the blood issue procedure. If the answer is ***no***, the Blood Bank Technologist will explain each step of the procedure and then directly observe their performance of the procedure.
6. The blood product will be handed to the transporter. The Blood Bank Technologist will retain the printed Blood Component/Cross match/Emergency Tag and the read procedure will be performed.
7. The transporter will read all of the following information from the label of the blood product and the Blood Bank staff member will verify that all information read is the same as the information on the printed Blood Component/Cross match/Emergency Tag:
    a. Patient's name and medical record number from the Laboratory label placed on the blood unit.
    b. Patient's Blood Bank wristband number located on the unit. This will be a red or white sticker located next to the Laboratory label. If many units have been dispensed, the wristband number may be written on the Laboratory label because there are no stickers available.
    c. The description of the blood or blood component.
    d. The donor's (unit) 13 digit Identification Number.
    e. The blood type of the donor unit.
    f. The expiration date of the donor unit.
8. The Blood Bank technologist will verify that the compatibility testing has been done and the unit is type specific/type compatible with the patient's blood type.
9. If all the information is correct and complete, the transporter and the Blood Bank Technologist will both sign the Blood Component/Cross match/Emergency Tag using their user name. In addition, the Blood Bank Technologist will:
    a. Document "Yes" next to IRR (Irradiated) if the unit is irradiated.
    b. Document "Neg" next to CMV if the unit is CMV negative, as indicated on the label of the blood unit.

c. Document the hematocrit value next to HCT for red blood cells aliquoted for NICU babies.

10. At the completion of the reading and verification of information, the Blood Bank Technologist will permanently attached the Blood Component/Cross match/Emergency Tag to the donor unit using a plastic "cable tie." This tag must remain attached to the unit for the duration of the transfusion.

CALIBRATION:

N/A

CALCULATIONS:

N/A

QUALITY CONTROL:

See Daily Quality Control SOP 8.1

RESULTS:

N/A

REFERENCES:

Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, Current Edition.

Cohn, Claudia S., et.al. Technical Manual. Bethesda, MD: American Association of Blood Banks, Current Edition.

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Paper copy reviewed on 12/12/2023 by Janette O'Neill.
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2/27/2024, 8/8/2022, 6/5/2020, 12/1/2016, 12/1/2013, 3/1/2012

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Step Description	Approver	Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	2/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	2/27/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/18/2024

Status **Active** PolicyStat ID **15265411**

Origination	4/1/2004	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	2/27/2024		
Effective	2/27/2024	Policy Area	Laboratory Services - Blood Bank
Last Revised	2/27/2024		
Next Review	2/26/2026		

L.BB.33 Sickle Cell Testing - Donor Units

PRINCIPLE:

SICKLEDEX is a qualitative solubility test for testing for the presence of sickling hemoglobins in human blood or sickle control material. Deoxygenated Hb-S is insoluble in the presence of a concentrated phosphate buffer solution and forms a turbid suspension that can be easily visualized. Normal Hemoglobin A and other hemoglobins remain in solution under these conditions. These different qualitative outcomes allow for the detection of sickle cell disease and its traits.

SICKLEDEX uses Saponin to lyse the red blood cells. Sodium Hydrosulfite then reduces the released hemoglobin. Reduced Hb-S is insoluble in the concentrated phosphate buffer and forms a cloudy, turbid suspension. Other sickling hemoglobin subtypes may also give a positive result.

CLINICAL SIGNIFICANCE:

Sickle-cell anemia occurs when Hemoglobin S (Hb-S) is present in the homozygous state. When sickle-cell crisis occurs, the patient suffers hemolytic anemia, which effects the spleen, kidneys, lungs, retinas, central nervous system and bones. ***It is extremely important to transfuse such patients with Sickle Cell negative units.***

REAGENTS AND MATERIALS:

STRECK SICKLEDEX KIT

- SICKLEDEX Solubility Buffer
- SICKLEDEX Solubility Reagent Powder
- Dispenser caps for Solubility Buffer
- 12 Polystyrene disposable test tubes (12x75mm)

- 12 20 µL transfer pipettes
- Paperboard test tube rack

STRECK SICKLE-CHEX CONTROL KIT

- Positive control
- Negative control

BLOOD SAMPLE COLLECTION:

1. Fresh blood samples may be collected from a finger puncture.
2. Use anticoagulated whole blood.
3. Blood stored at 2°C to 10°C for up to 45 days may be used for testing.

REAGENT PREPARATION:

The working solubility buffer must be prepared before screening can be performed.

1. Bring buffer and reagent powder to room temperature before mixing.
2. Add the contents of one vial of SICKLEDEX Reagent Powder to one bottle of SICKLEDEX Solubility Buffer.
3. Place a white dispenser cap on the bottle of working solubility buffer. Dissolve the reagent powder completely with vigorous agitation.
4. Record the reconstitution date in the black space provided on the solubility buffer bottle.
5. Store the working solubility buffer tightly capped at 2°C to 10°C when not in use.
6. ***Reconstituted buffer must be used within 45 days.***

CONTROL PREPARATION:

1. Remove the vial of the control from the refrigerator and warm to room temperature (18°-30°C) for 15 minutes before use.
2. To mix: (Do not mix mechanically)
    a. Hold vial horizontally between the palms of the hands and roll the vial back and forth for 20 to 30 seconds.
    b. Mix by rapid inversion to ensure the cells are suspended.
    c. Vials stored for an extended period may require extra mixing.
    d. Gently invert the vials 8 to 10 times immediately before sampling.
3. Refer to the reagent test kit instructions for analyzing control and patient materials.
4. Test kits that require a 20 µL sample should use 1 drop of Sickle-Chex control. Test kits that require a 60 µL sample should use 3 drops of Sickle-Chex control. For accurate delivery volume, the control vial **MUST** be inverted and held vertically directly over the test tube.
5. After sampling, return to refrigeration for maximum open-vial stability. Wipe the threads of

both vial and cap before replacing cap and returning to refrigeration.

6. Storage and Stability: ***Sickle-Chex is stable through the expiration date when stored at 2°-10°C. Open-vial stability is 100 days, based on one opening per day. After opening, Sickle-Chex is stable throughout the open-vial dating when stored at 2°C to 10°C, not to exceed the expiration date stated on the product vial.***

PROCEDURE:

1. Dispense 2.0 mL of cold working SICKLEDEX Solubility Buffer into a 12 x 75 mm disposable polystyrene tubes supplied with 12-test kit. Return working solubility buffer to 2°C to 10°C immediately after use. Allow working solution in test tubes to warm to room temperature (18°C to 30°C). The use of reagents below room temperature can give false results.
2. Add 20 µL of whole blood or 10 µL of packed red cells to the test tube. When running control samples add 20 µL of control.

   Directions for use of plastic pipettes provided with 12-Test Kit:

   Never squeeze the plastic tube while sampling. Filling is automatic.

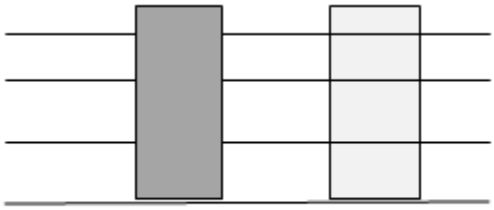
   Step 1: Hold the tube horizontally, and touch the tip of the tube to the sample. Capillary action will automatically draw the sample to the fill line and stop.

   Step 2: To expel the sample, align the tip of the tube with the sample target and squeeze the bulb. If a sample won't expel, hold the tube vertically and slide finger over the vent hole. Then squeeze bulb to deliver sample.

   If the hematocrit is ≤15%, centrifuge the sample for 5-10 minutes at 1200 rpm. Pipet 10 µL of the packed cell volume from the bottom of the tube and add it to the SICKLEDEX Solubility buffer test tube.
3. Mix the contents of the test tube thoroughly by swirling the tube several times. Place the test tube in the test tube rack.
4. Allow the sample to stand at room temperature (18°C to 30°C) for at least six (6) minutes. Observe the sample for turbidity. Results may be observed for up to sixty (60) minutes.

EXPECTED RESULTS:

1. The reaction is read macroscopically by looking through the test tubes at the black lines of the test tube rack.
2. A POSITIVE test for sickling hemoglobin is indicated by a cloudy, turbid suspension through which the black lines are NOT VISIBLE. (Place a Hb-S positive label on the unit)
3. A NEGATIVE test for sickling hemoglobin is indicated by a transparent suspension through which the black lines are CLEARLY VISIBLE.(Place a Hb-S negative label on the unit)



LIMITATIONS:

This procedure will only be used to test donor units of blood and not patient specimens.

REFERENCES:

Streck, 7002 S. 109 Street, Omaha, NE 68128 USA, Product Insert, SICKLEDEX, Current Package Insert.

Streck, 7002 S. 109 Street, Omaha, NE 68128 USA, Product Insert, Sickle-Chex, Current Package Insert.

Cohn, Claudia S., et. al. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2023. 21st Edition.

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	2/27/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	2/27/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/18/2024