



October 17, 2025

TO: Legal Counsel

News Media

Salinas Californian

El Sol

Monterey County Herald

Monterey County Weekly

KION-TV

KSBW-TV/ABC Central Coast

KSMS/Entravision-TV

The next regular meeting of the **BOARD OF DIRECTORS OF SALINAS VALLEY HEALTH¹** will be held **THURSDAY, OCTOBER 23, 2025, AT 4:00 P.M., CISLINI PLAZA BOARD ROOM, SALINAS VALLEY HEALTH MEDICAL CENTER, 450 E. ROMIE LANE, SALINAS, CALIFORNIA.**

(Visit <https://www.salinasvalleyhealth.com/about-us/healthcare-district-information-reports/board-of-directors/board-committee-meetings-virtual-link/> for Public Access Information).

A handwritten signature in black ink, appearing to read "Allen Radner", is positioned above the printed name.

Allen Radner, MD
President/Chief Executive Officer

¹Salinas Valley Memorial Healthcare System operating as Salinas Valley Health

**REGULAR MEETING OF THE BOARD OF DIRECTORS
SALINAS VALLEY HEALTH¹**

**THURSDAY, OCTOBER 23, 2025, 4:00 P.M.
CISLINI PLAZA BOARD ROOM**

**Salinas Valley Health Medical Center
450 E. Romie Lane, Salinas, California**

(Visit salinasvalleyhealth.com/virtualboardmeeting for Public Access Information)

AGENDA

Presented By

- | | |
|--|------------------------------|
| 1. CALL TO ORDER / ROLL CALL | <i>Joel Hernandez Laguna</i> |
| 2. CLOSED SESSION <i>(See Attached Closed Session Sheet Information)</i> | <i>Joel Hernandez Laguna</i> |
| 3. RECONVENE OPEN SESSION/REPORT ON CLOSED SESSION
<i>(Estimated time 4:30 pm)</i> | <i>Joel Hernandez Laguna</i> |
| 4. AWARDS & RECOGNITION | <i>Allen Radner, M.D.</i> |
| 5. PUBLIC COMMENT | <i>Joel Hernandez Laguna</i> |

This opportunity is provided for members of the public to make a brief statement, not to exceed three (3) minutes, on issues or concerns within the jurisdiction of this District Board which are not otherwise covered under an item on this agenda.

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| 6. CONSENT AGENDA - GENERAL BUSINESS <i>(Board Member may pull an item from the Consent Agenda for discussion.)</i> | <i>Joel Hernandez Laguna</i> |
| A. Minutes of Special Meeting of the Board of Directors September 24, 2025 | |
| B. Minutes of Regular Meeting of the Board of Directors September 25, 2025 | |
| C. Policies/Plans Requiring Approval | |
| 1. Adult Sepsis Management | |
| 2. Business Continuity Access (EHR Downtime) | |
| 3. Cardiac Cath Lab Emergency On-Call Procedure with Support Personnel Backup | |
| 4. Cardiac Catheterization Patient Care | |
| 5. Carotid Artery Stenting | |
| 6. Complete Decongestive Therapy for Management of Lymphedema | |
| 7. Echocardiography Lab Quality Assurance/Quality Review Process and Correlation | |
| 8. Instrument Preventative Maintenance | |
| 9. Magnesium Sulfate in the Obstetric Patient | |
| 10. Maternal and Newborn Substance Abuse Evaluation | |
| 11. Neonatal Medication Administration | |
| 12. Newborn Abandonment | |
| 13. NICU Family Centered Care/Patient Participation | |
| 14. Pharmacy – Sterile Compounding | |
| 15. Scope of Service: Clinical Research Program | |
| 16. Sedation for the Mechanically Ventilated Adult | |

¹Salinas Valley Memorial Healthcare System operating as Salinas Valley Health

- Board President Report
- Questions to Board President/Staff
- Public Comment
- Board Discussion/Deliberation
- Motion/Second
- Action by Board/Roll Call Vote

7. BOARD MEMBER COMMENTS AND REFERRALS

Joel Hernandez Laguna

8. REPORTS ON STANDING AND SPECIAL COMMITTEES

A. QUALITY AND EFFICIENT PRACTICES COMMITTEE

Catherine Carson

Minutes of the October 13, 2025 Quality and Efficient Practices Committee meeting have been provided to the Board for their review. Additional Report from Committee Chair, if any.

B. PERSONNEL, PENSION & INVESTMENT COMMITTEE

Catherine Carson

Minutes of the October 13, 2025 Personnel, Pension and Investment Committee meeting have been provided to the Board for their review. The following recommendation has been made to the Board.

1. Consider Recommendation for Board Approval of (i) Findings Supporting Recruitment of Martin Kamper, M.D., (ii) Contract Terms for Dr. Kamper' Recruitment Agreement, and (iii) Contract Terms for Dr. Kamper's Pulmonary and Critical Care Professional Services Agreement

- Questions to Committee Chair/Staff
- Motion/Second
- Public Comment
- Board Discussion/Deliberation
- Action by Board/Roll Call Vote

C. FINANCE COMMITTEE

Victor Rey, Jr.

Minutes of the October 20, 2025 Finance Committee meeting have been provided to the Board for their review. The following recommendations have been made to the Board.

1. Consider Recommendation for Board of Directors Approval to Award Construction Contract to C. Overaa & Co. for the Salinas Valley Health X-Ray Room 1 & 2 Equipment Replacement Project

- Questions to Committee Chair/Staff
- Motion/Second
- Public Comment
- Board Discussion/Deliberation
- Action by Board/Roll Call Vote

2. Consider Recommendation for Board Approval of Purchase of Seven (7) Canon Ultrasound Units and Associated Forty-Eight-Month Service Agreement for Salinas Valley Health Clinics Imaging and Salinas Valley Health Obstetrics & Gynecology

- Questions to Committee Chair/Staff
- Motion/Second
- Public Comment
- Board Discussion/Deliberation
- Action by Board/Roll Call Vote

D. TRANSFORMATION, STRATEGIC PLANNING & GOVERNANCE COMMITTEE

Victor Rey, Jr.

Minutes of the October 15, 2025 Transformation, Strategic Planning & Governance Committee meeting have been provided to the Board for their review. Additional Report from Committee Chair, if any.

9. REPORT ON BEHALF OF THE MEDICAL EXECUTIVE COMMITTEE (MEC) MEETING OF OCTOBER 9, 2025 AND RECOMMENDATIONS FOR THE FOLLOWING BOARD APPROVALS:

Vincent Defilippi, M.D.

- A. Reports
 1. Credentials Committee Report
 2. Interdisciplinary Practice Committee Report
- B. Policies/Procedures/Plans and Agreements Recommended for Approval:
 1. Aerosol Transmitted Diseases Exposure Control Plan
 2. Bioterrorism Readiness Plan
 3. Laboratory Critical Call Values
 4. Respiratory Virus (Influenza) Pandemic Plan
- C. Other Items (Informational)
 1. Medical Staff Excellence Committee (MSEC) Charter Update
 - Chief of Staff Report
 - Questions to Chief of Staff
 - Motion/Second
 - Public Comment
 - Board Discussion/Deliberation
 - Action by Board/Roll Call Vote

10. BOARD EDUCATION

Gary Ray

11. ADJOURNMENT

Joel Hernandez Laguna

The next Regular Meeting of the Board of Directors is scheduled for **Thursday, November 20, 2025, at 4:00 p.m.**

The Salinas Valley Health (SVH) Board packet is available at the Board Meeting, electronically at <https://www.salinasvalleyhealth.com/about-/healthcare-district-information-reports/board-of-directors/meeting-agendas-packets/2025/>, and in the SVH Human Resources Department located at 611 Abbott Street, Suite 201, Salinas, California, 93901. All items appearing on the agenda are subject to action by the SVH Board.

Requests for a disability related modification or accommodation, including auxiliary aids or Spanish translation services, in order to attend or participate in-person at a meeting, need to be made to the Board Clerk during regular business hours at 831-759-3050 at least forty-eight (48) hours prior to the posted time for the meeting in order to enable the District to make reasonable accommodations.

**SALINAS VALLEY HEALTH BOARD OF DIRECTORS
THURSDAY, OCTOBER 23, 2025, 4:00 P.M.**

AGENDA FOR CLOSED SESSION

Pursuant to California Government Code Section 54954.2 and 54954.5, the board agenda may describe closed session agenda items as provided below. No legislative body or elected official shall be in violation of Section 54954.2 or 54956 if the closed session items are described in substantial compliance with Section 54954.5 of the Government Code.

CLOSED SESSION AGENDA ITEMS

HEARINGS/REPORTS

(Government Code §37624.3 & Health and Safety Code §§1461, 32155)

Subject matter: (Specify whether testimony/deliberation will concern staff privileges, report of medical audit committee, or report of quality assurance committee):

1. Medical Executive Committee
 - Report of the Medical Staff Executive Committee (With Comments)
2. Medical Staff Quality and Safety Committee Consent Agenda
 - Pharmacy and Therapeutics

ADJOURN TO OPEN SESSION

CALL TO ORDER
ROLL CALL

(Chair to call the meeting to order)

CLOSED SESSION

*(Report on Items to be
Discussed in Closed Session)*

*RECONVENE OPEN SESSION/
REPORT ON CLOSED SESSION*

(Meeting Chair)

AWARDS AND RECOGNITION

(Verbal)

(DR. RADNER)

PUBLIC COMMENT



DRAFT SALINAS VALLEY HEALTH¹
SPECIAL MEETING OF THE BOARD OF DIRECTORS
MEETING MINUTES
SEPTEMBER 24, 2025

Board Members Present: President **Joel Hernandez Laguna**, appearing via teleconference pursuant to Government Code Section 54953(f)(2)(A)(i), Vice-President **Catherine Carson**, **Isaura Arreguin**, **Rolando Cabrera, M.D.**, and **Victor Rey, Jr.**;

Absent: None;

Also Present:

Allen Radner, MD, President/Chief Executive Officer

Matthew Ottone, Esq., District Legal Counsel

Kathie Haines, Executive Support

Dr. Cabrera left the meeting at 8:35a.m.

1. READING OF THE NOTICE OF SPECIAL MEETING

President Hernandez Laguna read the following: The Special meeting of the Board of Directors of Salinas Valley Health¹ will be held Wednesday, September 24, 2025, at 7:30 a.m., Downing Resource Center, Conference Rooms A, B, and C, Salinas Valley Health Medical Center, 450 E. Romie Lane, Salinas, California to discuss in Closed Session: Report Involving Trade Secret: Strategic Planning, New Programs and Services.

2. CALL TO ORDER/ROLL CALL

A quorum was present and President Hernandez Laguna called the meeting to order at 7:34 p.m. in the Downing Resource Center, Rooms A, B, and C.

3. PUBLIC COMMENT: None

4. CLOSED SESSION

President Hernandez Laguna announced the item to be discussed in Closed Session as listed on the posted Agenda is *Report Involving Trade Secret-Trade Secret, Strategic Planning, Proposed New Programs and Services*. The meeting recessed into Closed Session under the Closed Session Protocol at 7:36 a.m. The Board completed its business of the Closed Session at 8:52 p.m.

5. RECONVENE OPEN SESSION/REPORT ON CLOSED SESSION

The Board reconvened Open Session at 8:52 a.m. President Hernandez Laguna reported that in Closed Session, the Board discussed *Report Involving Trade Secret-Trade Secret, Strategic Planning, Proposed New Programs and Services*. The Board received and accepted the report listed on the Closed Session agenda. No other action was taken.

6. ADJOURNMENT

The next Regular Meeting of the Board of Directors is scheduled for **Thursday, September 25, 2025, at 4:00 p.m.** There being no further business, the meeting was adjourned at 8:53 p.m.

Rolando Cabrera, MD
Secretary, Board of Directors

¹Salinas Valley Memorial Healthcare System operating as Salinas Valley Health

DRAFT SALINAS VALLEY HEALTH¹
REGULAR MEETING OF THE BOARD OF DIRECTORS
MEETING MINUTES
SEPTEMBER 25, 2025

Board Members Present: Vice-President Catherine Carson, Isaura Arreguin, Rolando Cabrera, M.D., and Victor Rey, Jr., President Joel Hernandez Laguna, appearing via teleconference pursuant to Government Code Section 54953(f)(2)(A)(i).

Absent: None.

Also Present:

Allen Radner, M.D., President/Chief Executive Officer

Rakesh Singh, M.D., Chief of Staff

Matthew Ottone, Esq., District Legal Counsel

Hanna Hitchcock, Esq.

Kathie Haines, Executive Support.

President Joel Hernandez Laguna joined the meeting via Webex at 5:54pm.

1. CALL TO ORDER/ROLL CALL

A quorum was present and Vice President Carson called the meeting to order at 4:03 p.m. in the Downing Resource Center, Rooms A, B, and C.

2. CLOSED SESSION

Vice President Carson announced items to be discussed in Closed Session as listed on the posted and revised Agenda are *(1) Hearings and Reports and (2) Report Involving Trade Secret – Trade Secret, Strategic Planning, Proposed New Programs and Services, (3) Conference with Labor Negotiator – National Union of Healthcare Workers, and (4) Public Employee Performance Evaluation: President/CEO.*

The meeting recessed into Closed Session under the Closed Session Protocol at 4:03 p.m.

The Board completed its business of the Closed Session at 4:27 p.m.

3. RECONVENE OPEN SESSION/REPORT ON CLOSED SESSION

The Board reconvened Open Session at 4:33 p.m. Vice President Carson reported that in Closed Session, the Board discussed *(1) Hearings and Reports and (2) Conference with Labor Negotiator – National Union of Healthcare Workers.* The Board received and accepted the reports listed on the Closed Session agenda. No other action was taken.

Vice President Carson announced there is a need for an extended closed session.

4. AWARDS AND RECOGNITION

Dr. Radner announced it was his pleasure to open the Awards and Recognition portion of the Board of Directors. The following was presented:

¹Salinas Valley Memorial Healthcare System operating as Salinas Valley Health

- **Marketing Awards Recognition:** Claudia Villalobos Director of Marketing & Communications recognized the team Janet Marcroft, Creative Lead, Claudia Otero, Community Outreach Lead, and Chris Haubert, Creative Content Writer, who all contributed to SVH receiving the following awards:
 - Aster Awards: Gold Winner/Community Report, Silver Winner/Publication-Internal, Silver Winner/Newsletter-Internal, Silver Winner Magazine Publication/Coastal Grower
 - 42nd Annual Healthcare Advertising Awards: Gold/Podcast, Silver/Special Video, Silver/Community Report, Bronze/Special Video, and Merit Winner/External Publication

BOARD MEMBER DISCUSSION: Director Rey commented that he has worked with all four members of the Marketing & Communications Team and they make it a very easy and professional experience; he is not surprised they received the awards as the Marketing Department is spectacular.

- **Vaccine Campaign:** Dr. Radner reported on our new messaging campaign on “Vaccinations Save Lives.” The goal is to educate families and community on the importance of vaccinations and to reach as many people as possible. This will be a bilingual campaign in print, digital, and signage rolling out in the next few months.
- **NICU Event:** Melissa Gross, Director Strategic Development, reported on the NICU Reunion 2025 which was a wonderful celebration at Ryan Ranch to bring families together who spent time in our NICU. Melissa recognized fellow members of the NICU Reunion Planning Committee as Dr. Robert Castro, Julie Vasher, Karina Kessler, Janet Rubio, Claudia Pizarro Villalobos, Ana Pimentel Calero, Janet Marcroft, Claudia Otero, Karina Rusk and Leonela Gonzalez. Robert Castro, M.D., Neonatologist, thanked the Board for their support for what we do for the families and babies.
- **Honoring/Acknowledging Dr. Singh.:** Dr. Radner thanked Rakesh Singh, M.D., for his dedication and leadership as Chief of Staff from October 1, 2023 through September 30, 2025. This will be his last Board meeting in this role. Dr. Singh said it has been a great experience and that there is alignment at SVH between the physicians and hospital which is unique.

5. PUBLIC COMMENT:

None.

6. CONSENT AGENDA – GENERAL BUSINESS

It was noted the following policies has been removed for consideration from the published Consent Agenda: (1) *Adult Sepsis Management* and (2) *Sedation for the Mechanically Ventilated Adult*. These policies will return for consideration at a later date.

Recommend Board Approval of the Following:

- A. Minutes of the Regular Meeting of the Board of Directors August 28, 2025
- B. Policies/Plans Requiring Approval
 - 1. Device and Media Control
 - 2. Echocardiography on Call and STAT
 - 3. Intra-Abdominal Pressure Monitoring

4. Intracranial Bolt Monitoring, Care and Removal
5. Lower Extremity Nerve Block
6. Scope of Service: Biomedical Services
7. Scope of Service: Clinical Research Program
8. Scope of Service: Volunteer Services

PUBLIC COMMENT: None.

BOARD MEMBER DISCUSSION: None

MOTION:

Upon motion by Director Dr. Cabrera, second by Director Rey, the Board of Directors approves the Consent Agenda, Items (A) through (B) as listed.

ROLL CALL VOTE:

Ayes: Arreguin, Dr. Cabrera, Carson, , and Rey;

Nays: None;

Abstentions: None;

Absent: Hernandez Laguna.

Motion Carried

7. BOARD MEMBER COMMENTS AND REFERRALS

Director Rolando Cabrera, M.D.: None

Director Catherine Carson: Introduced and welcomed Brenda Inman, Vice President Quality and Risk Management and that Brenda will have oversight of quality, risk, regulatory, infection prevention and patient safety.

Director Victor Rey, Jr.: (1) Thanked Dr. Radner for being included in promoting the vaccine campaign. (2) He attended the SVH/Chamber Lunch & Learn on Expanding Access to Care featuring Orlando Rodriguez, M.D. It was a great session with lots of engagement. (3) He attended the Governance Institute Leadership Conference which was very educational.

Director Isaura Arreguin: She also attended the Lunch and Learn and the photo session for the vaccine campaign. She stated she is glad the vaccine campaign is bilingual.

8. REPORTS ON STANDING AND SPECIAL COMMITTEES

A. COMMITTEE APPOINTMENTS

Director Carson announced the new Medical Staff Leadership is effective October 1, 2025. Matt Ottone, District Legal Counsel, advised that since all the committees are Board Committees that exist pursuant to the Board of Directors Bylaws, all committee seats are appointed by the Board President. The Committee Charters designate membership of those committees as 2 Board members, 2 Admin Members, and 1 Medical Staff member.

As Board of Directors President, Joel Hernandez Laguna appointed Medical Staff committee seats as follows:

- **Quality & Efficient Practices Committee:** Richard Gerber, M.D., Vice Chief of Staff
- **Finance Committee:** Steven Regwan, D.O., Medical Staff Treasurer
- **Corporate Compliance & Audit Committee:** Alison Wilson, D.O., Chief of Staff

B. QUALITY AND EFFICIENT PRACTICES COMMITTEE

A report was received from Director Carson regarding the Quality and Efficient Practices Committee. The minutes of the September 15, 2025 meeting were provided for Board review. Director Carson stated the presentations were: (1) Patient Care Services update on the Professional Development Council, (2) the AHA Age Friendly Initiative, (3) Leapfrog programs, and (4) CMS Hospital Star Rating. The Consent agenda included reports as listed on the Board of Directors Hearings and Reports Consent Agenda. There are no recommendations.

A. FINANCE COMMITTEE

A report was received from Director Rey regarding the Finance Committee. The minutes of the September 22, 2025 meeting were provided for Board review. The Financial Reports of the meeting were included in the packet for review (informational). It was noted the following recommendation has been tabled for consideration *Consider Recommendation for Board Approval of DRC 80 Ton Chiller and Cooling Tower*.

The following recommendations were made.

- 1. CONSIDER RECOMMENDATION FOR BOARD APPROVAL OF PROJECT FUNDING AND AWARD CONSTRUCTION CONTRACT TO AVILA CONSTRUCTION FOR THE SALINAS VALLEY HEALTH 5 LOWER RAGSDALE ROOFING REPLACEMENT PROJECT**

PUBLIC COMMENT: None.

BOARD MEMBER DISCUSSION: None.

MOTION:

Upon motion by Director Dr. Cabrera, and second by Director Arreguin, the Board of Directors approves (i) the total estimated project cost for the SVH 5 Lower Ragsdale Roofing Replacement Project in the amount of \$2,769,745.00, and (ii) award construction contract to Avila Construction for the SVH 5 Lower Ragsdale Roofing Replacement Project in the amount \$2,372,745.00.

ROLL CALL VOTE:

Ayes: Arreguin, Dr. Cabrera, Carson, and Rey;

Nays: None;

Abstentions: None;

Absent: Hernandez Laguna.

Motion Carried

- 2. CONSIDER RECOMMENDATION FOR BOARD APPROVAL OF LEASE AMENDMENT TO EXTEND THE LEASE AGREEMENT FOR 1756 NORTH MAIN STREET, SALINAS FOR ONE YEAR**

PUBLIC COMMENT: None.

BOARD MEMBER DISCUSSION: The property is not for sale. This will be a month-to-month lease extending the current lease term per Lease Agreement with a CPI Index increase of a minimum of two percent (2%) and a maximum of four percent (4%) over the prior year's Fixed Minimum Rent.

MOTION:

Upon motion by Director Dr. Cabrera, and second by Director Rey, the Board of Directors approves the Lease Amendment to Extend the Lease Agreement for 1756 North Main Street, Salinas for One Year.

ROLL CALL VOTE:

Ayes: Arreguin, Dr. Cabrera, Carson, and Rey;

Nays: None;

Abstentions: None;

Absent: Hernandez Laguna.

Motion Carried

3. **CONSIDER RECOMMENDATION TO THE SVH BOARD OF DIRECTORS TO APPROVE (i) THE PURCHASE OF ADDITIONAL UNITS OF VOTING MEMBERSHIP INTEREST IN MONTEREY PENINSULA SURGERY CENTER, AND (ii) THE EXECUTION OF THE MPSC SUBSCRIPTION AGREEMENT BY THE SVH PRESIDENT/CEO, AS APPROVED BY DISTRICT LEGAL COUNSEL**

PUBLIC COMMENT: None.

BOARD MEMBER DISCUSSION: None

MOTION:

Upon motion by Director Dr. Cabrera, and second by Director Rey, the Board of Directors approves (i) the purchase of additional units of Voting Membership Interests in Monterey Peninsula Surgery Center for the amount of \$661,000.00, and (ii) the execution of the MPSC Subscription Agreement by the SVH President/CEO, as approved by District Legal Counsel.

ROLL CALL VOTE:

Ayes: Arreguin, Dr. Cabrera, Carson, and Rey;

Nays: None;

Abstentions: None;

Absent: Hernandez Laguna.

Motion Carried

9. **CONSIDER RECOMMENDATION FOR BOARD APPROVAL OF (i) FINDINGS SUPPORTING RECRUITMENT OF ARTINEH HAYRAPETIAN, MD, (ii) CONTRACT TERMS FOR DR. HAYRAPETIAN'S RECUIRTMENT AGREEMENT, AND (iii) CONTRACT TERMS FOR DR. HAYRAPETIAN'S DIAGNOSTIC IMAGING PROFESSIONAL SERVICES AGREEMENT**

PUBLIC COMMENT: None.

BOARD MEMBER DISCUSSION: None.

MOTION:

Upon motion by Director Rey, and second by Director Dr. Cabrera, the Board of Directors approves the following:

1. The Findings Supporting Recruitment of Artineh Hayrapetian, MD:
 - That the recruitment of a diagnostic imaging radiologist to Salinas Valley Health Clinics is in the best interest of the public health of the communities served by the District; and

- That the recruitment benefits and incentives the hospital proposes for this recruitment are necessary in order to attract and relocate an appropriately qualified physician to practice in the communities served by the District;

2. The Contract Terms of the Recruitment Agreement for Dr. Hayrapetian; and
3. The Contract Terms of the Diagnostic Imaging Professional Services Agreement for Dr. Hayrapetian.

ROLL CALL VOTE:

Ayes: Arreguin, Dr. Cabrera, Carson, and Rey;

Nays: None;

Abstentions: None;

Absent: Hernandez Laguna.

Motion Carried

10. REPORT ON BEHALF OF THE MEDICAL EXECUTIVE COMMITTEE (MEC) MEETING ON SEPTEMBER 11, 2025, AND RECOMMENDATION FOR BOARD APPROVAL OF THE FOLLOWING:

Rakesh Singh, M.D., Chief of Staff, reviewed the reports of the Medical Executive Committee (MEC) meeting of September 11, 2025. A full report was provided in the Board packet. It was noted the following charter has been removed for consideration *Medical Staff Excellence Committee (MSEC) Charter*. The charter will return for consideration at a later date.

Recommend Board Approval of the following Reports and Policy as listed on the Agenda.

PUBLIC COMMENT: None.

BOARD DISCUSSION: None.

MOTION:

Upon motion by Director Rey, second by Director Arreguin, the Board of Directors receives and accepts the Medical Executive Committee Credentials Committee Report and Interdisciplinary Practice Committee Report and approves the policy as follows:

- A. Reports
 1. Credentials Committee Report (Including the following)
 - Taylor Farms Family Health & Wellness Center (TFFHWC) Clinical Privilege Form
 2. Interdisciplinary Practice Committee Report (Including the following)
 - Revised Certified Registered Nurse Anesthetist (CRNA) Privilege Form
- B. Policies/Procedures/Plans and Agreements Recommended for Approval:
 1. Dose Rounding for Biologic and Chemotherapeutic Agents

ROLL CALL VOTE:

Ayes: Arreguin, Dr. Cabrera, Carson, and Rey;

Nays: None;

Abstentions: None;

Absent: Hernandez Laguna.

Motion Carried

11. EXTENDED CLOSED SESSION

Vice President Carson announced items to be discussed in Extended Closed Session are *(1) Report Involving Trade Secret – Trade Secret, Strategic Planning, Proposed New Programs and services, (2) Public Employee Performance Evaluation: President/CEO*. The meeting recessed into Closed Session under the Closed Session Protocol at 5:21 p.m. The Board completed its business of the Closed Session at 6:32 p.m.

12. RECONVENE OPEN SESSION/REPORT ON CLOSED SESSION

The Board reconvened Open Session at 6:32 p.m. Vice President Carson reported that in Extended Closed Session, the Board discussed *(1) Report Involving Trade Secret – Trade Secret, Strategic Planning, Proposed New Programs and services, (2) Public Employee Performance Evaluation: President/CEO*. No action was taken.

13. CONSIDERATION OF PROPOSAL FOR MODIFICATION OF ANNUAL COMPENSATION TO PRESIDENT/CHIEF EXECUTIVE OFFICER

Vice President Carson reported that the following is a summary of Proposed Modification of the Annual Base Compensation of the President/Chief Executive Officer

The proposal is to increase the base annual compensation for the President/CEO from its current amount of \$840,000 by 6% to a new amount of \$890,400.00 retroactive to July 7, 2025. There are no other changes to the Employment Agreement.

MOTION: Upon motion by Director Hernandez Laguna, and second by Director Dr. Cabrera, the Board of Directors approves the proposal for modification of annual compensation to the President/Chief Executive Officer as stated above.

ROLL CALL VOTE:

Ayes: Arreguin, Dr. Cabrera, Carson, Rey, and Hernandez Laguna;

Nays: None;

Abstentions: None;

Absent: None.

Motion Carried

14. ADJOURNMENT

The next Regular Meeting of the Board of Directors is scheduled for **Thursday, September 25, 2025, at 4:00 p.m.** There being no further business, the meeting was adjourned at 6:35 p.m.

Rolando Cabrera, MD
Secretary, Board of Directors

Memorandum

To: Board of Directors
 From: Clement Miller, COO
 Date: October 23, 2025
 Re: Policies Requiring Approval

As required under Title 22, CMS, and The Joint Commission (TJC), please find below a list of regulatory required policies with summary of changes that require Board of Directors approval.

	Policy Title	Summary of Changes	Responsible Exec
Consent Agenda Policies			
1.	Adult Sepsis Management	Wording changed slightly for how quickly IV abx should be administered and added updated references. Approved by Dr. Gray.	Carla Spencer, CNO
2.	Business Continuity Access (EHR Downtime)	New policy for EPIC downtime	Carla Spencer, CNO
3.	Cardiac Cath Lab Emergency On-Call Procedure with Support Personnel Backup	References updated.	Clement Miller, COO
4.	Cardiac Catheterization Patient Care	Formatting corrections and updated references.	Clement Miller, COO
5.	Carotid Artery Stenting	Updated with most recent CMS decision memo, formatting corrections and updated references.	Clement Miller, COO
6.	Complete Decongestive Therapy for Management of Lymphedema	Board rejected 8/28/25. Requested changes made. Resubmitting.	Clement Miller, COO
7.	Echocardiography Lab Quality Assurance / Quality Review Process and Correlation	Formatting corrections and updated references.	Clement Miller, COO
8.	Instrument Preventative Maintenance	Monthly changed to “as needed” for Q1 and Q2.	Alysha Hyland, CAO
9.	Magnesium Sulfate in the Obstetric Patient	Corrected formatting of bullets under general information, removed competency requirement, maintained education and/or training to be provided as needed. Updated references. Changed Omnicell to automated dispensing cabinet.	Carla Spencer, CNO
10.	Maternal and Newborn Substance Abuse Evaluation	Updated reporting form, added new link, updated toxicology testing and notification process.	Carla Spencer, CNO
11.	Neonatal Medication Administration	Regularly scheduled review. Reference updated.	Carla Spencer, CNO
12.	Newborn Abandonment	Removed Charge Nurse from procedure flow to designate person to take custody of newborn. Updated references.	Carla Spencer, CNO
13.	NICU Family Centered Care/Parent Participation	Regularly scheduled review. Reference updated.	Carla Spencer, CNO

	Policy Title	Summary of Changes	Responsible Exec
Consent Agenda Policies			
14.	Pharmacy - Sterile Compounding	Updates to align with USP 800. Updates to reflect current doffing requirements. Updated references.	Clement Miller, COO
15.	Scope of Service: Clinical Research Program	Board rejected 8/28/25. Updated IRB reliance agreements per request by Board member.	Timothy Albert, CCO
16.	Sedation for the Mechanically Ventilated Adult	Table updated, references updated and updated sedation titration parameters to match Med Use policy.	Carla Spencer, CNO

MEC			
MEC Policies/Plans			
1.	Aerosol Transmitted Diseases Exposure Control Plan	Minor edits needed by EHS, updated Job Titles for 2024-2025, and significant edits to transfer language in section ii. Referral and transfer of Air ID cases to all rooms or facilities. There are two exceptions to the requirement to transfer. Updates for job roles & transfer language.	Timothy Albert, CCO
2.	Bioterrorism Readiness Plan	Reviewed and updated the referral links in response to changes on the CDC website.	Timothy Albert, CCO
3.	Laboratory Critical Call Values	Added clear wording to call all outpatient critical results regardless of previous critical results, with the exception of renal patients. Added missing category on phos, corrected typo on K 1-14 yr and updated reference.	Clement Miller, COO
4.	Respiratory Virus (Influenza) Pandemic Plan	Reviewed and updated a few CDC referral links, due to weblink updates by the CDC.	Timothy Albert, CCO



Origination 07/2022
Last N/A
Approved
Next Review 3 years after approval

Owner David Thompson:
Director Nursing
Area Patient Care

Adult Sepsis Management

I. POLICY STATEMENT

A. N/A

II. PURPOSE

A. To guide the staff in caring for the patient with sepsis or suspected sepsis.

III. DEFINITIONS

A. Systemic Inflammatory Response Syndrome (SIRS): clinical response to an insult either infectious or noninfectious in origin. Defined as having two or more of the following:

- Temp > 38.3 or < 36
- HR > 90
- RR > 20
- Pulse Oximetry <90%
- WBC > 12,000, < 4,000 or > 10% bands

B. Sepsis: SIRS + suspected or documented infection

- Source of suspected clinical infection should be identified and documented

C. Severe Sepsis: Sepsis + acute organ dysfunction

- Meets SIRS criteria plus sign of organ dysfunction:
 1. SBP less than 90, or MAP less than 65, or SBP decrease more than 40 mm Hg from the last previously recorded SBP considered normal for the patient
 2. Creatinine greater than 1.0 or urine output less than 0.5 ml/kg/hr for 2 hours

3. Bilirubin greater than 2 mg/dL
 4. Platelet count less than 100,000
 5. INR greater than 1.5 or aPTT greater than 60 seconds
 6. Lactate greater than 2 mmol/L
- D. Septic Shock: Severe Sepsis + persistent hypotension despite fluid resuscitation
- Documentation of severe sepsis plus
 - Tissue hypoperfusion persists in the hour after crystalloid evidenced by either:
 1. SBP less than 90
 2. MAP less than 65
 3. Decrease in SBP decrease more than 40 mm Hg from the last previously recorded SBP considered normal for the patient
 4. lactate level greater than or equal to 4 mmol/L

IV. GENERAL INFORMATION

- A. If a patient has been identified as meeting the sepsis criteria, the sepsis protocol should be initiated. RN's will screen patients approximately every twelve hours using standardized criteria. If the patient meets SIRS criteria, the physician will be notified.

V. PROCEDURE

- A. Early identification of the patient with sepsis and implementation of the sepsis protocol in a timely manner is the goal of treatment. (see attachment A).
- B. Patients are screened for SIRS/Sepsis criteria by the RN:
- In ED: on admission per [SEPSIS MANAGEMENT STANDARDIZED PROCEDURE](#)
 - Inpatient units: every 12 hours with vital sign assessment and as necessary.
 1. The RN will monitor vital signs, alerts and labs for trends for the past 24 hour period
 - a. If alerted by a device such as a SMART bed, the RN will go to the room and physically assess the patient for SIRS/Sepsis criteria.
 2. If the patient meets criteria, the RN notify the physician of the findings
 - Perinatal patient population (antepartum, intrapartum and postpartum): on admission, shift assessment and as needed for suspected sepsis (see attachment B)
- C. Once the patient meets sepsis criteria the following should take place within designated time frames:
- Within three hours of screening:
 1. Ordered labs should be drawn STAT, and reported to physician. Serum lactate level is reported for decision tree

2. Ordered cultures should be obtained STAT
 3. Administration of IV antimicrobials should be initiated as soon as possible after recognition and within 1 hour for both a) septic shock and b) sepsis without shock
 4. Initial fluid bolus of approximately 30ml/kg of NS or LR is given rapidly, using non-IV pump tubing, over 30 min.
- Within six hours of screening:
 1. Either repeat focused exam by licensed independent practitioner should be performed, including vital signs, cardiopulmonary, capillary refill, pulse, and skin findings
 2. OR: Two of the following:
 - a. Measure CVP
 - b. Measure ScvO₂
 - c. Bedside cardiovascular ultrasound
 - d. Dynamic assessment of fluid responsiveness (such as passive leg raise)
 3. Apply vasopressors as ordered
 4. If MAP continues to be less than 65 mm Hg or if initial lactate was greater than or equal to 4 mmol/L, clinician should re-assess volume status and perfusion
 5. Re-measure lactate if elevated

D. Documentation:

1. Nurses will document sepsis screening in the electronic health record (EHR).

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed.

VII. REFERENCES

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- B. Evans, Laura¹; Rhodes, Andrew; Alhazzani, Waleed; Antonelli, Massimo; Coopersmith, Craig M.; French, Craig; Machado, Flávia R.; McIntyre, Lauralyn; Ostermann, Marlies; Prescott, Hallie C.; Schorr, Christa; Simpson, Steven; Wiersinga, W. Joost; Alshamsi, Fayez; Angus, Derek C.; Arabi, Yaseen; Azevedo, Luciano; Beale, Richard; Beilman, Gregory; Belley-Cote, Emilie; Burry, Lisa; Cecconi, Maurizio; Centofanti, John; Coz Yataco, Angel; De Waele, Jan; Dellinger, R. Phillip; Doi, Kent; Du, Bin; Estenssoro, Elisa; Ferrer, Ricard; Gomersall, Charles; Hodgson, Carol; Hylander Møller, Morten; Iwashyna, Theodore; Jacob, Shevin; Kleinpell, Ruth; Klompas, Michael; Koh,

Younsuck; Kumar, Anand; Kwizera, Arthur; Lobo, Suzana; Masur, Henry; McGloughlin, Steven; Mehta, Sangeeta; Mehta, Yatin; Mer, Mervyn; Nunnally, Mark; Oczkowski, Simon; Osborn, Tiffany; Papathanassoglou, Elizabeth; Perner, Anders; Puskarich, Michael; Roberts, Jason; Schweickert, William; Seckel, Maureen; Sevransky, Jonathan; Sprung, Charles L.; Welte, Tobias; Zimmerman, Janice; Levy, Mitchell. Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021. Critical Care Medicine 49(11):p e1063-e1143, November 2021. | DOI: 10.1097/CCM.0000000000005337

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- E. Gilbert, B. W., Reichert, M., Fletcher, S., Alexander, E., & Allen, J. (2019). Strategies for the Management of Sepsis. AACN Advanced Critical Care, 30(1), 5–11.

Attachments

 [A: Sepsis Guidelines: Timeframe Goals for Resuscitation Bundle](#)

 [B: Maternal Sepsis Evaluation Algorithm](#)

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
Dr. Gray	Katherine DeSalvo: Director Medical Staff Services	10/2025
CNO	Carla Spencer: Chief Nursing Officer	09/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	09/2025
Policy Owner	David Thompson: Director Nursing	09/2025

Standards

No standards are associated with this document



Origination	11/2025	Owner	Anna Linn: EPIC
Last Approved	N/A		Nursing Champion
Next Review	3 years after approval	Area	Patient Care

Business Continuity Access (EHR Downtime)

I. POLICY STATEMENT

A. N/A

II. PURPOSE

- A. To provide guidelines to ensure the provision of care during downtimes and to maintain an accurate medical legal record of care provided.

III. DEFINITIONS

- A. Planned downtime: A previously announced period of time when the clinical documentation system is unavailable.(Define abbreviations and other terminology).
- B. Unplanned downtime: Sudden and unanticipated period of time when the clinical documentation system is unavailable.
- C. Downtime: Period of system unavailability, either planned or unplanned. There are several different types of downtimes. Some examples:

Type	Description	What Still Works	What Doesn't Work
Server Downtime	Epic servers are unavailable, but the network and internet remain functional.	Internet, email, shared drives, other applications.	Epic access (all functions).
Network Downtime	Hospital network or internet connection is unavailable.	Local applications (Word, Excel, files saved on workstation).	Epic, email, web-based applications, shared drives.

Type	Description	What Still Works	What Doesn't Work
Power Outage	Electrical power is unavailable on non-emergency outlets.	Devices connected to emergency power (critical workstations, phones on backup power).	Workstations and devices without emergency power.

- D. **Recovery** - the time following a planned or unplanned downtime in which there is a return to normal system operation.
- E. **Shadow Read-Only (SRO)**: A read-only copy of the Epic system, allowing users to view patient data but not enter new information. Available on clinical or mobile workstations.
- F. **BCA Web**: Business Continuity Access, a web-based interface for viewing patient reports (e.g., Medication Administration Records (MAR), patient census, schedules). Data entry is limited, and paper forms are used for documentation during downtime.
- G. **BCA PC**: Designated computers (Downtime PCs) or workstations used for storing and printing downtime reports with critical patient data up to the point of outage.
- H. **Disaster Recovery (DR)**: Refers to the scenario in which the organization fails over from the primary Production environment to the Disaster Recovery Production environment located in the secondary data center. The DR environment provides users with access to a near real-time copy of Production in full read/write mode, allowing continuation of normal workflows.
- I. **Downtime Forms**: Paper forms used to record patient care when the system is unavailable. They can be found in the BCA binder and in a folder marked Downtime Forms on the BCA PC.

J.

	SRO Downtime	BCA Web Downtime	BCA PC Downtime	Disaster Recovery
Definition:	Epic Production is down, SRO=Read Only	Epic Production & SRO (Read Only) Hyperspace are down	System Power or Network Outage	Fail over from Production to secondary DR environment with full read/write Epic access
Example of Downtime Type:	System Upgrade	Data Center or Network Issue	System Power or Network Outage	Major production failure (e.g., PRD corruption, extended outage)
What computers can be used?	All normally used computers and WOWs (workstations on wheels)	All normally used computers and WOWs	BCA PCs only (Downtime PCs)	All standard Epic access points once DR activation complete
Report Status:	View and Print from SRO	View and print from BCA Web	View and print from BCA PC's	Full Epic functionality in read/write mode

	Hyperspace		only	
Where to access Downtime Forms:	Downtime Binder and Electronically via folder on BCA PC	Downtime Binder and Electronically via folder on BCA PC	Downtime Binder and Electronically via folder on BCA PC	Downtime binder as backup; standard Epic documentation available in DR environment

IV. GENERAL INFORMATION

- A. When the clinical documentation system is unavailable, downtime procedures will be initiated to allow for continuity of care and uninterrupted clinical operations during planned and unplanned downtime.
- B. System users are notified of downtime and once the downtime period is lifted.
- C. Communications identified in this procedure are subordinate to the Incident Response and Emergency Management procedures.
- D. Referenced policy: [Emergency Management Program Plan](#)

V. PROCEDURE

- A. Notification
 1. Planned Downtime is scheduled when there are system updates. Staff is notified in advance of planned downtime.
 2. Unplanned Downtime
 - a. Staff who identify a problem with the EHR should call 1738 (Help Desk) to report the issue. The issue will be analyzed and triaged to the appropriate IT/Informatics analyst for review and further escalation to Epic if necessary.
 - b. After troubleshooting for 15 minutes with no resolution, it should be escalated to the following to declare a downtime.
 - c. Nurse Supervisor, IOC, AOC, Incident Commander and IT Incident Lead can declare a downtime. IOC: IT/Informatics on Call. AOC: Administrator on Call. "IOC" and "AOC" are roles found in TigerConnect.
 - i. This person will be responsible for initiating communication procedures.
 - ii. Typically, this point person will be the IOC, IT/Informatics manager on call.
 - iii. Consider using a tree model.
 - a. Downtime point-person contacts operational leads.
 - b. Operational leads communicate the downtime to department leads.

- c. Department leads inform their staff.
- d. An email from "IT Bulletin" will be sent once it is determined that all or part of the clinical documentation system is down. Only if email is available.
- e. The Nursing Supervisor and Hospital Operator will be notified.
- f. The Operator will overhead page the downtime and applications affected, if appropriate.
- g. A broadcast TigerConnect will be sent.
- h. System users should initiate downtime forms and processes for their respective areas.
- i. ADT (admit, transfer and discharge) events must be recovered prior to beginning clinical recovery. Call the Registration Supervisor.
- j. System restoration will be communicated via IT Bulletin and overhead page.
- k. When downtime—planned or unplanned—is initiated, all staff are to log off Epic and discontinue use of the system until the system is available. Announcements will be made once the downtime is resolved.

B. Accessing Patient Data During Downtime

1. **SRO Access:** Use SRO as the first resource to view patient charts in read-only mode. No discrete data entry is allowed. If unavailable, proceed to BCA Web or BCA PC.
2. **BCA Web:** Access via clinical workstations. Reports include MAR, patient census, orders, and schedules, but no discrete data entry is allowed.
3. **BCA PC:** Use designated workstations to view and print reports stored locally. These are critical for accessing patient data like recent medications or scheduled procedures.
4. Downtime forms are located in patient care units in both the BCA binder and in an electronic folder on the BCA PC. Each unit is responsible for adequately stocking their downtime forms.

C. Patient Access (ADT)

1. Registration will maintain the census in BCA Web (if available).
2. Procedure During Downtime: Use the standard ADT downtime report to show all census beds. This report includes information that is patient specific (patient name, patient identifier, attending provider, service, patient class, sex, diagnosis, DOB and admit date), as well as the patient's unit, room and bed status. Print this report from the BCA PC.
3. Collecting Registration Information: Collect patient information using paper downtime registration forms.
4. Logging Patient Events: Each ADT event should be entered on a Daily Census Record. Each Daily Census Record should be entered into DEL (Downtime Event Log), which is an excel spreadsheet located on recovery PCs to help sort downtime events.

5. Documentation Recovery Steps: Upon recovery of the system, ADT users will need to back-enter ADT events into the system by using the DEL (Downtime Event Log).
 - a. Enter Patients who only have a discharge event first to avoid bed locks.
 - b. Prioritize events where the event is still in-house after downtime ends.
 - i. Work on logging transfer-only events as well as admissions that occurred during downtime first and in chronological order.
 - ii. Events where patients arrived and left during downtime can be prioritized second since there will be no dependence on these events.

D. Order Process

1. All orders will be written on downtime order sheets.
2. Physician's orders form is used to record orders; medication orders will be faxed to pharmacy. Pharmacy will enter all medication orders when system is available per Pharmacy Policy & Procedure for downtime.
3. Downtime order forms are used to enter requests for Laboratory, Diagnostic Imaging, Echocardiology/EKG, Neurodiagnostics/EEG, Respiratory Care, Physical Therapy, Occupational Therapy, Speech Therapy, Nutrition Services or Engineering and to notify Pharmacy about allergies, height, and weight.
4. Current day orders: apply patient identification label, complete information (including reason for test/exam) and fax to the appropriate department.
5. STAT orders: fax and call department. Retain form in chart until request is completed.
6. Future orders: apply patient identification label, complete information (including reason for test/exam) and hold on unit. These orders are to be batched (entered into computer) by Nursing at later time. White original copy will be placed in folder and kept at nurses' station to be entered at the end of downtime. The yellow copy will be communicated to the ordering unit via telephone call or fax; lab results will be placed in the chart for the nurse to verify orders.
7. All new Dietary Orders and Consults will be entered into the computer by the ordering department, when the computer system is back on-line.
8. Once orders are completed by the ancillary department, any results will be printed in the lab and sent to the floors.
9. When the system is available, the Nurse will enter all future orders utilizing the forms.
10. All orders faxed to departments will be entered by the receiving department.

E. Clinical Documentation

1. Planned Downtime
 - a. Each nursing unit should print three sets of patient Clinical Summaries (2 for the RNs and 1 for the CNAs).
 - b. Medication Administration Records (MARs) should be printed just prior to

the planned downtime. Printing issues should be reported to the Help Desk.

2. Paper Forms: Use downtime paper forms to document clinical activities (e.g., patient name, MRN, DOB, CSN, department-specific data). These forms are later back-entered into Epic during recovery.
3. Data Entry (Limited): In specific cases (e.g., Admissions, Discharge, Transfer events in the Emergency Department or Transfer Center), BCA Web may be set to "Edit Data" mode by a BCA administrator to allow limited online documentation.

F. Downtime Medication Administration Record (MAR)

1. MARS are printed for each patient and will show the past 24 hours of medication given and medications due for next 24 hours.
2. Medication Administration will be documented on the MAR.
3. Nursing and Respiratory Care will share MAR for medication administration.
4. New medication orders are to be transcribed on to Downtime Medication Administration Record form.
5. High Alert medications will be co-signed

G. New Admissions

1. Inpatient units with new admissions will utilize downtime forms for the following: Allergies/Height/Weight, Admission History, MRSA Screening, Admission/Home Medication Reconciliation, Shift Assessment, Downtime Patient Care Record, Patient Progress Notes, and Downtime MAR.

H. Current Patients

1. For existing patient utilize downtime forms: Shift Assessment, Downtime Patient Care Record, Patient Progress Notes, and Downtime MAR.

I. Discharges

1. Discharge instructions are to be written on the downtime Discharge Instructions form.
2. Education provided from Micromedex CareNotes can be accessed from www.micromedexsolutions.com.

J. Emergency Department (ED)

1. Refer to ED downtime process.
2. For patients being admitted, the ED will back-enter medication administration once systems are restored if the downtime is less than four hours.

K. Ancillary Services

1. Should initiate appropriate downtime forms to provide current therapies.
2. Should use Patient Progress Notes for any related patient notes.

L. Recovery Documentation

1. Enter clinical data into Epic once the system is operational.
 - a. If downtime is less than 4 hours
 - b. Back-enter documentation when system is restores
 - c. Use the MAR as a reference and record medication administration with Full Documentation
 2. If downtime is greater than 4 hours or spans a full shift, perform the following:
 - a. Place downtime forms in the patient's chart which will then be scanned into the record by HIM after the charts are received.
 - b. Reconcile overdue (red) MAR medications using Full Documentation and document as "Not Given-Reason: Downtime"
 - i. If downtime crosses midnight:
 - ii. Create a handwritten downtime MAR including all active medication orders
 3. Required data to back-enter into Epic:
 - a. Allergies, height and weight
 - b. Home medications
 - c. Last set of vital signs
 - d. I/O totals for shift (intake/output)
- M. Routine Testing - The downtime computers and printers should be checked on a regular basis by the Credentialed Trainers assigned to that application. This is done by going to the Start Menu of the downtime computer, accessing the BCA program, and ensuring that the patient information is viewable, and current.

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed.

VII. REFERENCES

- A. The Joint Commission Information Management Standards IM.01.01.0

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending

Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
ELG	Rebecca Alaga: Regulatory/ Accreditation Coordinator	10/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	10/2025
Policy Owner	Anna Linn: EPIC Nursing Champion	10/2025

Standards

No standards are associated with this document



Origination06/2022

Last ApprovedN/A

Next Review3 years after approval

OwnerMegan Giovanetti: Director Cardiovascular Services and Sleep

AreaCardiology Departments

Cardiac Cath Lab Emergency On-Call Procedure with Support Personnel Backup

I. POLICY STATEMENT

A. N/A

II. PURPOSE

A. To guide staff in providing 24-hour per day, 7-days per week coverage for emergency catheterizations.

III. DEFINITIONS

A. N/A

IV. GENERAL INFORMATION

A. The Cardiac Cath Lab shall provide 24-hours per day, 7-days per week coverage for emergency heart catheterizations and interventional cardiac procedures. An on-call team shall consist of at least three cardiac catheterization laboratory personnel; one of which is a registered nurse. Additional staff will be added as deemed necessary based upon complexity and acuity of the patient. The on-call staff will be available by telephone or hospital provided pager. The on-call team will respond to the emergency call and arrive within thirty (30) minutes from the time they were notified of the emergency.

V. PROCEDURE

A. Each day at the end of operations, the Cath Lab clerk, Charge RN or designee will ensure that

Call Scheduler is up to date. When an individual on-call staff member needs to make a trade or switch and it occurs after distribution of the daily call schedule, the staff member must personally perform the following:

1. The on-call staff member will update the on-line call scheduler.
2. The on-call staff member will update the Charge RN, and operator as needed

B. Procedure at Time of Emergency

1. **Physician:** The physician notifies the Administrative Supervisor to contact on-call Cardiac Cath Lab staff. The following information will be provided to the on-call team: the patient's name, location, and type of procedure to be performed. Staff is not contacted for "possible" procedures. Staff is to be contacted when it has been verified that the emergency patient is in route to the hospital or in-house.
2. **Nursing Supervisor:** The nursing supervisor contacts on-call staff first by hospital provided pager, then home phone or cell phone.
3. **On-Call Staff:** The on-call staff will report promptly to the Cardiac Cath Lab and notify the cardiologist and the Emergency Department (if patient is in the Emergency room) of their arrival.

C. Documentation:

1. The on-call team schedule will be updated in Call Scheduler

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed

VII. REFERENCES

- A. 2025 ACC/AHA/ACEP/NAEMSP/SCAI guideline for the management of patients with acute coronary syndromes.

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- B. 2013 ACCF/AHA Guideline for Management of ST-Elevation Myocardial Infarction A report of

the American College of Cardiology Foundation/American Heart Task Force of Practice Guidelines

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Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
Cath Lab Medical Director - Dr. Zetterland	Megan Giovanetti: Director Cardiovascular Services and Sleep	10/2025
CNO	Carla Spencer: Chief Nursing Officer	09/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	09/2025
Policy Owner	Megan Giovanetti: Director Cardiovascular Services and Sleep	08/2025

Standards

No standards are associated with this document



Origination 11/2018
Last Approved N/A
Next Review 3 years after approval

Owner **Megan Giovanetti:**
Director
Cardiovascular Services and Sleep
Area Patient Care

Cardiac Catheterization Patient Care

I. POLICY STATEMENT

A. N/A

II. PURPOSE

A. To guide the staff in the assessment, monitoring, and care of patient after cardiac procedure.

III. DEFINITIONS

- A. PCI – Percutaneous Coronary Intervention
- B. DES – Drug eluting stents
- C. PTCA – Percutaneous transluminal coronary angioplasty
- D. EP – Electrophysiology Study
- E. PPM – Permanent pacemaker implantation
- F. AICD/ICD – Automated implantable cardioverter defibrillator

IV. GENERAL INFORMATION

- A. Various cardiac procedures are performed inpatient and outpatient by the interventional cardiologist. Immediate post procedural care are managed by the interventional cardiologist.
- B. Consent signed by patient will include the name of the cardiologist as well as the interventional cardiologist performing the cardiac procedure.

V. PROCEDURE

A. Equipment

1. Cardiac Monitor
2. Non-invasive blood pressure monitor.
3. Doppler (if unable to palpate pedal pulse).
4. Pressure tubing - Heparinized Saline bag (1000 units/ 500ml.) with pressure cuff inflated to 300 mmHg (used in Surgery and Cath Lab only).
 - a. If patient returns to nursing unit with pressure tubing/bag in place, RN will change Heparinized saline bag to Normal Saline 500ml bag.
5. Plethysmographic sensor (O2 saturation sensor) on the thumb of involved extremity for the observation of pulsatile waveform.
6. Mechanical compression devices – Hemostasis Band
 - a. Radial - TR Band/Hemoband
 - b. Femoral – FemoStop

B. Operation

1. Cardiac Catheterization Procedures:
 - a. Right/Left catheterization
 - b. Diagnostic angiography – Coronary pressure measurements
 - c. Percutaneous coronary intervention (PCI)
 - d. Balloon Angioplasty
 - e. Stenting – DES or bare metal stents
 - f. Atherectomy
2. Peripheral Angiography
 - a. Peripheral Intervention
 - i. Atherectomy
 - ii. Thrombectomy
 - iii. Lysis
 - iv. Angioplasty and stenting
3. Electrophysiologic procedures
 - a. Device implantation (PPM, ICD, Lead revisions, Loop recorders, Watchman, CardioMems HF)
 - b. EP studies and Ablations
4. At completion of procedure, physician may address the access site with the use of the following:

1. Manual compression – using 2-3 fingers apply continuous downward pressure above the puncture sites for 20 minutes or until hemostasis is achieved.
2. Vascular compression devices (Angioseal, Perclose, Mynx) are associated with decreased compression time and improved patient comfort but not with significant decreased bleeding or vascular complications
3. Mechanical compression device:
 - a. Radial artery – TR Band or Hemoband
 - b. Femoral artery - FemoStop
4. Nursing Care includes the assessment, recognition and effective management of complications; patient comfort and safety; and providing education to patients and their families.
5. Assure immobilization of affected extremity, bedrest guidelines per physician order
6. Standard assessment of access site with each vital sign.
7. Begin titration of compression devices used to achieve hemostasis per protocol or as ordered by physician.
8. Print ECG rhythm strip upon return from cath lab or as needed for chest pain.
9. Monitor for cardiovascular, pulmonary and neurologic status and notify physician of any variances from baseline.
10. Assessment of peripheral circulation includes evaluation of bilateral pulses for comparison, warmth and color of affected extremity and capillary refill.
11. Slight oozing is normal. Should excessive bleeding/hematoma occur, immediately increase applied pressure from mechanical compression device and notify physician. May use topical hemostatic bandage (D-Stat) applied to vascular access site, which can control surface bleeding.
12. Following physician order, encourage fluids after procedure to facilitate elimination of contrast material and prevent renal damage.
13. Assess the need for analgesic and may log roll side to side for patient comfort.
14. When arterial or venous sheath left in place, patency is maintained by attaching the arterial port to a pressurized Normal Saline 500ml iv bag/ tubing. Venous port is flushed or an IV fluid can be infused as ordered by physician.
15. Assess patient for evidence of vascular related complications including bleeding (retroperitoneal and/or entry site), hematoma, pseudoaneurysm, arteriovenous fistula, nerve compression, and dissection. Instruct patient to notify nurse immediately if chest pain, pressure, diaphoresis, or shortness of breath occur. Obtain 12-lead ECG as ordered.

16. When bed rest discontinued, assist patient with ambulation. Sit patient at side of bed, and then ambulate to chair in room. Reassess groin site and pedal pulse at end of ambulation.
17. Provide care notes and review discharge instruction to patient and family. Educate patient on the importance of modifying cardiovascular risk factors. Review discharge medications and reinforce the importance of antiplatelet therapy after stent procedures.

C. Documentation

1. Document in the electronic medical record.
 - a. PostAngio/PTCA cath for inpatients
 - b. OPS Pre/Post for outpatient
 - c. Intra Aortic Balloon Pump when arterial or venous sheath left in place

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed.

VII. REFERENCES

- A. Schahab N, Kavsar R, Mahn T, Schaefer C, Kania A, Fimmers R, Nickenig G, Zimmer S. Endovascular management of femoral access-site and access-related vascular complications following percutaneous coronary interventions (PCI). PLoS One. 2020 Mar 19;15(3):e0230535. doi: 10.1371/journal.pone.0230535. PMID: 32191751; PMCID: PMC7082010.
- B. Terumo Corporation (2022) "TR Band Radial Compression Device'. ONLINE, Accessed November 18, 2022 via web at: <https://www.terumo.com/products/closure/tr-band.html>
- C. Valaker I, Norekvål TM, Råholm M-B, Nordrehaug JE, Rotevatn S, Fridlund B. Continuity of care after percutaneous coronary intervention: The patient's perspective across secondary and primary care settings. European Journal of Cardiovascular Nursing. 2017;16(5):444-452. doi:10.1177/1474515117690298

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/Accreditation Coordinator	Pending

Cath Lab Medical Director	Megan Giovanetti: Director Cardiovascular Services and Sleep	10/2025
CNO	Carla Spencer: Chief Nursing Officer	09/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	09/2025
Policy Owner	Megan Giovanetti: Director Cardiovascular Services and Sleep	08/2025

Standards

No standards are associated with this document



Origination07/2022

Last ApprovedN/A

Next Review3 years after approval

OwnerMegan Giovanetti: Director Cardiovascular Services and Sleep

AreaCardiology Departments

Carotid Artery Stenting

I. POLICY STATEMENT

A. N/A

II. PURPOSE

A. The purpose of this policy is to delineate requirements healthcare providers must meet for carotid artery stenting as defined by Centers for Medicare and Medicaid Services (CMS).

III. DEFINITIONS

- A. ACLS: Advanced Cardiac Life Support
- B. BLS: Basic Life Support
- C. CAS: Carotid Artery Stenting
- D. CMS: Centers for Medicare and Medicaid Services
- E. CHF: Congestive Heart Failure
- F. CEA: Carotid Endarterectomy
- G. DI: Diagnostic Imaging
- H. LVEF: Left Ventricular Ejection Fraction
 - I. ASA: American Society of Anesthesiologists Physical Status Classification
- J. NIH: National Institutes of Health
- K. NIHSS: NIH Stroke Scale
- L. IRB: Institutional Review Board

IV. GENERAL INFORMATION

- A. All Carotid Artery Stenting (CAS) patients/procedures meet the criteria as defined by the Centers for Medicare and Medicaid Services (CMS).
- B. All CAS patients/procedures meet the additional criteria defined by this policy.

V. PROCEDURE

- A. Patient selection criteria are defined as:
 - 1. Patients with symptomatic carotid artery stenosis $\geq 50\%$;
 - a. Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA in the opinion of the surgeon. Significant comorbid conditions include but are not limited to:
 - i. Congestive heart failure (CHF) class III / IV
 - ii. Left ventricular ejection fraction (LVEF) $< 30\%$
 - iii. Unstable angina
 - iv. Contralateral carotid occlusion
 - v. Recent myocardial infarction (MI)
 - vi. Previous CEA with recurrent stenosis
 - vii. Prior radiation treatment to the neck Physician privileging requirements will be met as set forth by the Medical Staff
 - viii. Patients who are enrolled in clinical trials and meet the criteria established by that trial.
 - 2. Patients with asymptomatic carotid artery stenosis $\geq 70\%$
- B. Staff will receive training to assist CAS procedures.
 - 1. Staff will maintain the following certification:
 - a. **Registered Nurse (RN)**
 - i. All RN's will maintain the following.
 - ii. Advanced Cardiac Life Support (ACLS)
 - iii. **Certified Radiologic Technologist (CRT)** All CRT's will maintain the following:
 - iv. Advanced Cardiac Life Support (ACLS) is optional but recommended.
 - v. BLS (Basic Life Support)
 - vi. **Cardiovascular Technologist (CVT)**
 - a. All CVT's will maintain the following:

- i. Advanced Cardiac Life Support (ACLS) is optional but recommended
- ii. BLS (Basic Life Support)

b. Scheduling

- i. Patients are scheduled by physician through the Cardiac Cath Lab office scheduling processes.
- ii. Pre procedure imaging must be performed prior to scheduling.
 - i. First-line evaluation of carotid artery stenosis must use duplex ultrasound.
 - ii. Computed Tomography angiography or magnetic resonance angiography, if not contraindicated, must be used to confirm the degree of stenosis and provide additional information about the aortic arch, and extra- and intracranial circulation.
 - iii. Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results, or in lieu of computed tomography angiography or magnetic resonance angiography if these are contraindicated.
- iii. Prior to Carotid Artery Stenting, the practitioner must engage in a formal shared decision-making interaction with the patient.
- iv. Cardiac Cath Lab personnel will notify the Cath Lab Director , charge nurse or designee,) or Charge Nurse (DI), or designee, immediately upon scheduling a CAS patient.
- v. Prior to the start of the procedure, the registered nurse will ensure that the following medications are immediately available:
- vi. Dopamine (400mg/250ml D5W) pre-mixed infusion must be primed on infusion pump

ready to begin.

- vii. Neosynepherine (1mg per ml pre-mixed by Pharmacy). Medication must be drawn up in labeled syringe for immediate administration.
- viii. Atropine (1mg per ml vial obtained from Pyxis) Medication must be drawn up in labeled syringe for immediate administration.

c. Pre-Procedure

- i. Prior to leaving the sending unit, documentation of baseline neurologic status including:
- ii. National Institute of Health stroke scale (NIHSS) completed by independent physician (not intervening physician) or RN II or above who is certified to perform NIHSS.
- iii. The registered nurse (RN) will complete a base-line neurological assessment in addition to pre-procedure assessment.
- iv. The RN will obtain baseline vital signs, pain assessment, oxygen saturation and assess baseline cardiac rhythm within the 15 minutes immediately prior to the start of sedation.
- v. The RN will review pertinent patient history in the history and physical.
- vi. The RN will assess baseline peripheral pulses prior to the procedure.
- vii. Pre-Procedure Medication
- viii. Please see Appendix A for medications to be prepped and ready prior to beginning of the procedure.
 - i. The RN with the assistance of the CRT or CVT will validate with the physician what equipment will be required for the procedure.
 - ii. The RN with the assistance of the CRT or CVT will validate that universal protocol has been followed. UNIVERSAL PROTOCOL: PREVENTION OF WRONG

ix. **Intra-Procedure**

- i. The RN will perform on-going neurological assessments as directed by the physician.
- ii. The RN will document vital signs, cardiac rhythm and oxygen saturation a minimum of every 5 minutes during the procedure.
- iii. The RN will perform ongoing assessment and documentation of patient's pain level and response to analgesia if needed during the procedure.
- iv. The RN will document patient response to medications during the procedure.
- v. The RN or monitoring tech will document percent pre-stenosis, lesion length, and percent post-procedure stenosis.
- vi. The RN or monitoring tech will document devices used – sheaths, wires, balloons, stents, etc.
- vii. The RN or monitoring tech will document distal protection device used.
- viii. The RN or monitoring tech will document inflation pressures in atmospheres and duration of inflation.
- ix. The RN or monitoring tech will collect Intra procedure data in the hemodynamic monitoring system

x. **Post-Procedure**

- i. The RN will perform post-procedure neurological assessment and report any variances from pre-

procedure assessment to the physician immediately.

- ii. The monitoring tech will document fluoroscopy time, contrast volume and arterial time at the end of the procedure
- iii. The monitoring tech will document closure method/device and arterial site status.
- iv. Prior to transfer out of the procedure room, the patient will have achieved an Aldrete score greater than or equal to 8 with 2 points in the respiratory category.
- v. The RN, in the recovery nursing unit, will assess and document vital signs,
- vi. Cardiac rhythm and oxygen saturation post-procedure every 15 minutes x 4, every 30 minutes x 4, and hourly x 4.
- vii. The RN will perform post procedure assessment and documentation of patient's pain level and response to analgesia if needed post procedure.
- viii. The RN will assess and document post-procedure peripheral pulses every 15 minutes x 4, every 30 minutes x 4 and hourly x 4.

xi. Post-procedure NIH Stroke Scale

score or Modified Rankin Score, will be performed by independent physician or RN II or above, certified in NIHSS and/or Modified Rankin.

- xii. Requirements will be re-evaluated against Centers for Medicare and Medicaid Services (CMS) standards as changes occur.
- xiii. Equipment will meet the CMS requirements as follows:
 - i. FDA approved carotid artery stenting systems and embolic protection devices.
 - ii. High-quality X-ray imaging equipment with capability of subtraction, magnification, road mapping, and orthogonal angulation.
 - iii. Advanced physiologic monitoring to include real time and archived physiologic, hemodynamic, and cardiac rhythm monitoring equipment.
 - iv. Emergency management equipment and systems such as resuscitation equipment, a defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation capability, and anesthesia support.
- xiv. Data will be maintained on all CAS procedures and analyzed routinely to ensure patient safety. The data will be used for re-credentialing by CMS. The data will be made available to CMS upon request.

C. Documentation:

1. Documentation regarding the procedure and the patient response and condition during/after the procedure will be completed in the medical record per department policy.

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed

VII. REFERENCES

- A. **Centers for Medicare & Medicaid Services.** (2023). *Percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting: Decision memo (NCAId 311)*. Medicare Coverage Database. Retrieved July 24, 2025, from <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=311>
- B. **US Department of Health and Human Services.** (2007). *Medicare decision memorandum for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery with Stenting*. Retrieved April 20, 2014, from <http://www.cms.hhs.gov/>.

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
Cath Lab Medical Director - Dr. Zetterland	Megan Giovanetti: Director Cardiovascular Services and Sleep	10/2025
CNO	Carla Spencer: Chief Nursing Officer	09/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	09/2025
Policy Owner	Megan Giovanetti: Director Cardiovascular Services and Sleep	09/2025

Standards

No standards are associated with this document



Origination	N/A
Last Approved	N/A
Next Review	3 years after approval

Owner	Jessica Graziano: Manager Rehab Services
Area	Rehabilitation

Complete Decongestive Therapy for Management of Lymphedema

I. POLICY STATEMENT

- A. N/A

II. PURPOSE

- A. To guide the staff in providing Complete Decongestive Therapy for the management of Lymphedema.

III. DEFINITIONS

- A. PT: Physical Therapist
- B. OT: Occupational Therapist
- C. MLD: Manual Lymphatic Drainage
- D. RN: Nurse
- E. CDT: Complete Decongestive Therapy

IV. GENERAL INFORMATION

- A. Lymphedema bandaging is a multilayer system of short stretch, non-elastic pure cotton bandages, which are applied over padding to create compression and comfort around the circumference of the involved area.
- B. The therapeutic effects of bandaging in the treatment of Lymphedema are;
 - 1. A reduction in the return of lymph to the involved area once mobilized by MLD
 - 2. A reduction in the production of new lymph via ultra-filtration by increasing tissue pressure

3. An increase in re-absorption of other lymphatic loads by increasing tissue pressure
 4. An improvement in the efficiency of the muscle and joint pumps as a lymph propellant
 5. A mechanical manipulation and improvement in lymphatic fibrosis as movement is performed.
- C. PTs and OTs performing CDT and/ or applying multilayer bandaging for lymphedema management as long as the following criteria are met;
1. An order from the patient's physician is in the medical records
 2. The patient meets the "indications" criteria and clinical assessment does not show evidence of contraindications.
- D. The PT and/or OT has received training and education in this process and their certification/ training has been documented.

V. PROCEDURE

- A. Clinicians providing CDT therapy for patients will follow Evidence based practice
- B. Patients being managed and monitored for any evidence of excessive compression (e.g. pallor or cyanosis of toes, complaints of pain, diminished sensation). Patients and/or family members will be educated on these signs/ symptoms as well. If sign/symptoms present, the bandages will be removed promptly
- C. The bandaging will be changed as needed per therapists' protocol.
- D. Patients will be assessed by the therapists as to whether they benefit from application.
1. Precautions
 - a. Hypertension
 - b. Mild Arterial Disease
 - c. Limb paralysis
 - d. Diabetes
 - e. History of Congestive Heart Failure (Seek physician approval)
 2. Contraindications
 - a. Acute Infections
 - b. Moderate to advanced heart failure
 - c. Acute Deep Venous Thrombosis
 - d. Uncontrolled Hypertension
 - e. Advanced arterial disease
 - f. Malignancy
 - g. Advanced Renal Disease
- E. Documentation (This will be at the end of the procedure and if there is no specific

documentation then type N/A)

VI. EDUCATION/TRAINING

A. Education and/or training is provided as needed.

VII. REFERENCES

- A. Tzani I, Tsihlaki M, Zerva E, Papathanasiou G, Dimakakos E. Physiotherapeutic rehabilitation of lymphedema: State-of-the-art. *Lymphology*. 2018 Jul 2;51(1):1-2.
- B. Executive Committee. The diagnosis and treatment of peripheral lymphedema: 2016 consensus document of the International Society of Lymphology. *Lymphology*. 2016 Mar 21;49(4):170-84.
- C. Michopoulos E, Papathanasiou G, Vasilopoulos G, Polikandrioti M, Dimakakos E. Effectiveness and Safety of Complete Decongestive Therapy of Phase I: A Lymphedema Treatment Study in the Greek Population. *Cureus*. 2020 Jul 19;12(7).
- D. Cohen SR, Payne DK, Tunkel RS. Lymphedema: strategies for management. *Cancer: Interdisciplinary International Journal of the American Cancer Society*. 2001 Aug 15;92(S4):980-7.
- E. Norton School of Lymphedema Course Manual for Manual Lymph Drainage/ CDT certification Training 2004-2013

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
ELG	Rebecca Alaga: Regulatory/ Accreditation Coordinator	10/2025
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Policy Owner	Jessica Graziano: Manager Rehab Services	08/2025

Standards

No standards are associated with this document



Origination 07/2022
Last Approved N/A
Next Review 3 years after approval

Owner Megan Giovanetti:
Director
Cardiovascular Services and Sleep

Area Cardiology Departments

Echocardiography Lab Quality Assurance / Quality Review Process and Correlation

I. POLICY STATEMENT

A. N/A

II. PURPOSE

- A. To ensure and provide guidelines to meet the following goals:
1. Perform high uniform quality exams
 2. Prepare complete and accurate reports
 3. Ongoing education to improve knowledge and technique
 4. Continuous compliance with IAC Standards for Echocardiography Accreditation

III. DEFINITIONS

A. IAC - Intersocietal Accreditation Commission

IV. GENERAL INFORMATION

- A. The Quality Improvement Program includes:
1. Test Appropriateness
 2. Technical Quality Review (Sonographer Performance Variability)
 3. Interpretative Quality Review (Physician Interpretation Variability)
 4. Final Report Completeness and Timeliness

5. Correlation
6. QI Documentation and Record Retention
7. Quality Improvement Meetings

V. PROCEDURE

- A. **Test Appropriateness:** 10 consecutive cases will be sampled quarterly for appropriate use and scored. The reference for scoring is the Appropriate Use Criteria for Echocardiography, JASE March 2011 and ASE 2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease. Scoring will be categorized as appropriate/usually appropriate, may be appropriate, or rarely appropriate/usually not appropriate. Findings are compiled using the Salinas Valley Health Medical Center (SVHMC) Appropriate Use Criteria spreadsheet.
- B. **Technical Quality Review (Sonographer Performance Variability):** Quarterly two echocardiographic exams will be reviewed at random for each sonographer on staff. The Sonographer Performance Variability Checklist will be utilized to review:
 1. Technical quality of images for clarity and/or evaluation of suboptimal images or artifact
 2. Completeness of the procedure
 3. Adherence to department imaging protocol

A summary of these reviews will be reported on Echocardiography Lab QI Sonographer Performance Variability Form.

- C. **Interpretative Quality Review (Physician Interpretation Variability):** Two cases per month will be reviewed as part of the Echo Lab QI program. All cases are selected randomly, blinded and reviewed confidentially. The QAS Physician Review Form is utilized. The review includes but is not exclusive to
 1. Quality of accuracy of interpretation based on acquired images
- D. **Final Report Completeness and Timeliness:** 25 randomly selected reports will be sampled each quarter for timeliness and completeness. The selected reports must represent as many physicians as possible. Inpatient routine echocardiograms should be read within 48 hours, outpatient exams should be read within 48 hours or by the end of the next business day, urgent echoes within 12-24 hours and STAT echoes within 60 minutes. Review of the reports will be evaluated for compliance to IAC standards:
 1. Report components (demographics, 2D, M-mode, Doppler)
 2. Standard report format
 3. Evaluation of required cardiac structures and valves
 4. Free of misinterpretations or inconsistencies
 5. Time from study to final report

A Timeliness report can be queried in the Cardiology PACS. A TTE (Transthoracic

Echocardiogram) Report Checklist for Completeness is used. A summary of findings is reported on the Quarterly Report Timeliness and Completeness Worksheet.

- E. **Correlation:** Two cases per quarter will be chosen and correlation evaluated with other appropriate imaging modalities, cardiac CT, MRI, cardiac catheterization, nuclear perfusion studies, and surgical findings. Several PACS reports are available to query for patients having Cath and Echo, Lexiscan stress test and Echo, and Cath and Echo for aortic stenosis. Findings are reported on the Correlation of Documentation Form. Findings are submitted to the Medical Director as part of Echo Dept QA and distributed to the interpreting physicians.
- F. **QI Documentation and Record Keeping:** All QI documentation (QI measures, summary of findings, meeting minutes) are maintained on the Cardiopulmonary Dept shared drive, folder title IACL. The Technical Director will upload quarterly findings for all measures into the meeting minute's template. The Medical Director reviews and discusses findings with staff in attendance. Staff unable to attend will review meeting minutes via email, read receipt required. The Technical Director will add their name to the minutes. The Medical Director or designee is responsible for any corrective action, education, communication associated with findings and recording recommended action within the meeting minutes.
- G. **Quality Improvement Conference:** Two QI meetings per year will be held to review and discuss quality measures. All staff, sonographers and cardiologists, must attend one meeting per year. These conferences may be held in conjunction with other regularly scheduled meetings such as Cardiology Executive Committee or Cardiac Case conference. Minutes and attendance will be recorded by the Technical Director or designee (refer to QI Documentation and Record Keeping).
- H. Documentation:
 - 1. All documentation is in the IAC folder in the Cardiopulmonary Dept shared drive.

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed.

VII. REFERENCES

- A. Intersocietal Accreditation Commission Standards and Guidelines for Adult Echocardiography Accreditation April 1, 2025.
- B. ASE 2019 Appropriate use Criteria for Multimodality Imaging in the Assessment of Cardiac Structures and Function in Nonvalvular Heart Disease.
- C. JASE 2011 Appropriate Use Criteria for Echocardiography

Approval Signatures

Step Description

Approver

Date

Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
Cath Lab Medical Director - Dr. Zetterland	Megan Giovanetti: Director Cardiovascular Services and Sleep	10/2025
CNO	Carla Spencer: Chief Nursing Officer	09/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	09/2025
Policy Owner	Megan Giovanetti: Director Cardiovascular Services and Sleep	09/2025

Standards

No standards are associated with this document



Origination	05/2018
Last Approved	N/A
Next Review	3 years after approval

Owner	Aisha Huebner: Director Perioperative Services
Area	Perioperative Services

Instrument Preventative Maintenance

I. POLICY STATEMENT

A. N/A

II. PURPOSE

A. To maintain the optimum quality and integrity of surgical instruments in the operating room.

III. DEFINITIONS

- A. AORN – Association of Operating Room Nurses.
- B. AAMI – Association of the Advancement of Medical Instrumentation.
- C. SSPD – Surgical Sterile Processing Department.

IV. GENERAL INFORMATION

A. N/A

V. PROCEDURE

- A. A certified instrument technician trained in the field of refurbishment and instrument maintenance will do visual inspection, evaluation of mechanical operation and needed refurbishment of instruments for the operating room. This will be done annually on a rotating schedule as follows:
 - 1. Quarter 1
 - a. General Major & Minor Sets for refurbishment.
 - b. Plastics, Ortho, Neuro Sets inspected and evaluated, repairs as needed.

2. Quarter 2
 - a. General Major & Minor Sets inspection evaluated, repairs as needed.
 - b. Ortho and Neuro sets for refurbishment.
 3. Quarter 3
 - a. General Major, Minor, Plastic Sets inspected, repaired as needed.
 - b. Endoscopy instruments inspected, repaired and refurbished as needed.
 4. Quarter 4
 - a. General Major, Minor, Plastic sets inspected, repaired as needed.
- B. Operating Room and Surgery Sterile Processing staff will visually inspect all instrumentation before use for proper operation and safe use and remove non-operational instruments from service.
1. A complete inspection, adjustment and refurbishment of instruments will be done as needed by a certified instrument technician.
- C. Documentation:
1. Vendor Audit Reports of repair/services.

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed.

VII. REFERENCES

- A. AAMI – Association for the Advancement of Medical Instruments.
- B. AORN Recommended Practices for Perioperative Nursing.

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
ELG	Rebecca Alaga: Regulatory/ Accreditation Coordinator	10/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	09/2025

Policy Owner

Aisha Huebner: Director
Perioperative Services

08/2025

Standards

No standards are associated with this document



Origination 06/2022
Last Approved N/A
Next Review 3 years after approval

Owner Daniela Jago:
Clinical Manager
Area Women's and
Children's
Services

Magnesium Sulfate in the Obstetric Patient

I. POLICY STATEMENT

A. N/A

II. PURPOSE

A. To guide the staff in the nursing management of magnesium sulfate administration in the obstetric patient.

III. DEFINITIONS

- A. DTR – deep tendon reflexes
- B. FHR – fetal heart rate
- C. Independent double check - An independent double check is defined as verification of the drug, dose concentration (calculations), dose rate settings, and verification of the correct patient. It is a process in which a second practitioner conducts a verification independent of the first practitioner.

IV. GENERAL INFORMATION

- A. Magnesium sulfate is a high alert medication and requires an independent double check by two (2) RNs prior to administration, when titrating the medication, changing the medication bag, and when care is transferred from one RN to another. (See [MEDICATION USE](#))
- B. The American College of Obstetricians and Gynecologists support the use of magnesium sulfate in obstetric care for appropriate conditions and for appropriate durations of treatment, which include the following:
 - 1. Prevention and treatment of seizures in women with preeclampsia or eclampsia
 - 2. Fetal neuroprotection before anticipated early preterm (less than 32.0 completed weeks gestation) delivery

- a. Recommended that the duration is limited to ≤ 24 hours
- C. Short-term prolongation of pregnancy (up to 48 hours) to allow for administration of antenatal corticosteroids in pregnant women who are at risk of preterm delivery within 7 days. Tocolysis is not recommended beyond 34 weeks of gestation, and it is generally not recommended before 24 weeks of gestation but may be considered based on individual circumstances at 23 weeks.
- D. Contraindications specific to magnesium sulfate administration include, but are not limited to heart block, myocardial damage, anuria, and Myasthenia Gravis.
- E. Magnesium sulfate should always be administered using an infusion pump, utilizing the guardrails library on the infusion pump. When magnesium sulfate is discontinued, turn off the infusion pump, close the roller clamp, and disconnect the tubing from the mainline IV.
- F. Magnesium sulfate should never serve as the primary or mainline IV and should be piggybacked into the mainline tubing at the most proximal site to the patient.
- G. Pregnant or postpartum patients may need a higher level of care and may receive magnesium sulfate administration on other care units. If needed, staff is encouraged to consult with labor/delivery or mother/baby charge RN.

V. PROCEDURE

- A. Label IV tubing with a magnesium sulfate sticker.
- B. Remain with the patient continuously during initial bolus.
- C. Assess and document vital signs every 15 minutes during the first hour of administration and every 30 minutes during the second hour.
- D. After 2 hours, assess and document vital signs hourly.
- E. Assess deep tendon reflexes (DTRs) every 2 hours. If DTRs are absent, stop the infusion, order STAT magnesium levels, and notify the physician.
- F. Assess oxygen saturation hourly.
- G. Auscultate lung sounds every 2 hours.
- H. Complete the **Magnesium Sulfate Checklist** every four (4) hours:
 - Deep tendon reflexes present
 - Respiratory rate greater than 12/minute
 - O₂ saturation $\geq 95\%$
 - Total urine output equal to or greater than 120 mL during the last 4-hour period
 - Medication, pump settings, safety label, and infusion rate verified by RN
- I. Observe for signs of magnesium toxicity. If toxicity is suspected, turn off infusion and notify physician. Signs of magnesium toxicity include:
 - Hypotension
 - Loss of DTRs
 - Respiratory depression

- Respiratory arrest
 - Oliguria
 - Shortness of breath
 - Chest pain
 - Abnormal cardiac rhythm
- J. Calcium gluconate is used for magnesium toxicity and is stored in the automated dispensing cabinet in Labor & Delivery, and Mother Baby. Administer 1gram (10 mL of a 10% solution) IV over 1-2 minutes.
- K. Documentation:
1. Document fetal assessment per [FETAL HEART RATE MONITORING](#) according to high risk criteria while magnesium sulfate is administered.
 2. Magnesium sulfate checklist every 4 hours
 3. Document independent double check of magnesium sulfate by two RNs when initiating or titrating the medication, hanging a new bag of medication, and at handover.

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed.

VII. REFERENCES

- A. American College of Obstetricians and Gynecologists. (2020). Gestational hypertension and preeclampsia. (Practice Bulletin No. 222). Washington, D.C.
- B. American College of Obstetricians and Gynecologists. (2016; reaffirmed 2020). Management of preterm labor. (Practice Bulletin No. 171). Washington, D.C.
- C. American College of Obstetricians and Gynecologists. (2018; reaffirmed 2023). Magnesium sulfate before anticipated preterm birth for neuroprotection. Committee opinion 455. Washington, D.C.
- D. Simpson, K., & Creehan, P., O'Brien-Abel, N., Roth, C., Rohan, A. (2021). *Perinatal nursing*. (5th ed.). Philadelphia: Lippincott, Williams & Wilkins.

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending

Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
Women & Children's Service	Katherine DeSalvo: Director Medical Staff Services	10/2025
CNO	Carla Spencer: Chief Nursing Officer	08/2025
Director of WCS	Julie Vasher: Director Women's & Children's Services	08/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	08/2025
Policy Owner	Daniela Jago: Clinical Manager	08/2025

Standards

No standards are associated with this document



Origination	06/2022
Last Approved	N/A
Next Review	3 years after approval

Owner	Daniela Jago: Clinical Manager
Area	Women's and Children's Services

Maternal and Newborn Substance Abuse Evaluation

I. POLICY STATEMENT

A. N/A

II. PURPOSE

- A. To guide staff in the identification, evaluation, treatment, and referral for infants with known or suspected exposure to drugs and/or alcohol during the prenatal period.
- B. To guide the staff regarding toxicology screening of mothers and infants pre- and post-delivery at Salinas Valley Health Medical Center (SVHMC) and provide the correct protocol to follow if infant testing is positive.

III. DEFINITIONS

A. N/A

IV. GENERAL INFORMATION

- A. Informed consent is not required to complete maternal or infant toxicology testing provided there are medical indicators and the test will be used only for the purpose of determining appropriate medical treatment. If results are to share with a state agency such as Child Protective Services, it is recommended that informed consent is obtained and documented in the electronic health record.
- B. Infants who have suspected or confirmed exposure to drugs and/or alcohol will have an evaluation performed. The evaluation may consist of toxicology screens, physical histories of mother and infant and psycho-social history of mother/family. An evaluation will be completed on any patient meeting the following criteria:
 - Signs and symptoms of neonatal abstinence syndrome may not be exhibited for up to 72 hours

- Most common signs and symptoms of neonatal abstinence syndrome are central nervous system hyperirritability, gastrointestinal dysfunction, respiratory distress, and autonomic instability.
 1. Restlessness
 2. Tremors (disturbed to undisturbed)
 3. High pitched cry
 4. Increased muscle tone
 5. Irritability and inconsolability
 6. Increased deep tendon reflexes
 7. Exaggerated Moro reflex
 8. Seizures
- Maternal history of drug or alcohol use, present or past.
- Any mother with signs and/or symptoms suggestive of drug/alcohol abuse.
- Medical conditions that have signs and symptoms that mimic drug withdrawal (e.g. sepsis) and have been ruled out.
- Any mother with inadequate pre-natal care (< three visits).
- Any mother equal to or less than seventeen (17) years of age.
- Maternal history of abruption placenta.
- Any mother with unexplained hypertension or unexplained vascular accidents (e.g. CVA or MI).

C. HOW TO USE THE NEONATAL ABSTINENCE SCORING SYSTEM

1. Neonatal Abstinence Scoring System assists in the detection of the onset of withdrawal symptoms and charts the progression and response to therapeutic intervention.
2. Scoring system can be used to assess withdrawal from opioids and non-lipid CNS depressants
3. Assess high-risk infants 2 hours after birth and then every 4 hours.
4. If, at any point, the score is 8 or greater, the scoring should be initiated every 2 hours and should be continued for at least 24 hours.
5. If pharmacotherapy is not needed, the infant is scored for the first 96 hours of life.
6. If the infant scores 8 or higher on three consecutive scoring times, the infant should be evaluated for pharmacotherapy.
7. Because NAS symptoms simulate common neonatal metabolic conditions such as hypoglycemia, hypocalcemia, sepsis, and meningitis, a complete blood cell count and calcium and glucose levels should be obtained before therapy is initiated.

D. PHARMACOLOGICAL TREATMENT OF NAS

1. Pharmacologic treatment is commenced only if withdrawal is not controlled by

supportive measures.

2. Opiates do not make the infant drowsy or interfere with infant feeding and they are effective in controlling gastrointestinal disturbances.
3. Once withdrawal is under control, pharmacologic treatment can be gradually withdrawn.
4. Control is defined as meeting the following conditions:
 - a. Scores of 8 or less.
 - b. Easily consolable infant.
 - c. Rhythmic sleep and feeding cycle.
 - d. Steady weight gain.

V. PROCEDURE

- A. The hospital will comply with California Health and Safety Code § 123605 regarding the application and use of an assessment of the needs of, and a referral for, substance abuse exposed infants to a county welfare department. The assessment of the needs shall be performed by a health practitioner, as defined in Section 11165.8 of the Penal Code, or a medical social worker.
- B. The needs assessment shall be performed before the infant is released from the hospital. The purpose of the needs assessment is to do all of the following:
 - Identify needed services for the mother, child, or family including, where applicable, services to assist the mother in caring for her child and services to assist in maintaining children in their homes.
 - Determine the level of risk to the newborn upon release to the home and the corresponding level of services and intervention, if any, necessary to protect the newborn's health and safety, including a referral to the county welfare department for child welfare services.
 - Gather data for information and planning purposes.
- C. A positive toxicology screen (mother or infant) at the time of delivery is not in and of itself a sufficient basis for reporting child abuse or neglect, but should lead to an assessment.
- D. Neonatal Drug Withdrawal Procedure: The Mother/Baby Unit staff or the Neonatal Intensive Care Unit (NICU) nurses, with a physician's order, will be responsible for the following:
 - Collection of urine specimen:
 1. Obtain a 1cc minimum of urine and send to the Laboratory for a toxicology screen.
 2. Urine may be collected from several voids until sufficient amount is obtained. Collected urine is to be stored in the refrigerator.
 3. The specimen is to be labeled per SVHMC policy, refer to [SPECIMEN TRANSPORT PROCEDURE](#) as needed.
- E. Qualitative toxicology testing is performed on the Chemistry Analyzer for the following

substances:

- Amphetamines
- Barbiturates
- Benzodiazepines
- Cannabinoids
- Cocaine
- Fentanyl
- Methamphetamines
- Opiates
- PCP

- F. Any positive result shall have a confirmation specimen sent to a reference laboratory. Additional toxicology testing may be ordered and performed by the reference laboratory.
- G. Healthcare personnel will notify the hospital Social Services Department of all suspected drug/ alcohol exposure by Social Services Consult via the electronic health record (EHR) system. On weekends or off hours when a hospital social worker is not available, it will be necessary for the RN to contact the "on-call" Child Protective Services (CPS) social worker if needing to file a Suspected Child Abuse Report by calling 831-755-4661 and following-up with a written report within 72 hours by faxing form SS8583 to Monterey County Department of Family and Children's Services at 831-796-8529.
- The hospital Social Worker will:
 1. Make referrals to the Monterey County Public Health Nurse and the Suspected Child Abuse Network (SCAN) team (utilize Child Abuse Investigation Report Form SS 8583).
 2. Coordinate with Perinatal Services staff and the CPS Social Worker.
 3. Send all Child Protective Services forms to the Monterey County Department of Family and Children's Services.
- H. Physicians may prescribe sedation if indicated. Indications include, but are not limited to:
- Seizures;
 - Persistent vomiting and/or poor feeding for a period of time > 48 hours;
 - Respiratory distress in addition to poor feeding and/or diarrhea;
 - Prolonged (>5 days) withdrawal;
 - Withdrawal score > 8 or higher on three (3) consecutive scorings using the Neonatal Abstinence scoring screen in the EHR.
- I. The infant may be placed on police hold if directed by the Policy Department in collaboration with Child Protective Services (CPS) of Monterey County:
- Police holds will be arranged by the CPS of Monterey County
 - The infant would be placed in protective custody by CPS of Monterey County until placement can be arranged.

- CPS may forgo a police hold and instead detain the child from Court.
- Infants may be discharged when cleared by CPS of Monterey County.

J. Infant Pre-delivery

- A urine drug test may be completed on the mother prior to infant delivery if there is suspected substance abuse based on clinical presentation of presenting behaviors. Informed consent may be required if this result may be shared with a state agency.

K. Documentation:

1. Completion of Neonatal Abstinence screen in the EHR.
2. Child Abuse Investigation Report Form SS 8583 https://post.ca.gov/portals/0/post_docs/publications/child_abuse/Suspected_Child_Abuse_Report.pdf

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed

VII. REFERENCES

- A. California Health and Safety Code § 123605
- B. California Penal Code §11165.8
- C. Gardner, S., Carter, B., Enzman-Hines, Mary & Niermeyer, S. (2021). Merenstein & Gardner's Handbook of Neonatal Intensive Care. (9th ed.). St. Louis: Elsevier.Gardner

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
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Policy Owner	Daniela Jago: Clinical Manager	08/2025

Standards

No standards are associated with this document



Origination 07/2022
Last Approved N/A
Next Review 3 years after approval

Owner Julie Johnson:
Clinical Manager
Area Women's and
Children's
Services

Neonatal Medication Administration

I. POLICY STATEMENT

A. N/A

II. PURPOSE

A. To guide the nurse in administration of medication to the neonate.

III. DEFINITIONS

A. N/A

IV. GENERAL INFORMATION

- A. Neonatal medications may be administered by an RN who has successfully passed the Neonatal Medication Test, IV Therapy nursing competencies and has been oriented to the Department of Women's / Children's Services.
- B. Refer to [MEDICATION USE](#).
- C. Use at least two (2) patient identifiers – patient's name and date of birth [PATIENT IDENTIFICATION POLICY](#).

V. PROCEDURE

- A. Administer medications as recommended by manufacturer and pharmacological resources. [MEDICATION USE](#)
- B. PO Medications
 - 1. **Nipple:** Medications may be administered by nipple. May add 1 to 2 ml's of formula or breast milk for dilution and allow infant to suck.
 - 2. **Syringe:** The medication should be placed on the front portion of the tongue very

slowly. Placing it on the back portion of the tongue may cause gagging, regurgitation, and/or aspiration.

3. **Volufeeders:** If infant is a good feeder, medications may be mixed with a small amount of formula or breast milk (usually 5-10 ml's) in a volufeeder.
4. **Gavage:** If gavage feeding, the medication may be given by gavage tube. To ensure complete delivery of the medication, back the medication with a small amount of formula (if not feeding, back with small amount of air).

C. IM/ SQ Medications

1. Use preservative-free diluents.
2. Check that drug concentration is a pediatric dilution.
3. A filter needle is used to withdraw medication from ampules.
4. Maximum volume of injection at any one site should not exceed one (1) ml.
5. Buttocks are **NOT** used as an injection site.
6. The right or left vastus lateralis are the preferred site. The deltoid muscle may be used with physician order.
7. Rotate sites. Inject slowly.

D. I. V. Medications (Administered **ONLY** in the NICU):

1. Always check dilution required for each medication.
2. A filter needle is used to withdraw medications from ampules.
3. Continue primary IV infusion when possible.
4. Refer to manufacturer and pharmacological resources for administration recommendations. In general:
 - a. **Emergency Drugs:** Injected directly through the most proximal port. Medication should be followed with adequate flush to ensure delivery to the infant.
 - b. **Routine Drugs:** May be given slow push through the most proximal port, or delivered volume/time with infusion pump. Infusion pump is the preferred method of delivery.

E. Document administration in Medication Administration Record (MAR) in the patient's electronic health record (EHR).

F. Record I&O as appropriate.

VI. EDUCATION/TRAINING

A. Education and/or training is provided as needed

VII. REFERENCES

A. Verklan, M.T. & Walden, M. (2020) Core Curriculum for Neonatal Intensive Care Nursing (6th

Ed.) – a joint publication of the Association of Women's Health, Obstetric and Neonatal Nursing, American Association of Critical Care Nurses, & the National Association of Neonatal Nurses.

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
NICU Medical Director	Robert Castro: PHYSICIAN	10/2025
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Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	08/2025
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Standards

No standards are associated with this document



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Last N/A
Approved
Next Review 3 years after approval

Owner David Thompson:
Director Nursing
Area Administration

Newborn Abandonment

I. POLICY STATEMENT

- A. Salinas Valley Health Medical Center (SVHMC) Emergency Department Registered Nurse (RN) will be designated to accept physical custody of a newborn appearing to be up to seventy-two (72) hours old that is voluntarily surrendered by a parent or other person with legal custody. A medical screening examination and any necessary medical care will be provided to the newborn. No identifying information regarding the parent or the newborn will be asked.
- B. SVHMC will post signs bearing the state approve logo that notifies the public of the location where the newborn may be safely surrendered.

II. PURPOSE

- A. To establish procedures in the event a newborn, who appears to be up to seventy-two (72) hours old, is voluntarily surrendered by a parent or other person with legal custody to a designated employee on duty at the Hospital Emergency Department and to ensure these procedures are in compliance with California State Newborn Abandonment Law (SB 1368). The intent of the law is to encourage parents who would otherwise abandon their babies in unsafe environments to leave their newborn in a safe environment.

III. DEFINITIONS

- A. Newborn: Any baby up to seventy-two (72) hours old whose custody is surrendered by a parent or individual who has lawful custody.

IV. GENERAL INFORMATION

- A. N/A

V. PROCEDURE

- A. The Administrative Supervisor will designate appropriate personnel to accept physical custody of the newborn. The Emergency Medical Treatment and Active Labor Act (EMTALA) will apply to abandoned newborns.
- B. Parents/custodians presenting at areas other than the Emergency Department who indicate their intention to voluntarily surrender their newborn to SVHMC should be physically escorted to the Emergency Department. If the parent/custodian is reluctant to go to the Emergency Department and wants to simply leave the newborn, staff should inform the parent/custodian that he/she is not designated to accept newborns being surrendered and the employee needs to physically escort the parent/custodian to the Emergency Department. If the parent(s)/custodian(s) refuses to go to the Emergency Room and the infant is surrendered to personnel other than an Emergency Department RN, that employee/staff needs to take the infant to the Emergency Department.
- C. Upon assuming physical custody, the Emergency Department RN will take the newborn directly to the Emergency Department treatment area.
- D. **NOTIFY CHILD PROTECTIVE SERVICES (CPS) IMMEDIATELY AND DOCUMENT SUCH IN THE EMERGENCY ROOM CHART. PROVIDE THEM WITH THE INFORMATION AS REQUESTED. WHEN CPS IS NOTIFIED, THEY THEN ASSUME TEMPORARY LEGAL CUSTODY OF THE INFANT. THIS NOTIFICATION WILL TAKE PLACE NO LATER THAN FORTY-EIGHT (48) HOURS AFTER TAKING CUSTODY.**
- E. Initiate an ED chart, medical screening examination and any necessary stabilizing treatment. Initiate the medical records as "Baby John/Jane Doe".
 1. Consent from the parent or person with legal custody is not required to provide examination and treatment of the newborn.
 2. Notify the Nursery RN, who will come to the ED to assist in care.
 3. Obtain an "Abandonment of Newborn" packet from triage drawer in the ED triage desk, which will include the following:
 - a. Numerical identification bands (2) for the infant.
 - b. Corresponding numerical identification band to be given to the person surrendering newborn. (DO NOT ask the person for any identification).
 - c. Family medical questionnaire with four (4) digit identification band number noted on it.
 - i. Medical questionnaire will be in 12-point font type and read as follows:

NOTICE: THE BABY YOU HAVE BROUGHT IN TODAY MAY HAVE SERIOUS MEDICAL NEEDS IN THE FUTURE THAT WE DON'T KNOW ABOUT TODAY. SOME ILLNESSES, INCLUDING CANCER, ARE BEST TREATED WHEN WE KNOW ABOUT THE FAMILY MEDICAL HISTORY'S. IN ADDITION, SOMETIMES RELATIVES ARE NEEDED FOR LIFE-SAVING TREATMENTS. TO MAKE SURE THIS BABY WILL HAVE A HEALTHY FUTURE, YOUR ASSISTANCE IN

*COMPLETING THIS QUESTIONNAIRE FULLY IS ESSENTIAL.
THANK YOU.*

- ii. Hospital self-addressed, stamped envelope with attn: Emergency Department Director.
 - iii. Provide CPS phone number to the parent/custodian (831-755-4475).
 - iv. Referral numbers should be provided to the surrendering person.
- F. Place the newborn ID bands on the each of the newborn's ankles. Make a "good faith effort" to give the corresponding adult ID band to the person surrendering the newborn to facilitate reclaiming the newborn later.
- G. Clearly document the 4-digit ID band number on the newborn's medical record.
- H. Provide, or make good faith effort to provide, medical information questionnaire to the person surrendering the newborn and ask that person to complete the family medical history questionnaire and ensure them their identity will not be questioned Inform them that the information obtained will allow us to better care for the infant. The person may decline to complete the questionnaire; ask the surrendering person to complete it and return it at a later date. Give the surrendering person a stamped, self-addressed envelope with the questionnaire.
- I. Once the medical screening, examination and stabilizing medical care have been provided, the ED Physician will contact the Physician on call for Pediatrics to arrange for the infant to be admitted if medically indicated.
- J. Notify the Administrative Supervisor who will then notify Administration, Patient Experience, Public Relations, Risk Management and Security.
- K. *Note:* If a person surrendering the newborn returns to reclaim the infant, contact the Administrative Supervisor immediately.
- 1. If the parent or other person surrendering the newborn requests the hospital to return the newborn to her/him, the hospital must do so if it still has custody and if the dependency petition has not yet been filed.
 - 2. If the designated RN has any doubts as to whether the person attempting to reclaim a newborn is indeed the person who surrendered the newborn, the Administrative Supervisor should be contacted and legal counsel should be contacted immediately. Possession of the ankle bracelet identification in and of itself does not establish parentage or a right to custody of the child.
 - 3. If the dependency petition has not already been filed, the person surrendering the newborn may reclaim the newborn within fourteen (14) days.
 - 4. If the hospital still has physical custody of the newborn at the time the newborn is reclaimed, the hospital must obtain a copy of the court order and review it before releasing the newborn. Legal counsel shall be contacted if there are any questions regarding the release of an abandoned newborn.
 - 5. **Confidentiality.** SVHMC must maintain the confidentiality of any identifying information that pertains to a parent or individual who surrenders a newborn pursuant to the safe surrender law that is obtained as a result of the questionnaire or in any other manner. Identifying information must not be disclosed by any personnel

of a safe surrender site that accepts custody of a surrendered newborn.

6. The voluntary surrender of a newborn in accordance with the law is not in and of itself a sufficient basis for suspecting abuse or neglect.
7. Make sure the Charge Nurse Checklist and the Administrative Supervisor Checklist are completed. The Administrative Supervisor Checklist is to be given to the Administrative Supervisor, who will make sure it is delivered to Administration. The Charge Nurse ChecklistattD is to stay with the newborn's medical record.

L. Documentation:

1. The Emergency Room chart will document the disposition of the newborn and notification of Child Protective Services (CPS).
2. Staff education will be documented in each employee's In-service Record.

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed

VII. REFERENCES

- A. [California Newborn Abandonment Law \(SB 1368, Brulte\)](#).
- B. California Hospital Association Consent Manual, Pages 10.3 – 10.5 and Form 10-5.
- C. Health and Safety Code Section 1255.7
- D. Welfare and Institutions Code, Section 319

Approval Signatures

Step Description	Approver	Date
Board Approval	Kathryn Haines: Administrative Assistant - PD	Pending
Board Approval	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
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Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	10/2025
Policy Owner	David Thompson: Director Nursing	08/2025

Standards

No standards are associated with this document



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Approved
Next Review 3 years after approval

Owner Karina Kessler:
Clinical Manager
Area Women's and
Children's
Services

NICU Family Centered Care/Parent Participation

I. POLICY STATEMENT

- A. Patient-centered care is crucial in the prevention of medical errors. Families are the core to delivering patient-centered care in the NICU, making family-center care vital to promoting patient safety.

II. PURPOSE

- A. To encourage parent/guardian participation and to foster a family centered care environment.
- B. To incorporate the family's cultural values and perspectives into an individualized plan of care for each infant.
- C. To promote the development of partnerships between healthcare professionals and families that capitalizes on the expertise of both.

III. DEFINITIONS

- A. N/A

IV. GENERAL INFORMATION

- A. Family Centered Care (FCC) is a philosophy of care in which the pivotal role of the family in the lives of infants is recognized and respected.
- B. The core concepts of FCC include the following:
- Dignity and Respect
 - Information sharing
 - Collaboration
 - Participation

V. PROCEDURE

- A. The multidisciplinary healthcare team will collaborate with parents/guardians about the care of their infant, respecting their choices and decisions.
- B. All members of the healthcare team are responsible for assessing the parents'/guardians' understanding of their infants' illness and the skills required to care for them.
- C. All healthcare providers will participate in teaching needed skills, evaluate the teaching provided, and make appropriate referrals when necessary.
- D. Families are invited to participate in patient discharge rounds.
- E. Parent education and return demonstration may include but are not limited to:
 - Diapering
 - Bathing
 - Feeding
 - Auxiliary temperature
 - Comfort/Calming techniques
 - Medication administration
 - CPR instructions
 - Suctioning
 - Assessing their infants stress cues
 - Home care equipment or oxygen needs
 - Any special procedure that will be a part of care giving
 - Infant safety (i.e. car seat, bulb syringe)
- F. As parents/guardians learn required care-giving skills they are encouraged to participate in infant's day-to-day care.
- G. The multidisciplinary plan of care is developed, reviewed and revised in collaboration with parents/guardians. Interdisciplinary decision making regarding the plan of care takes place at least once a week during multidisciplinary discharge rounds.
- H. Documentation:
 - 1. Family education and family conferences are documented in the electronic health record.

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed

VII. REFERENCES

- A. American Academy of Pediatrics & American College of Obstetricians and Gynecologists. (2018). Guidelines for Perinatal Care (8th edition). American Academy of Pediatrics;

Washington, DC: American College of Obstetricians and Gynecologists.

- B. National Association of Neonatal Nurses. (2023). Developmental Care of Newborns and Infants; A guideline for health professionals (3rd edition). National Association of Neonatal Nurses; Wolters Kluwer

Approval Signatures

Step Description	Approver	Date
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Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
NICU Medical Director	Robert Castro: PHYSICIAN	10/2025
CNO	Carla Spencer: Chief Nursing Officer	08/2025
Director of Women's and Children's Services	Julie Vasher: Director Women's & Children's Services	08/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	08/2025
Policy Owner	Karina Kessler: Clinical Manager	08/2025

Standards

No standards are associated with this document



Origination	03/2024
Last Approved	N/A
Next Review	1 year after approval

Owner	Genevieve delos Santos: Director Pharmacy
Area	Pharmacy

Pharmacy - Sterile Compounding

I. POLICY STATEMENT

A. N/A

II. PURPOSE

A. The Salinas Valley Health Medical Center (SVHMC) Pharmacy Department shall be responsible for the safe and accurate preparation and dispensing of compounded sterile products (CSPs) in accordance with professional standards and both California State and Federal requirements.

III. DEFINITIONS

- A. ACPH - Air Changes Per Hour - The rate at which the entire volume of air within a space or room is exchanged.
- B. BSC - Biological Safety Cabinet - A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust, which is designed to provide worker protection from exposure to airborne drugs and to provide an ISO class 5 environment for sterile compounding of hazardous drugs.
- C. BUD - Beyond-Use Date - Either the date, or hour and the date, after which a CSP must not be used, stored, or transported. The BUD is determined from the date and time that preparation of the CSP is initiated.
- D. CFU - Colony Forming Unit
- E. CR - Compounding Record
- F. CSP - Compounded Sterile Product
- G. DOP - Director of Pharmacy, also the Pharmacist-in-Charge (PIC)
- H. DP - Designated Person(s) - One or more individuals assigned by the Pharmacist-in-Charge (PIC) to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded sterile products.

- I. EHR - Electronic Health Record
- J. GFT - Gloved Fingertip and Thumb Test
- K. IP - Inpatient Pharmacy
- L. ISO class - Air quality classification from the International Organization for Standardization.
- M. LAFH - Laminar Air Flow Hood - A device that provides an ISO class 5 or better environment for sterile compounding.
- N. MFR - Master Formulation Record
- O. OIC - Outpatient Infusion Center Pharmacy
- P. PAPR - Powered Air Purifying Respirator
- Q. PATT - Personal Aseptic Technique Test
- R. PEC - Primary Engineering Control - A device that provides an ISO class 5 environment for sterile compounding.
- S. SEC - Secondary Engineering Control - The area where the PEC is placed (e.g., cleanroom suite).
- T. SVHMC - Salinas Valley Health Medical Center - General Acute Care Hospital and Other Approved Services licensed by State of California Department of Public Health (License 070000083)

IV. GENERAL INFORMATION

A. Overview & Scope

1. Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a compounded sterile product (CSP).
 - a. CSP Categories -- CSP Categories are primarily based on the following: the environment or conditions where the CSP is compounded, the probability for microbial growth during the time that the CSP will be stored, and the time period within which the CSP must be used (i.e., beyond-use date or BUD).
 - i. **Category 1 CSP** - CSP using sterile ingredients and is compounded under the least controlled environmental conditions, such as when a CSP is prepared in an ISO class 5 PEC located in a classified cleanroom suite with reduced or compromised environmental controls (e.g., experiencing a loss of pressure due to prolonged power failure).
 - ii. **Category 2 CSP** - CSP using sterile ingredients and is compounded in an ISO class 5 PEC in a classified cleanroom suite that meets all the USP <797> environmental requirements.
 - iii. **Category 3 CSP** - CSP involving the use of non-sterile ingredients. The SVHMC Inpatient Pharmacy and the Outpatient

Infusion Center Pharmacy shall not compound any CSP using non-sterile ingredients. Therefore, further references to Category 3 sterile compounding will not be addressed in this document.

- b. The following preparations shall not be performed in either the SVHMC Inpatient Pharmacy or the Outpatient Infusion Center Pharmacy and are therefore not addressed in this document:
 - i. CSPs that incorporate infectious materials (e.g., BCG);
 - ii. CSPs that require manipulation of a patient's blood-derived or other biological material (e.g., autologous serum);
 - iii. CSPs that are considered an allergenic extract.
 - c. Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental material as provided by the product's manufacturer. The policy and procedures herein do not apply to the preparation of a conventionally manufactured sterile product only if the following apply:
 - i. The product is prepared as a single dose for an individual patient; and
 - ii. The approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time.
- B. The SVHMC Pharmacy Department sterile compounding program will adhere to the policies and procedures described herein to ensure safe and accurate preparation and dispensing of CSPs from the cleanroom suites located at both the Inpatient Pharmacy (IP) and Outpatient Infusion Center (OIC) Pharmacy practice settings.
- C. All CSPs prepared by SVHMC are intended for patients registered for treatment at SVHMC and will not be supplied to any other location.
- D. The Director of Pharmacy (DOP) and the Designated Person(s) (i.e., Manager of Pharmacy Operations, Manager of Pharmacy Outpatient Services, and Pharmacy Operations Coordinator) will have direct oversight and ensure compliance with all aspects of the sterile compounding program at SVHMC Pharmacy Department. As such, they will be responsible and accountable for the performance and operation of the SVHMC Pharmacy Department sterile compounding program.
- E. The sterile compounding program policies and procedures will undergo, at a minimum, annual review by the DOP and by the Designated Person(s). This annual review, as well as any reviews related to any changes/updates, will be electronically documented via the SVHMC policy software application.
- 1. The sterile compounding program policies and procedures will be updated to reflect changes to compounding processes, facility changes, and other changes that impact the CSPs.
 - 2. Any changes/updates made to the sterile compounding policies and procedures will be immediately communicated by the DOP and/or the DP to all Pharmacy staff

members with documented participation in the program.

- F. The SVHMC sterile compounding program policies and procedures will be rooted by the following domains: personnel competency, control of the compounding environment, ongoing evaluation of CSP quality, and proper handling, storage, and disposition of all prepared CSPs.

1. Personnel Competency

- a. Personnel training and evaluation
- b. Personnel hygiene and adherence to established garbing requirements

2. Control of the compounding environment

- a. Facilities and engineering controls
- b. Certification and recertification
- c. Microbial air and surface monitoring
- d. Cleaning in the compounding areas

3. Ongoing evaluation of CSP quality

- a. Adherence to established compounding methods
- b. Maintenance of equipment, supplies and components
- c. Maintenance of a master formula and compounding records
- d. Inspection and testing of compounded sterile products
- e. Labeling requirements
- f. Methods for assignment of beyond-use dates
- g. Quality assurance and quality control (QA/QC)

4. Proper handling, storage and disposition

- a. Compounded sterile product handling and storage
- b. Allergenic extracts, infectious and biologic materials

- G. The SVHMC sterile compounding program will include a Quality Assurance and Quality Control (QA/QC) Program (See *Attachment G*), in addition to the procedure described in Section C, #7. The DOP and the DP will review the QA/QC Program every 12 months. The review will be documented electronically via the SVHMC policy software application, as well as in the SVHMC California MERP document.

V. PROCEDURE

A. Personnel Competency

1. Personnel training and evaluation

- a. The following Pharmacy staff members will undergo initial didactic and practical training to ensure a full understanding of the professional standards of sterile compounding prior to engaging in any unsupervised independent activities related to SVHMC Pharmacy sterile compounding program:

- i. Designated Person(s)
 - ii. Personnel involved in the preparation and/or compounding of CSPs
 - iii. Personnel who have direct oversight of compounding personnel, including personnel who perform in-process checks or final verification of CSPs
- b. Pharmacy staff members involved in the preparation and/or compounding of CSPs must also maintain a fundamental understanding of both California State and Federal requirements related to sterile compounding prior to engaging in any unsupervised independent activities related to the sterile compounding program.
- c. All participants of the sterile compounding program must, at a minimum, complete baseline and annual competency evaluations to ensure initial and perpetual understanding of the program requirements. Competency evaluations will include assessment of the following elements:
 - i. Maintenance of satisfactory personnel hygiene requirements
 - ii. Understanding and execution of established hand hygiene and garbing requirements
 - iii. Fundamental understanding of facilities and engineering controls
 - iv. Fundamental understanding of certification and microbial monitoring
 - v. Understanding and execution of established cleaning and disinfection requirements
 - vi. Accuracy of calculations and proper utilization of a master formula recipe
 - vii. Understanding and execution of established aseptic compounding technique, including: proper use of the primary engineering control (PEC), measuring, and mixing
 - viii. Satisfactory creation of compounding records and final CSP labels
 - ix. Fundamental understanding of quality assurance and control parameters
 - x. Understanding and execution of handling and storage requirements for CSPs
- d. All competency elements will be assessed by didactic and/or practical skills evaluations under the direct supervision of the DOP and/or the Designated Person(s) with advanced training in the professional standards of sterile compounding. Competency and testing shall include:
 - i. Written competency on sterile compounding procedures and pharmacy calculations

- ii. Garbing and hand hygiene competency evaluation, including direct observation and gloved fingertip and thumb (GFT) sampling. (See *Attachment A*)
 - a. Initial Evaluation:
 - i. Must successfully complete 3 separate times and must be in succession.
 - i. Failure of any of the 3 initial garbing competency evaluations require repeat testing until personnel successfully complete 3 evaluations in a row.
 - ii. Each of the 3 initial competency evaluations must occur after performing a separate and complete hand hygiene and full garbing procedure.
 - ii. All garbing competencies must be completed with GFT sampling of both hands after garbing and a documented visual audit while performing hand hygiene and garbing procedures.
 - i. GFT sampling after garbing, but before applying sterile 70% isopropyl alcohol to gloves, must be performed on donned sterile gloves on both hands in a classified area.
 - iii. Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or GFT sampling that results in action levels.
 - i. In the event of a failure, results must be documented and maintained. Documentation will include the following:
 - i. Name of person being evaluated
 - ii. Date and time and location of sampling
 - iii. Media and components: Manufacturer, lot #, expiration date, starting temp of incubation,

dates of incubation

- iv. Results and name of observer and personnel reading and documenting results.

b. Continuing Evaluation:

- i. Must successfully complete the garbing and hand hygiene competency at least 1 time every 6 to 12 months, depending on the personnel function.

iii. Aseptic technique competency evaluation, including direct observation, media fill testing, post-GFT and surface sampling. (See *Attachment B*)

- a. The aseptic technique competency must be completed successfully initially and every 6 to 12 months, depending on personnel function.
- b. Immediately following the media fill test, GFT sampling must be performed on both hands and inside of an ISO class 5 PEC.
- c. Surface sampling must also be conducted after the media fill test. (See *Attachment D*)
- d. Failure is indicated by visual turbidity. Document as stated above in GFT sampling procedure.

e. Frequency of training, competency, and testing are as follows:

Personnel Function	Training and Written Competency	Garbing and Hand Hygiene Competency (including GFT)	Aseptic Technique Competency (Media Fill with post-GFT and Surface Sampling)
Designated Person(s)	Initial and every 12 months	Initial and every 12 months	Initial and every 12 months
Compounding Personnel	Initial and every 12 months	Initial and every 6 months	Initial and every 6 months
Personnel with Direct Oversight of Compounding Personnel	Initial and every 12 months	Initial and every 12 months (unless also compounding - then every 6 months)	Initial and every 12 months (unless also compounding - then every 6 months)

The above must be successfully completed prior to personnel independently compounding CSPs and/or having direct oversight of compounding personnel. In addition, personnel with direct oversight of compounding personnel cannot compound unless they successfully meet the requirements of compounding personnel.

- f. Personnel who fail written tests or whose GFT results exceed the action levels stated in the table below or whose media fill kit shows visible turbidity or other visual manifestations of growth shall receive immediate re-instruction and re-evaluation by the Designated Person(s). If personnel fails re-testing, then they shall not be allowed to perform any independent sterile compounding activities until passing the evaluations.

Gloved Fingertip and Thumb Sampling	Action Levels (CFU, Total from both hands)
After garbing	> 0
After media fill testing	> 3

Microbial identification of the CFU is not required for either GFT or media fill testing.

- g. The Pharmacy shall maintain records of staff: orientation, training, and completion of didactic and practical skills competency evaluations for a minimum of three (3) years following completion.

2. **Personnel hygiene and adherence to established garbing requirements:**

- a. Any personnel entering the clean room suite, whether preparing a CSP or not, must meet the requirements in personal hygiene and garbing as described herein.
- b. **Preparation prior to entering the compounding area:**
 - i. Food (including gum and mints) and drinks must not enter the anteroom, the buffer room, or placed inside the ISO 5 PEC (i.e., LAFH and BSC).
 - ii. Cosmetics are not allowed and must be removed prior to entering.
 - iii. Remove all hand, wrist, and other exposed jewelry (i.e., rings, necklaces, watches, bracelets), including piercings that could interfere with garbing.
 - a. Personnel with visible non-removable piercings/ jewelry will not be allowed to enter the compounding area.
 - iv. Ear buds or headphones are not allowed.
 - v. Nails must be clean and neatly trimmed. Artificial nails and/or nail polish/gels are not allowed and must be removed.

- vi. Wipe eyeglasses, if worn.
- vii. Individuals must report the following conditions to the Designated Person(s), who is responsible for evaluating whether the individual should be excluded from working in the compounding area before the condition is resolved:
 - a. Rash
 - b. Recent tattoo
 - c. Oozing sore
 - d. Conjunctivitis
 - e. Active respiratory infection
- viii. Exposed skin must be minimized (i.e., covered) as much as possible when entering the cleanroom suite.

c. Personnel shall don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest:

- i. Garbing activities considered the dirtiest include donning of dedicated low-lint shoe covers, low-lint head and facial hair covers and low-lint face masks and eye shields. Eye shields are optional unless working with irritants such as germicidal disinfectants (e.g., during scheduled monthly cleaning).
- ii. When entering the anteroom, sit on the stainless steel bench that straddles the line of demarcation. Place a shoe cover on the right or left foot, then place the right or left foot on the clean side of the line. Place a shoe cover on the opposite foot, and then place the opposite foot on the clean side of the line. It is then permissible to stand on the clean side of the line and continue with the garbing process.
- iii. Clean underneath fingernails under warm running water using a disposable nail cleaner.
- iv. Wash hands and forearms up to the elbows thoroughly for at least 30 seconds with soap and water.
- v. Dry hands and forearms up to the elbows completely with sterile, low-lint disposable wipes.
- vi. Don a disposable non-shedding gown with sleeves that fit snugly around the wrist and enclosed at the neck.
 - a. When preparing a hazardous CSP, don a disposable, non-shedding and non-permeable chemo gown.
 - b. If wearing a PAPR when cleaning, clean the equipment with sterile 70% isopropyl alcohol low-lint wipes prior to entering the anteroom and don the PAPR after gowning.

- vii. Prior to entering the positive pressure buffer room, apply and sanitize hands with waterless alcohol-based hand scrub.
- viii. **After entering the Positive Pressure buffer room:**
 - a. Don sterile non-latex, powder-free gloves just prior to using the ISO class 5 PEC (i.e., LAFH). Utmost care must be taken to not expose skin inside the ISO class 5 PEC.
 - b. Sanitize gloves with sterile 70% isopropyl alcohol immediately before compounding and regularly throughout the compounding process.
 - c. Gloves must be inspected for holes, punctures, or tears and must be replaced immediately if such defects are detected.
 - d. Personnel who find it necessary to leave the clean room shall carefully remove their gown at the entrance of the area and hang it inside out for re-donning upon re-entry.
 - i. This procedure can only be done during the same shift and only applies to gowns.
 - ii. Hair covers, masks, and gloves should be discarded and new ones donned prior to re-entry.
 - e. Garb worn or taken outside the confines of the clean room cannot be worn in the clean room.
- ix. **After entering the Negative Pressure buffer room:**
 - a. Only ASTM D6978 nitrile gloves may be worn when preparing chemotherapy CSPs.
 - i. Two pair of gloves must be worn at all times:
 - i. Sanitize the first pair of gloves with sterile 70% isopropyl alcohol and let air dry.
 - ii. Don the second pair of sterile ASTM D6978 non-latex, powder-free nitrile gloves over the first pair.
 - iii. Sanitize gloves with sterile 70% isopropyl alcohol immediately before compounding and regularly throughout the compounding process.

- iv. Gloves must be inspected for holes, punctures, or tears and must be replaced immediately if such defects are detected.
- v. Outer gloves shall be replaced between each different HD preparation.
- b. Personnel who find it necessary to leave the clean room shall discard their gown prior to leaving.
 - i. If continuously compounding, gowns should be changed every 2 to 3 hours or immediately after a spill or splash.
 - ii. Hair covers, masks, and gloves should be discarded and new ones donned prior to re-entry.
- c. Garb worn or taken outside the confines of the clean room cannot be worn in the clean room.

B. Control of the Compounding Environment

1. **Facilities and engineering controls**

- a. The cleanroom suite must be outfitted properly to minimize the risk of contamination of CSPs.
 - i. Sterile compounding will be conducted in a specifically designed room (i.e., cleanroom suite) that is separated from areas not directly related to compounding.
 - ii. Tacky mats will be placed outside of the entrance to the cleanroom suite. Tacky mats will never be placed inside the cleanroom suite.
 - iii. The anteroom will have a line of demarcation that separates the dirty side from the clean side of the cleanroom suite.
 - iv. The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the cleanroom suite must be smooth, impervious, free from cracks and crevices, and nonshedding.
 - v. Junctures between the ceiling and the walls and between the walls and the floor must be sealed to eliminate cracks and crevices.
 - vi. Walls must be made of durable materials and the integrity of the surface must be maintained.
 - vii. The buffer room must not contain plumbed water sources (i.e., sinks, floor drains, eye wash station).
 - viii. The anteroom must not contain floor drains.

- b. The cleanroom suite environment must be maintained to provide a comfortable working environment, to minimize airborne contamination, and to minimize the risk of microbial proliferation.
 - i. **Air quality**
 - a. Anteroom, positive buffer room, and negative buffer room must meet at least ISO class 7 air quality (defined as a limit of 352,000 particles sized 0.5 µm or larger per cubic meter).
 - b. LAFH and BSC shall provide an environment of at least ISO class 5 (defined as a limit of 3,520 particles sized 0.5 µm or larger per cubic meter).
 - i. In addition, the BSC and the negative buffer room must be externally vented.

- ii. **Temperature and humidity**

- a. Temperature should be maintained at 20°C (68°F) or cooler and a relative humidity should be maintained at 60% or below.
- b. Temperature and humidity will be monitored and documented by a continuous recording device and records will be readily retrievable.
- c. Temperature and humidity will be controlled through an HVAC system.
 - i. Free-standing air conditioners or dehumidifiers shall not be used in the cleanroom suite.

- iii. **Air exchange**

- a. A minimum of 30 total HEPA-filtered air exchanges per hour (ACPH) must be supplied to the ISO class 7 anteroom and buffer rooms.
 - i. At least 15 ACPH (out of the total 30 SCPH) must come from the HVAC through HEPA filters located in the ceiling.

- iv. **Pressure differentials**

- a. The pressure differential between the anteroom and the unclassified area (i.e., outside the cleanroom suite) must not be less than 0.020-inch water column.
- b. A minimum differential positive pressure of 0.020-inch water column is required between the anteroom and the buffer rooms.
- c. The negative buffer room must maintain a negative pressure between 0.01 and 0.03-inch water column.

- d. A pressure differential monitoring device must be used to continuously monitor the pressure differentials.
 - i. Loss of air flow integrity will result in an alarm sounding if the anteroom door or any of the buffer room doors remain open for greater than 30 seconds. Closing the door will reset the alarm.
 - ii. Loss of air flow integrity due to a power outage:
 - i. If pressure differentials are out-of-range for greater than one hour, compounding CSPs may take place in a functioning LAFH and/ or BSC (i.e., blowers are on for 30 minutes and surfaces are cleaned and sanitized). All CSPs will have a BUD of 12 hours at room temperature or 24 hours refrigerated (or less, if warranted).
 - ii. When room pressures are back in range, pharmacy personnel will perform a terminal clean of the cleanroom suite prior to resuming assigning maximum BUDs to CSPs.
- c. Furniture, equipment and materials entering the cleanroom suite must be limited to only those necessary for performing compounding activities, must be low-shedding, and must be easily cleaned and disinfected.
 - i. No corrugated or uncoated cardboard is allowed to be brought into the cleanroom suite.
 - ii. Frequently used supplies will be removed from their boxed carton and then cleaned and disinfected with sterile 70% isopropyl alcohol prior to placing them in the pass-through for transfer into the cleanroom suite.
 - iii. Carts that are used to transport components into the cleanroom suite must be constructed from nonporous materials with cleanable casters and wheels. The entire cart, including the casters, must be cleaned and disinfected when moving a cart from the dirty side to the clean side of the anteroom.
 - iv. Equipment required for maintenance or cleaning activities (i.e., cleanroom certification equipment, air sampler, PAPR) must be cleaned and disinfected prior to entering the clean side of the anteroom.

2. **Certification and recertification**

- a. The cleanroom suite (i.e., anteroom, positive buffer room, negative buffer room) and PECs (i.e., LAFH and BSC) must be independently certified by a qualified contractor to ensure that the cleanroom suite meets the requirements of USP <797> standards.
 - i. Certification will be performed initially and then recertified at least every 6 months.
 - ii. Recertification must be performed if there are any changes to the cleanroom suite such as:
 - a. Redesign
 - b. Construction
 - c. Replacement or relocation of any PEC
 - d. Alteration in the configuration of the room that could affect airflow or air quality
- b. Certification and recertification must include the following components:
 - i. Airflow testing
 - ii. HEPA filter integrity testing
 - iii. Total particle count testing
 - iv. Dynamic airflow smoke pattern test
 - v. Microbial air and surface sampling
- c. Results must meet the requirements of USP <797> standards.
 - i. A sticker will be placed on each PEC documenting the date of inspection and that the PEC meets the ISO class 5 standards.
 - ii. A sticker will also be placed on each door documenting the date of inspection and that the air quality meets ISO class 7 standards.
- d. Certification records will be reviewed by the Designated Person(s). Documentation of the review will be in the form of a wet signature (for a paper report) or in the form of an electronic signature (for an electronic report).
- e. Corrective action plan:
 - i. A corrective action plan must be implemented and documented by the Designated Person(s) in response to any out-of-range results.
 - ii. An attempt to identify any microorganism will be made with the assistance of a microbiologist.
 - iii. Corrective action plans may include repeat cleaning, facility improvements, personnel training, HEPA filter replacement, etc.

- iv. The appropriate test(s) will be repeated to confirm that the actions taken were effective.

- f. Records will be retained for 3 years.

3. **Microbiologic air and surface monitoring**

- a. Microbiologic air and surface monitoring will be conducted in all classified areas during dynamic operating conditions to confirm that the required environmental quality is maintained.
 - i. Microbial air and surface sampling will be performed initially and during recertification (i.e., every 6 months).
 - ii. Microbial air and surface sampling must also be performed in the following circumstances:
 - a. Certification of new facilities and equipment
 - b. After any servicing of facilities and equipment
 - c. In response to identified problems (e.g., positive growth in sterility tests of CSPs)
 - d. In response to identified trends (e.g., repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination)
 - e. In response to changes that could impact the sterile compounding environment (e.g., change in cleaning agents)
 - iii. In addition to the surface sampling performed during certification and recertification, microbial surface sampling of the cleanroom suite will be performed monthly and in conjunction with media fill testing.

b. **Air sampling procedures**

- i. The Designated Person(s) shall be properly trained and deemed competent in performing air sampling procedures to ensure accurate and reproducible sampling. See *Attachment C*.
- ii. All impaction air samplers must be serviced and calibrated as recommended by the manufacturer.
- iii. Evaluate colony-forming unit (CFU) counts against the action levels below and examine counts in relation to previous data to identify any trends.:

ISO Class	Air Sampling Action Levels [CFU/cubic meter (1000 liters) of air/media device]
5	> 1
7	> 10

c. Surface sampling procedures

- i. The Designated Person(s) shall be properly trained and deemed competent in performing surface sampling procedures to ensure accurate and reproducible sampling. See *Attachment D*.
- ii. The monthly surface sampling should be performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected.
- iii. Evaluate CFU counts against the action levels below and examine counts in relation to previous data to identify any trends:

ISO Class	Surface Sampling Action Levels (CFU/media device)
5	> 3
7	> 5

d. Corrective action plan

- i. A corrective action plan must be implemented and documented by the Designated Person(s) in response to any CFU counts exceeding the action levels.
- ii. An attempt to identify any microorganism will be made with the assistance of a microbiologist.
- iii. Corrective action plans may include repeat cleaning, facility improvements, personnel training, HEPA filter replacement, etc.
- iv. The appropriate test(s) will be repeated to confirm that the actions taken were effective.

e. Records will be retained for 3 years.

4. Cleaning in the compounding areas

a. Cleaning personnel:

- i. All cleaning and disinfecting activities shall be performed only by trained and appropriately garbed pharmacy personnel.
- ii. Cleaning personnel may opt to use a PAPR during the monthly terminal cleaning activity.
 - a. Cleaning personnel shall be trained by the Designated Person(s) on the proper use of a PAPR prior to using it during a cleaning activity.
 - b. The PAPR must be wiped clean with sterile 70% isopropyl alcohol before introducing it into the anteroom as well as after its use and before returning it to its proper storage.

b. Cleaning agents:

- i. Use only organization-approved, non-corrosive cleaning and sanitizing agents.
- ii. A sterile disinfectant cleaner appropriate for the surface material and that comply with manufacturer or compendial recommendations will be used. Follow all manufacturer's recommendations on dilution and product contact time.
- iii. A sterile sporicidal cleaner will be used once a month to clean surfaces that comply with manufacturer or compendial recommendations. Follow all manufacturer's recommendations on dilution and product contact time.
- iv. Sterile 70% isopropyl alcohol must be applied:
 - a. After the application of sterile disinfectant cleaner, to remove any residue.
 - b. After the application of sterile sporicidal cleaner, to remove any residue.
 - c. Immediately before initiating compounding.
 - d. To the horizontal work surface of the PEC, including any removable work trays, at least every 30 minutes if compounding process takes 30 minutes or less. If compounding takes more than 30 minutes, compounding must not be disrupted and the work surface must be disinfected with sterile 70% isopropyl alcohol immediately after compounding.
- v. Using sterile, low-lint, disposable wipes, wipe and sanitize supplies for use in the buffer room and in the adjacent anteroom with sterile 70% isopropyl alcohol.

c. Cleaning tools and supplies:

- i. Wipers, sponges, pads, and mop heads must be low-linting and dedicated to only use in the IV room.
- ii. Wipers, sponges, pads, and mop heads must be disposable and must be discarded after each cleaning activity.
- iii. Reusable cleaning tools must be made of cleanable materials (e.g., must not be made of wood or other porous material) and must be cleaned and disinfected before and after each use.
- iv. Reusable cleaning tools must be dedicated for use in the clean room suite and must not be removed from the area except for disposal.

d. Daily cleaning of the LAFH and BSC:

- i. If necessary, remove visible particles, debris, or residue with Sterile Water for Irrigation using sterile, low-lint, disposable wipes.

- ii. Using a sterile, low-lint, disposable wipe, apply a sterile one-step disinfectant cleaner to equipment and all interior surfaces (top to bottom, back to front) of the PEC. Ensure that the minimum contact time specified by the manufacturer is achieved.
 - iii. Using a sterile, low-lint, disposable wipe, apply sterile 70% isopropyl alcohol to equipment and all interior surfaces (top to bottom, back to front) of the PEC. Allow the surface to dry completely before beginning compounding.
 - iv. Discard the disposable low-linting wipes used to clean the hood after use.
 - v. Document the cleaning of these areas at the beginning of each shift on the ELECTRONIC DOCUMENTATION SOFTWARE program.
- e. **Daily cleaning of the counter tops, passthrough chambers, garbage cans, and floors:**
 - i. With sterile, low-lint, disposable wipes, adequately clean and sanitize the counter tops and garbage cans prior to the end of the evening shift.
 - ii. With disposable non-linting wipes, clean the floors starting with the buffer rooms and working out towards the ante room.
 - a. First, clean up debris by dry mopping the floors with a designated dusting sheet.
 - b. Finish cleaning the floors by wet mopping with a sterile one-step disinfectant cleaner.
 - iii. Document the daily cleaning of the counter tops and passthrough chambers on the ELECTRONIC DOCUMENTATION SOFTWARE program.
 - iv. Document the daily mopping of the floors on the ELECTRONIC DOCUMENTATION SOFTWARE program.
 - v. Do not mop when aseptic operations are in progress. The mopping should start in the buffer room and then move to the ante room daily and as needed. Document these cleanings on the ELECTRONIC DOCUMENTATION SOFTWARE program.
- f. **Monthly cleaning:**
 - i. Perform all of the daily cleaning as described above with a sterile sporicidal cleaner, AND:
 - ii. Clean all wall surfaces of the positive and negative pressure clean rooms.
 - iii. Clean all ceilings in the anteroom and buffer rooms.
 - iv. Clean all metal exterior surfaces of the LAFH(s) and BSC(s).

- v. Clean chairs and stools in the IV clean room and chemo clean room.
- vi. Clean all totes and carts in the IV clean room and the chemo clean room.
 - a. Totes: Remove contents. Using a sterile, low-lint, disposable wipe with sterile sporicidal cleaner, clean the inside surfaces of the tote and then the entire exterior surfaces of the tote. Ensure manufacturer suggested contact time. Using a sterile, low-lint, disposable wipe with sterile 70% isopropyl alcohol, wipe surfaces and allow to dry. Replace contents of tote.
- vii. Clean plastic exterior surfaces of the hoods.
- viii. Document the monthly sanitization of the walls and ceiling of the anteroom and buffer room.
- ix. Empty storage shelving in the anteroom of all supplies and clean and sanitize them.
- x. Document these cleanings using the Terminal Cleaning Log. *(See Attachments E and F)*

C. Compounded Sterile Product Quality

1. **Adherence to established compounding methods**

- a. The SVHMC Inpatient Pharmacy and the Outpatient Infusion Center Pharmacy shall only compound Category 1 and Category 2 CSPs in a certified ISO class 5 PEC located in a classified cleanroom suite.
- b. **General access and introducing items into the SEC**
 - i. Access to the cleanroom is restricted to qualified pharmacy personnel with specific responsibilities or assigned tasks in the area.
 - a. Any personnel with an upper respiratory infection or active infection of any type will not be permitted to work in the cleanroom.
 - b. Non-pharmacy personnel who are required to perform equipment maintenance or testing (e.g., SVHMC Facilities personnel, clean room suite and IV hood certification personnel) shall follow the garbing procedures set herein.
 - ii. Traffic flow in and out of the clean room suite must be minimized.

c. **CSP ORDERING:**

- i. Pharmacy Preparations:

- a. The Inpatient Pharmacy and Outpatient Infusion Center Pharmacy shall prepare ALL intravenous fluids with additives (not available in pre-mixed form) and shall supply additives for piggyback medications upon receipt of an authorized order.
- b. Pharmacists shall interpret the order and check for incompatibility, instability, contraindications, and patient allergies.
- c. The initial time for CSP administration shall be determined by one of the following methods:
 - i. The pharmacist will determine the start time of the IV solution when processing new orders.
 - ii. A pharmacist may call the floor to determine the administration time.
- d. Administration times for continuing CSPs shall be determined by:
 - i. CSPs shall default to the standard administration times using the guidelines set by pharmacy.
 - ii. CSPs for all antibiotics shall continue on a schedule based on when the initial dose was given.
 - iii. Large volume CSPs will automatically be scheduled in the EHR according to its rate of infusion and verified by the technician.
 - iv. Orders for medications with short stabilities shall be mixed as close as possible to the time of administration.
- e. If order clarification is needed, the pharmacist shall:
 - i. Call the ordering physician.
 - ii. Notify nursing of clarifications or changes.
 - iii. Document clarifications or changes in the patient record with a read back system.

ii. STAT Orders:

- a. The Pharmacy will monitor the "STAT" queue and prioritize these indicated items as "HIGH" priority. Orders indicated as "STAT" will be processed first.
- b. Before dispensing the admixture, the pharmacist shall check the admixture prepared against the physician's order.

iii. Pharmacy Preparations Exceptions:

- a. Intensive Care Units, Surgery, Emergency Department may prepare cardiac medications (such as Norepinephrine, etc.) as defined by the organization's policy.
- b. Registered nurses (RNs) may prepare initial doses of IV solutions for emergency situations only. TJC only allows nurses to prepare doses if they are STAT orders or Pharmacy preparation is not feasible (e.g., short expiration time after admixing) as defined by the organization's policy.

d. **CSP PREPARATION:**

- i. At appropriate times the IV labels shall be generated during the 24 hour period in four batches.
- ii. All labels for the batch times indicated will be printed automatically on the appropriate printer.
 - a. Catch-up batches will print orders entered from the last batch print and the times indicated.
 - b. All orders entered after the catch-up batch should have the appropriate labels printed if the start time is before the next scheduled batch print.
- iii. Each batch will be prepared and dispensed prior to the START TIME.
- iv. Appropriate attention shall be given to additives which must be protected from light or do not require refrigeration.
- v. No components will be discarded until a pharmacist has made the final CSP check.
- vi. Adjusting IV Schedule:
 - a. The IV Technician shall generate a daily IV reschedule report and compare all large volume CSP administration times on the nursing IV report form against administration time set by pharmacy.
 - b. If any CSP is running ahead or behind schedule, the technician shall determine new administration times and reschedule the IV as needed.
 - c. If a CSP is off schedule, nursing personnel will notify the pharmacist regarding the time change.
 - d. If the time change is for an antibiotic, the pharmacist will discuss with the nurse appropriate administration times based on the hospital's approved administration schedules. (MEDICATION USE)

e. CSP COMPOUNDING:

- i. Use aseptic technique to perform sterile compounding.
- ii. Use an ISO class 5 PEC (LAFH or BSC).
- iii. Prepare only one type of drug product in the ISO class 5 PEC at one time.
- iv. Reconstitute all drug additives according to the manufacturer's recommendations or a current reference. All admixtures shall have beyond-use dates that are consistent with manufacturer recommendations and USP 797 standards.
- v. Single use vials must be discarded within 12 hours of initial puncture or entry, if stored in an ISO Class 5 PEC (LAFH or BSC) unless indicated otherwise by the manufacturer. DO NOT REMOVE from the ISO class 5 PEC.
- vi. Upon first use, initial and date multi-use sterile product containers.
- vii. Store multi-use containers under restricted access conditions and dispose of them when the beyond-use or expiration date is exceeded. Expiration dating not specifically referenced in the package insert should not exceed 28 days once the vial has been opened. Discard if suspected or visible contamination occurs.
- viii. Initial and date reconstituted vials with the date and time of reconstitution, concentration, and date of expiration according to manufacturer's recommendations.
- ix. If the volume of a drug to be added is greater than or equal to 10% of the bag volume, aseptically withdraw and discard the volume from the diluent bag equal to the volume of the drug to be added.
- x. After preparing admixtures, thoroughly mix the contents of the container and inspect for the presence of particulate matter, evidence of incompatibility, or other defects.
- xi. Dispose of sharps (including needles and syringes) in impervious labeled containers. Re-cap needles only when permitted by organization policy.
- xii. For parenteral nutrition solutions and fat emulsions, refer to the policy TPN PROTOCOL - ADULT PATIENTS.
- xiii. Compounding all hazardous CSPs must be done in a BSC and requires the use of a closed system transfer device.
- xiv. Medications with stabilities equal or less than 24 hours shall be prepared as close as possible to the time of administration.

f. CSP CHECKING:

- i. The prepared label with the proper expiration date shall be attached to the syringe or CSP.
 - a. Completed admixtures have the label affixed to the solution bag leaving the manufacturer's name of the solution or medication visible.
- ii. The beyond-use date (BUD) shall follow the BUDs set for Category 1 and Category 2 CSPs unless the stability data of the drug is shorter than the established BUD.
- iii. The completed CSP and all the materials used in preparing the CSP shall be placed in the checking area. If the CSP is prepared by a pharmacy technician, then the final checking shall be performed by a pharmacist using established procedures:
 - a. A pharmacist shall check label accuracy, accuracy of the addition of all drug products or ingredients used to prepare the finished product, their volumes or quantities, before signing off on all products prepared by pharmacy technicians.
 - b. When possible, two pharmacists shall check and sign off on ALL chemotherapy, Pediatric and NICU products before the product is dispensed for administration.
 - c. In addition, the CSP shall be checked for the presence of appropriate auxiliary labels.
- iv. Any CSP concentration not specified in the standardized dilution chart shall have a "CHECK DOSAGE" sticker placed on the label or bag.
- v. The final checked CSP shall be placed in the appropriate bin on the delivery cart.

g. DELIVERY OF CSPs:

- i. Completed CSPs are delivered to patient care areas before the intended time of administration.
 - a. CSPs are routinely delivered to care areas via the pneumatic tube system or the pharmacy delivery cart.
- ii. All chemotherapeutic agents and/or hazardous drugs are sealed in a "zip-locked" chemotherapy bag and are routinely delivered via delivery cart or pharmacy personnel.
 - a. Chemotherapeutic agents and/or hazardous drugs are never delivered via the pneumatic tube system.
- iii. CSPs shall be placed in the designated area (i.e., in the medication refrigerators or in the medication cassettes) on each nursing unit.
 - a. At the same time, the delivery person shall return all

CSPs that have been placed in the delivery bin for return to the pharmacy.

h. DISCONTINUED CSPs:

- i. Nursing personnel shall:
 - a. Place discontinued unrefrigerated CSP's in the plastic bin to return to pharmacy.
 - b. Place discontinued refrigerated CSP's in the return bin in the medication refrigerator to return to pharmacy.
- ii. Upon receiving order of the discontinued CSP, a pharmacist shall discontinue the CSP and notify the I.V. room technician.

i. REDISPENSING CSPs:

- i. Return all compounded sterile products that are not used as originally intended to the pharmacy for appropriate disposition, which may be redispensed in accordance with the organization's policy.
- ii. Redispensing may occur if the compounded sterile product has been maintained under continuous refrigeration and protected from light, if required.
- iii. Redispensing may occur if initial preparation and thaw times are documented and reliable measures have been taken to prevent and detect tampering.
- iv. CSPs can be redispensed only one (1) time after the initial return to the pharmacy if still within 48 hours of beyond use date, and within 72 hours of compounding. CSPs may not be redispensed after 72 hours unless the lot number and expiration dates of the diluent and the medication are properly recorded.
- v. CSPs cannot be re-dispensed if re-dispensing cannot be supported by the originally assigned beyond-use time.
- vi. CSPs that are ready-to-use and not activated are stable based on the manufacturer's literature.

2. Maintenance of equipment, supplies and components

- a. Equipment used in compounding CSPs
 - i. Equipment chosen to be used in compounding should have surfaces that are not reactive or sorptive.
- b. Supplies
 - i. Supplies used in compounding CSPs must be sterile and depyrogenated.
- c. Components
 - i. Components used in compounding CSPs must be sterile and

must be FDA-approved components.

3. **Maintenance of a master formula and compounding records**

- a. A master formulation record (MFR) is a detailed record of procedures that describes how the CSP is prepared.
 - i. An MFR must be created for all CSPs prepared for more than one patient.
 - ii. All new MFRs any alterations made to an existing MFR must be reviewed and approved by the DOP and the Designated Person(s).
 - iii. An MFR must include the following:
 - a. Name, strength or activity, and dosage form of the CSP
 - b. Identities and amounts of all ingredients; if applicable, relevant characteristics of components (e.g., salt form, solubility, etc.)
 - c. Type and size of container closure system(s)
 - d. Complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions)
 - e. Physical description of the final CSP
 - f. BUD and storage requirements
 - g. Reference source to support the stability of the CSP
 - h. Quality control (QC) procedures (e.g., pH testing, filter integrity testing)
 - i. Other information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, etc.)
- b. Compounding records (CR) documents the compounding process of each CSP.
 - i. A CR is created for all CSPs compounded at SVMHC with the use of the electronic IV workflow management system.
 - ii. The CR must include at least the following information:
 - a. Name, strength or activity, and dosage form of the CSP
 - b. Date and time of preparation of the CSP
 - c. Assigned internal identification number (e.g., prescription or order number)
 - d. A method to identify the individuals involved in the compounding process and individuals verifying the

final CSP

- e. Name of each component
- f. Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient
- g. Weight or volume of each component
- h. Strength or activity of each component
 - i. Total quantity compounded
 - j. Final yield (e.g., quantity, containers, number of units)
- k. Assigned BUD and storage requirements
 - l. Results of QC procedures (e.g., visual inspection, filter integrity, etc)
- m. If applicable, must also include the MFR reference for the CSP and
- n. Calculations made to determine and verify quantities and/or concentrations of components

4. **Inspection and testing of compounded sterile products**

- a. Samples of CSPs will be assayed for strength, potency, endotoxins, and sterility every 6 months.
- b. Samples may either be a Category 1 or Category 2 CSP.
- c. Results from the CSPs will be analyzed as follows:
 - i. Sterility must be negative.
 - ii. Potency must be within +/- 10% of the original compound sent.
 - iii. Endotoxin must be less than or equal to the upper limit of specification.
- d. An outside agency will be contracted to provide the results of each sample CSP.
- e. In the event that a sample's results are not in the reference range listed above, a product retest will be completed. A new sample with the same compounding personnel will be sent again for further analysis.
- f. If the second test comes back out of range, the remediation will include, at a minimum, an immediate investigation of cleaning and compounding operations as well as facilities management.
- g. CSPs that contain controlled substances shall not be selected for these assay tests.

5. **Labeling requirements:**

- a. Immediately label all admixtures including large volume parenterals (with additives) and piggyback medications with the following information:

- i. Patient name, location, medical record number, and account number
 - ii. Names and amounts or concentrations of active ingredients added
 - iii. Name of basic parenteral solution
 - iv. Total volume
 - v. Internal lot number or reference number of the compound
 - vi. Date and time of addition
 - vii. Appropriate route of administration
 - viii. Date, time, and rate of administration
 - ix. Name or initials of compounding personnel
 - x. Name or initials of personnel who performed the final check of the product
 - a. In addition, a final "wet" initial will be written on the label prior to final dispense.
 - xi. Supplemental instructions for safe use
 - xii. Beyond-use date (BUD) of the CSP
 - xiii. Ordering physician
 - xiv. "COMPOUNDED DRUG PRODUCT" auxiliary label
- b. Premixed IV solutions:
- i. Label premixed IV solutions supplied by the Pharmacy as above, except:
 - a. Do not label with a BUD unless it is shorter than the manufacturer expiration date printed on the container.
 - b. If the premixed IV is a frozen product, the label shall show the thaw date. The BUD of the thawed product can then be calculated using the thaw date.
 - ii. When possible, affix labels to the IV container so that the preprinted material on the container is on the same side as the label.
 - iii. To ensure that quality control checks are as accurate and effective as possible, the preprinted material must not be covered by the pharmacy label (i.e., the label will be placed on all premixed IVs such that the nurse administering the medication may see the original manufacturer label with the name of the drug visible).
- c. Non-standard CSPs:
- i. Non-standard CSPs are defined as any IV solution prepared by

the Pharmacy that does not have a defined standing order set in the EHR.

- ii. All non-standard CSPs are to have a "CHECK DOSAGE" sticker placed on the the IV bag/bottle.

d. Nursing labeling:

- i. Nursing labeling shall follow guidelines established by regulatory and professional standards.

6. **Methods for assignment of beyond-use dates:**

- a. The Pharmacy shall establish general guidelines for determining the maximum beyond-use dates (BUDs) of aseptically prepared CSPs and in the absence of passing a sterility test.

i. **BUD Limits for Category 1 CSPs**

Controlled Room Temperature (20 to 25°C)	Refrigerator (2 to 8°C)
≤ 12 hours	≤ 24 hours

ii. **BUD Limits for Category 2 CSPs**

Compounding Method	Controlled Room Temperature (20 to 25°C)	Refrigerator (2 to 8°C)	Freezer (minus 25 to minus 10°C)
Aseptically prepared and prepared from only sterile starting components	4 days	10 days	45 days

Note: One (1) day is equivalent to 24 hours.

- iii. A shorter BUD must be assigned when the physical and chemical stability of the CSP is less than the BUD limit stated in the tables above (e.g., nitroprusside in NS is stable at room temperature for 24 hours and thus will have a BUD of 24 hours instead of 4 days).
 - a. Medications with stabilities equal to or less than 24 hours shall be prepared as close as possible to the time of administration.
- iv. The BUD must not exceed the shortest remaining expiration date of any of the commercially available starting components.
- v. For CSPs prepared with a compounded component, the BUD should not exceed the shortest BUD of the compounded component.

b. Immediate-Use CSPs

- i. Immediate use preparations shall be compounded only in those limited situations where there is a need for immediate administrations of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering.
 - a. Immediate-use CSPs shall involve not more than 3 different sterile products.
 - b. The quantity of an immediate-use CSP shall only be in the quantity to meet the immediate need, and the circumstance for the need shall be documented.
 - c. The CSP shall be labeled "FOR IMMEDIATE USE ONLY" and administration shall begin no later than four (4) hours following the start of the compounding process.
 - d. If administration has not begun within four (4) hours following the start of preparing the CSP, then the CSP shall be promptly, properly, and safely discarded.
 - e. Unless immediately and completely administered by the person who prepared the CSP, or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact four (4) hours BUD and time.
- ii. Aseptic technique shall be used to prepare immediate-use CSPs.
- iii. Nursing Education is responsible to coordinate with the DOP and/or Designated Person(s) to provide appropriate nursing staff with initial and annual competency training for preparation of immediate-use CSPs.
 - a. Pharmacy will assist Nursing Education in providing in-service training to appropriate nursing staff regarding sterile compounding issues encountered from medication errors and other quality improvement activities.

c. Proprietary bag and vial systems

- i. **Immediate administration:** Docking and activation of proprietary bag and vial systems in accordance with the manufacturer's labeling for immediate administration to an individual patient is not considered compounding and may be performed outside of an ISO class 5 PEC.
- ii. **Future activation:** Docking and activation of proprietary bag and vial systems for future activation and administration is considered compounding and must be performed in an ISO class 5 PEC. Assigned BUDs must not be longer than those

specified in manufacturer's labeling.

7. Quality assurance and quality control (QA/QC)

a. Recalls due to equipment contamination:

- i. Whenever there is evidence of positive growth resulting from contact inoculation, swabbing, or impaction air testing, compounding shall immediately cease in the affected LAFH or BSC.
- ii. A report identifying all CSPs for the month prior to testing shall be compiled using the DoseEdge™ report writer and reviewed by the DOP and/or the Designated Person(s).
- iii. Any CSP prepared in the affected PEC shall be immediately removed from distribution and quarantined. This includes CSPs that have been delivered to the nursing units and/or CSPs compounded in batches that are subsequently stored in the pass-through refrigerator in the Main Pharmacy.
- iv. Infection Control shall be immediately notified.

b. Recalls due to personnel contamination:

- i. Whenever there is evidence of positive growth resulting from gloved fingertip and thumb sampling, the affected compounding personnel shall immediately cease all activities in the cleanroom suite.
- ii. A report identifying all compounded CSPs for the month by the affected individual prior to testing shall be compiled using the DoseEdge™ report writer and reviewed by the DOP and/or the Designated Person(s).
- iii. Any CSP prepared by the identified compounding personnel that is still available for use shall be immediately removed from distribution and quarantined. This includes CSPs that have been delivered to the nursing units and/or CSPs compounded in batches that are subsequently stored in the pass-through refrigerator in the Main Pharmacy.
- iv. The affected compounding personnel must retake and pass a media fill test before resuming activity in the cleanroom suite.
- v. Infection Control shall be immediately notified.

c. Manufactured CSP recalls:

- i. If the Pharmacy department alert system identifies that a medication has been recalled by the manufacturer or any recall database, the product shall be immediately identified and sequestered from the dispensing area.
- ii. If the recalled medication is an item that is compounded, a review of all records of compounding the item will be completed.

A hospital-wide search for the recalled compound will be conducted. All items identified will be sequestered. Additionally, the California State Board of Pharmacy will be notified within 12 hours of the recall notice.

- iii. All procedures outlined in the Medication Recall Policy will be followed. *Refer to Medication Recall policy.*

d. Complaint handling

- i. All complaints regarding CSPs will be immediately investigated by the Designated Person(s).
- ii. If necessary, the CSPs will be removed immediately from any dispensing area and will be segregated until the issue has been fully investigated and/or resolved.
- iii. A record of the complaint, including the date of the complaint, the nature of the complaint, and the response to the complaint will be documented and be maintained for 3 years.

e. Adverse event reporting

- i. Any adverse event associated with a CSP will be reported via the SVHMC safety reporting application and will be investigated fully.

f. Medication errors related to a CSP

- i. Any medication errors related to a CSP will be reported via the SVHMC safety reporting application and will be investigated fully.

D. Proper handling, storage, and disposal of CSP

1. CSP handling and storage

a. Maintain proper storage conditions:

- i. Pharmacy personnel must monitor drug storage areas to help ensure that CSP quality is maintained during storage.
- ii. Controlled temperature storage areas shall be monitored with a continuous temperature recording device and records must be retrievable.
 - a. Controlled room temperature: 20 to 25°C (68 to 77°F)
 - b. Controlled refrigerated temperature: 2 to 8°C (36 to 46°F)
 - c. Controlled freezer temperatures:
 - i. minus 20 to minus 10°C (minus 4 to +14°F)
 - ii. minus 50 to minus 15°C (minus 58 to minus 5°F)

b. Parenteral solutions, medications, supplies, and equipment used to

prepare CSPs shall be stored in accordance with manufacturer or USP requirements.

- c. CSPs will be sealed to prevent contamination.
- d. CSPs must be stored in accordance with the conditions stated on the label.
 - i. CSPs are only stored in designated areas.
 - ii. Store CSPs in the refrigerator at all times, unless otherwise recommended by the manufacturer or other literature.
 - iii. Discard any CSP that is known to have been exposed to temperatures warmer than the warmest labeled limit unless appropriate documentation or direct assay data confirms its continued stability.
 - iv. Any CSP exposed to temperatures warmer than 40°C for more than 4 hours are to be discarded immediately.
- e. Special handling:
 - i. All light-sensitive CSPs and injectables shall be protected by covering or enclosing the item with a UV light-resistant bag or container.
 - ii. CSPs that require refrigeration will be delivered to the appropriate nursing unit refrigerator. If administration will occur immediately, then delivery via pneumatic tube system is permissible unless it meets any of the conditions listed below.
 - iii. CSPs that are susceptible to degradation if shaken vigorously shall not be delivered via the pneumatic tube system.
 - iv. CSPs that contain controlled substances shall not be delivered via the pneumatic tube system.
 - v. Hazardous CSPs:
 - a. All hazardous drugs shall be prepared for administration only in a BSC.
 - b. Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.
 - i. Receiving hazardous drugs will be done in a space with neutral air pressure.
 - ii. Storage of hazardous drugs will be in a negative pressure room.
 - c. Hazardous drugs shall not be delivered via the pneumatic tube system.
- f. Frozen Products:

- i. Freezing of reusable sterile products:
 - a. Reusable compounded products returned to the pharmacy may be frozen for future use if suitable for the product.
 - b. Frozen products shall have a new expiration date assigned of 45 days from date of freezing or manufacture's recommendations.
 - c. Questionable products shall be discarded.
- ii. Thawing of frozen products:
 - a. Frozen products shall thaw completely and come to room temperature prior to administration.
 - b. Frozen products shall be thawed at room temperature until no crystalline particles are visible in the solution.
- iii. Identification of thawed products:
 - a. Thawed products shall be identified with a special label or mark.
 - b. Attach label: "FROZEN PRODUCT – DO NOT REFREEZE, DISCARD IF RETURNED"
- iv. Refreezing of thawed products:
 - a. Thawed products shall not be refrozen.
- v. Expiration dating of thawed products:
 - a. Thawed products shall be discarded 24 hours after thawing unless literature allows a longer retention period.
- g. Radiopharmaceutical CSPs:
 - i. SVHMC contracts all radiopharmaceutical preparation services with the Nuclear Pharmacy Division of Cardinal Health and all handling and dispensing is performed by Nuclear Medicine department.

2. **Allergenic extracts, infectious and biologic materials**

- a. The following preparations shall not be compounded in either the SVHMC Inpatient Pharmacy (IP) or the Outpatient Infusion Center (OIC) Pharmacy:
 - i. CSPs that incorporate infectious materials (e.g., BCG)
 - ii. CSPs that require manipulation of a patient's blood-derived or other biological material (e.g., autologous serum)
 - iii. CSPs that are considered an allergenic extract

VI. REFERENCES

- A. USP Chapter <797> Pharmaceutical Compounding - Sterile Preparations. Official Date 01-Nov-2023.
- B. California Board of Pharmacy 2025 Lawbook for Pharmacy.
- C. USP Chapter <1163> Quality Assurance in Pharmaceutical Compounding. Official Date 01-Dec-2012.

Attachments

- [!\[\]\(0d11da38853818dc5a6657c443337e9b_img.jpg\) Attachment A - Sterile Compounding - GFT Procedures - 02.22.2024.pdf](#)
- [!\[\]\(44a541ab775e1e40a756c5e59c05421a_img.jpg\) Attachment B - Sterile Compounding - Media Fill Procedures - 02.22.2024.pdf](#)
- [!\[\]\(5e17512195d76717988f08dadf8ac290_img.jpg\) Attachment C - Sterile Compounding - Air Sampling Procedures - 02.22.2024.pdf](#)
- [!\[\]\(53359bf82b8b4aa64d930a29dc5c3db5_img.jpg\) Attachment D - Sterile Compounding - Surface Sampling - 02.22.2024.pdf](#)
- [!\[\]\(502a0371aa2a8969d71912c9480cea93_img.jpg\) Attachment E - SVMHS - Inpatient Pharmacy - Terminal Cleaning Checklist - TEMPLATE.pdf](#)
- [!\[\]\(9cc80b4399677db6b11d318534b7e661_img.jpg\) Attachment F - SVMHS - Outpatient Infusion Center - Terminal Cleaning Checklist - TEMPLATE.pdf](#)
- [!\[\]\(186469881bfbe8abd833aaf8e5a46c91_img.jpg\) Attachment G - QA QC Program - August 2025.pdf](#)

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
LWG	Rebecca Alaga: Regulatory/ Accreditation Coordinator	10/2025
P&T	Genevieve delos Santos: Director Pharmacy	10/2025
P&T	Kiri Golleher: Pharmacy Clinical Coordinator	10/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	09/2025

Policy Owner

Genevieve delos Santos:
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09/2025

Standards

No standards are associated with this document



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Owner Terri Nielsen:
Manager Clinical Research
Area Scopes Of Service

Scope of Service: Clinical Research Program

I. SCOPE OF SERVICE

The Clinical Research Program supports the Mission, Vision, Values and Strategic Plan of Salinas Valley Health (SVH) and has designed services to meet the needs and expectations of patients, families and the community.

The purpose of the Clinical Research Program is to enhance patient services and health programs that help SVH remain a leading provider of medical care.

II. GOALS

The Clinical Research Program develops goals to to enhance patient services that help SVH remain a leading provider of medical care. We do so by maintaining a diverse portfolio of clinical research protocols that align with our patient population.

The Clinical Research Program provides support, leadership, and regulatory oversight of high quality, ethical human research conducted on SVH premises, inclusive of the SVH Clinics, to support outpatients who have consented or are considering consent to participate in IRB-approved clinical research protocols and the principal investigators who wish to conduct research involving human subjects.

III. DEPARTMENT OBJECTIVES

- A. Support the SVH research community in the conduct of ethical clinical research and human subject protection in compliance with the required federal, state, and local regulations.
- B. Meet or exceed the educational standards established by the leading professional associations such as the Society of Clinical Research Associates (SOCRA) and the Association of Clinical Research Professionals (ACRP), to support the provision of high quality service with a focus on a collaborative, multi-disciplinary approach to support clinical research protocol compliance.
- C. To provide research education and training, develop policy and processes, and lead quality improvement efforts in areas of clinical trial management.
- D. To create an interdisciplinary collaborative environment in our organization, fostering best

practices in the conduct of clinical research.

- E. To provide consultation on questions related to regulations and standards of practice governing human research.
- F. Community engagement: Educating the public about clinical research may help raise general awareness about the important role this research plays in safeguarding health and quality of life. Staff are available to volunteer for community education on clinical trials.
- G. ADDENDUM for compliance with the American College of Surgeons Commission on Cancer (ACS CoC) STANDARD 9.1: Clinical Research Accrual:⁸
 - 1. The National Comprehensive Cancer Network (NCCN) and the American College of Surgeons Commission on Cancer place a high value on cancer clinical trials. The NCCN Guidelines for all cancers are footnoted as follows: "NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged." To implement the NCCN best practice guideline, the research staff screen 100% of patients seen at the Salinas Valley Health Cancer Care Clinic for eligibility in our cancer clinical trials. Research staff notify the treating oncologist of potentially eligible patients. If the physician refers the patient to Research Team, a Clinical Research Coordinator will reach out to the patient to begin the informed consent process.
 - 2. Patients are provided with clinical research information in easily accessible formats. Brochures are available in the Cancer Resource Center and the Salinas Valley Health Cancer Care Clinic in print, and digitally on the Salinas Valley Health public website. The Cancer Clinical Trials Brochure is provided in English, and in Spanish using an ISO-certified translation service. Additional venues of community information on clinical trials, such as are Salinas Valley Health public events, may be utilized so long as any public-facing clinical research information is approved by the governing research oversight body (IRB or ROC). The clinical research coordinator(s) are available Monday through Friday during regular business hours to answer research-related questions from patients and their family members.

IV. POPULATION SERVED

- A. The patient population includes research participants currently consented on an IRB-approved research protocol at SVH, and prospective research participants who may be eligible to enroll in current IRB-approved research protocols at SVH. In addition to patients who are receiving care from SVH, research participants may include employees and / or members of the community.
- B. The Clinical Research Program provides support to physician investigators who conduct, or wish to conduct, investigational drug or device trials under U.S. FDA oversight. Areas of support include clinical trial contract administration, research budget development with insurance coverage analyses, IRB submissions and correspondence, research regulatory compliance, management of external research audits and CAPA plans if indicated.
- C. Research involving human subjects at Salinas Valley Health falls in one of two categories: (1) biomedical, evaluating under FDA oversight the efficacy and safety of investigational drugs or devices; or (2) social-behavioral-educational, which applies the behavioral and social sciences to the study of humans and is not under FDA oversight.
- D. Note: SVH provides medical care to the forensic population of a California state prison, and this vulnerable population is categorically excluded from research participation at SVH: "Inasmuch as

prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable." (46 CFR 46.302)

V. DEPARTMENT INFORMATION

- A. Hours of Operation:
The Clinical Research Program provides services Monday through Friday from 8:00 a.m. to 5:00 p.m. Flexible hours are occasionally required; staffing requirements will be met by authorizing overtime and/or utilizing temporary services.
- B. Location of department:
450 E. Romie Lane, Salinas, CA 93901.
- C. Admission, Discharge, Transfer Criteria (not applicable)
- D. Major Services - not a patient care department

VI. DEFINITION OF PRACTICE AND ROLE IN MULTIDISCIPLINARY CARE /SERVICE

- A. Salinas Valley Health, inclusive of the SVH Clinics, is an institution engaged in research involving human subjects. Salinas Valley Health, as a Research Institution, bears responsibility for compliance with federal and California laws and regulations governing the conduct of such research. The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) provide the regulations for the performance of biomedical research activities involving human subjects. The FDA monitors biomedical research through review of required reports from investigators, sponsors, institutions and IRBs, as well as through a program of on-site inspections and audits.
- B. Salinas Valley Memorial Healthcare System (dba Salinas Valley Health) is registered with the Office of Human Research Protections (OHRP) under a Federal wide Assurance of Compliance: FWA # 00007215. The Salinas Valley Health Clinics (SVHC) are listed as component institutions under SVMHS FWA#00007215.
- C. SVH follows clinical research Good Clinical Practices (GCPs). GCPs are the international ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing and reporting trials that involve the participation of human subjects.
- D. The Clinical Research Program reports to the Research Program Manager. The Research Program reports to the Chief Medical Officer service line. It is the Research Program Manager's duty to attend all administrative and technical functions within the Clinical Research Program. All personnel within the Clinical Research Program are under the guidance and direction of the Research Program Manager. In the Manager's absence, the Chief Medical Officer fills the position.
- E. COMPLEXITY OF CARE PROVIDED:

SVH is a public health care district organized and operating pursuant to Division 23 of the California Health and Safety Code. Its Research Program is a community-based research site, and as such does not conduct Phase I "first in humans" research protocols. Phase II, Phase III and Phase IV protocols are evaluated and considered based on complexity as part of the pre-IRB feasibility assessment conducted by the Research Oversight Committee (ROC). Prior to ROC

review, the Research Manager coordinates the feasibility assessment with relevant SVH stakeholders and ensures protocols are aligned with current patient population, organizational mission, and available resources.

F. SVH ROC:

The ROC is Salinas Valley Health's Human Research Protection Program (HRPP), and is a Sub-Committee of the Pharmacy & Therapeutics / Infection Control Committee (Medical Staff Bylaws section 10.14).

G. The ROC reviews and approves research proposals by:

1. Considering how the research benefits the patient population that our district serves (Local Context)
2. Evaluating if the proposed research is compatible with the mission and vision of SVH
3. Directing the Research Program Manager to gather multidisciplinary teams to coordinate the health care district resources needed to complete research.

H. INSTITUTIONAL REVIEW BOARD (IRB) STRUCTURE FOR SVH:

Research at SVH is governed by two bodies to provide research oversight and guidance: (1) the ROC and (2) an external Institutional Review Board of Record. SVH does not have an in-house IRB, but has adopted the model that relies on an external, centralized Institutional Review Board (IRB) review process. "An IRB that is at a different location from the research site can review the research, provided that the IRB is competent to understand the local context of the research. As stated in 21 CFR 56.107(a), this would require sensitivity to community attitudes and the ability to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice."¹

- I. The IRB of Record for a biomedical research protocol is required to (1) have an institutional Reliance Agreement (RA) with SVH, (2) be registered with OHRP, and (3) hold current accreditation with the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The RA sets forth the IRB's responsibilities and SVH's responsibilities, with a shared responsibility for Local Context Review.¹ SVH can have as many IRBs of Record as needed to support its research objectives, but must list each central IRB (with whom it holds a valid RA) under its FWA with the Office of Human Research Protections.

1. These are the 3 external IRB Reliance Agreements most frequently used at Salinas Valley Health:
 - a. Advarra IRB
 - b. WCG IRB
 - c. National Cancer Institute (NCI) CIRB

J. Research that may be exempt from IRB oversight:

At SVH, an IRB (with or without a reliance agreement with SVH) must make the determination of exemption from IRB oversight, approval and continuing review.

Under 45 CFR 46.101 (b), there are 6 categories of non-FDA regulated research for which an IRB will grant an exemption. Typically, the types of research at SVH that qualify for exemption are in Category 2 and Category 4.

Refer to Attachment: "Categories of Research that May be Exempt Under 46 CFR 14.101(b)."

K. Under this IRB oversight model, the ROC provides the mechanism to:

1. Ensure meaningful consideration of relevant local factors in conjunction with any central IRB with whom Salinas Valley Health holds an active Institutional Reliance Agreement in a shared responsibility for Local Context Review.
 - a. Addendum to this Scope of Service policy upholding the "Authorization Agreement and Division of Responsibilities Between the NCI Central Institutional Review Board and Salinas Valley Memorial Healthcare System (the Signatory Institution)" is as follows:
 - b. Excerpt from NCI CIRB Authorization Agreement: Salinas Valley Health ensures the safe and appropriate performance of the research at the Signatory Institution and at all Component Institutions (the Salinas Valley Health Clinics). This includes, but is not limited to:

Contractual Responsibility	Responsible party within our organization
Ensuring the initial and ongoing qualifications of investigators and research staff	Research Manager
Overseeing the conduct of the research	Principal Investigator in collaboration with the Research Manager
Monitoring protocol compliance	The ROC in collaboration with the Principal Investigator and the Research Manager
Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects	Principal Investigator, Research Manager and Clinical Research Coordinators
Providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research	The ROC, Salinas Valley Health's HRPP
Investigating, managing, and providing notification to the NCI CIRB of any study-specific incidence, experience, or outcome that seems to rise to the level of an unanticipated problem and/or serious or continuing noncompliance. When notifying the NCI CIRB of a potential unanticipated problem and/or serious or continuing noncompliance, the institution must provide a plan to manage the incident, experience, or	Research Manager, Principal Investigators and Clinical Research Coordinators

Contractual Responsibility	Responsible party within our organization
outcome, including measures to prevent similar occurrence	

NOTE: As part of ensuring safe and appropriate performance of research, the Signatory Institution has the authority to observe any aspect of the research process including observing the consent process. The NCI CIRB retains the authority to direct this to be done when necessary.

2. Receive new research project proposals at SVH, to ensure alignment and harmony with the institution's mission and goals in advance of IRB submission, ensuring compliance with relevant local, state and federal laws and regulations.
3. Provide the SVH HRPP a venue to receive and review research-related reports. Some examples are: (a) adverse events, (b) research subject communications, and (c) current clinical trial accruals and closures.
4. The ROC also provides the venue for the SVH to uphold its institutional responsibility and authority to stop any current research conducted on SVH premises.

L. Composition

The ROC is composed of medical staff, clinical research, compliance, nursing, quality assurance, risk management, regulatory, and community members as required for submitted agenda item review. Ad hoc, non-voting representatives from applicable departments or services will be invited when research affecting the department or service will be discussed. The following roles are required to be identified by DHHS OHRP for the SVH ROC's HRPP:

1. Conflicts of Interests Officer: Corporate Compliance Director
2. HRPP Administrator: Executive Leader over Research Program
3. Organizational Signatory Official: Chief Medical Officer

M. Duties

1. To serve as the HRPP for Salinas Valley Health. The Committee meets regularly to review interim status reports submitted by the clinical research team on all active clinical trials under IRB oversight (with subjects in treatment or follow-up) pertaining to accrual, closure, research-related adverse events, protocol deviations, protocol violations, Good Clinical Practice noncompliance, and any change in the status of any principal investigator conducting research on Salinas Valley Health premises.
2. Review all proposed clinical/biomedical research protocols conducted on Salinas Valley Health premises prior to their submission for external Institutional Review Board approval. This review shall include hearing presentations by principal investigators seeking approval of studies. Evaluation of proposed studies shall consider matters of local context, such as applicable state and local laws/standards, consistency with institutional policy and capacity (i.e., staffing and resources), and consideration of local subjects.
3. Review all proposed Social Behavioral / Educational (SBE) Research conducted on Salinas Valley Health premises prior to being submitted for external Institutional Review Board approval. This review shall include hearing presentations by principal investigators

seeking approval of studies. Evaluation of proposed studies shall consider matters of local context, such as applicable state and local laws/standards, consistency with institutional policy and capacity (i.e., staffing and resources), and consideration of local subjects. Proposed studies will be considered on a first-come, first-served basis.

4. Review all proposed Retrospective Records Review research prior to initiation. This may include hearing presentations by researchers seeking approval of studies.
5. Review all other research, evidence-based practice (EBP), quality improvement (QI) projects, and performance improvement (PI) projects and data management plans, which are all subject to HIPAA review.
6. Review all content that references SVH clinical research, clinical trials, or any specific clinical or social behavioral research under the oversight of the ROC, prior to its publication internally and externally.
7. Facilitate referral to Research Manager any Research / Non-Research Determinations and Exempt Research Determinations in collaboration with external commercial IRB of record.
8. Facilitate referral to Privacy Officer to Review / approve all projects with patient data collection, use and/or disclosure. Purpose: process for HIM to document HIPAA compliance for Salinas Valley Health, and identify/provide HIPAA compliance training needs as needed. Documentation is then available for external audit is needed.
9. Review all proposed Humanitarian Use Device protocols prior to submission. This may include consideration of intended patient population at SVH, principal investigator credentialing, IRB submission, facilitating HUD PI and staff training with the device manufacturer, and coordination of cost analysis in collaboration with Materials Management.
10. In its role as HRPP, the ROC follows AAHRPP Level 0 criteria.²
11. Serves as the venue to receive and address concerns from study participants and/or family members, community members and others about the conduct of research at Salinas Valley Health. The Salinas Valley Health Ethics Hotline is made available to our research participants in English and Spanish for identified or anonymous reporting.
 - a. Addendum for "**Authorization Agreement and Division of Responsibilities Between the NCI Central Institutional Review Board and the Signatory Institution:**" The study participant is provided, on the research informed consent form, four (4) mechanisms to address concerns about the conduct of the research at Salinas Valley Health: 1) Phone number for the Salinas Valley Health Principal Investigator that is available 24 hours/day, 7 days/week; 2) Phone number for clinical research staff available Monday-Friday during business hours; 3) Phone number for the NCI CIRB; and 4) Phone number for the Salinas Valley Health **Ethics Line** accessible to research participants and family members 24/7. These 4 methods to address any questions are explained to research participants as part of the research informed consent process.
12. Monitor protocol compliance of all research at SVH.
 - a. Addendum for the PURCHASE SERVICES AGREEMENT between Salinas Valley Health and ECOG-ACRIN Cancer Research Group, our Master Clinical Trials Agreement for NCI-sponsored protocols: the Committee receives the report of

the ECOG-ACRIN site monitoring Audit, which is conducted by the NCI National Clinical Trials Network (NCTN) and its Clinical Trials Monitoring Branch (CTMB) a minimum of every 3 years, and can be done at the discretion of NCTN at any intervening time with proper notice. The research staff uphold the NCTN and ECOG-ACRIN regulations and guidelines for protocol compliance. Areas of audit are: Regulatory, Study Drug Accountability and Clinical Case review.⁵

13. The Committee receives reports regarding any:
 - a. research-related serious adverse events involving participants enrolled at Salinas Valley Health
 - b. research protocol violations
 - c. clinical research Good Clinical Practice noncompliance
 - d. change in approved status of any principal investigator conducting research on SVH premises
14. The Committee delegates to the Research Program Manager the responsibility for verifying and collecting documentation of investigator credentials, licenses, curriculum vitae, human subject protections training and financial conflicts of interest disclosure; these are presented by the Manager to the ROC for approval.
15. The Committee evaluates and recommends policy, procedure and other guidelines related to the research program.
16. The Committee has directed that prior to submitting a new clinical trial to the IRB of Record, departmental feasibility assessment is required by means of a signature approval from department heads. An exception: oncology clinical trial feasibility is conducted in collaboration with the current Oncology Research Medical Director.

N. Meetings

1. The Committee shall meet as often as necessary, but at least quarterly.
2. The Committee shall maintain a record of its proceedings and shall report its activities to the Chief Medical Officer at least semiannually and the SVH Board of Directors at least annually.
3. The ROC Coordinator, functioning similarly to a Institutional Review Board (IRB) coordinator, plays a crucial role in managing the administrative and operational aspects of research oversight. They report to the ROC Chair and function under the direction of the Research Program Manager.

VII. REQUIREMENTS FOR STAFF

All individuals who provide Clinical Research Program services have the appropriate training and competence.

- A. Investigators: Prior to conducting research at SVH, Investigators in good standing³ must:
 1. Complete all training required by SVH and the protocol sponsor, including current certification of training in Human Subjects Protection and Good Clinical Practice (ICH and/or U.S. FDA standards).

2. Submit the proposed study through the ROC process and the IRB of Record
 3. Receive approval from both governing bodies; report quarterly to ROC until final closure of study with the IRB.
- B. The Research Program Manager assumes twenty-four (24) hour responsibility for the Clinical Research Program.
- C. Clinical Research Coordinators: Prior to coordinating human subjects research at SVH, Clinical Research Coordinators must:
1. Complete all training required by SVH and the protocol sponsor.
 2. Document Investigator and sponsor approval by signing the Delegation of Authority Log.
 3. Clinical Research Coordinators who are Registered Nurses are required to hold current California RN license.
 4. Clinical Research Coordinators regardless of clinical experience are required to have:
 - a. Current Collaborative Institutional Training Initiative ("CITI") Program certificate of completion for 2 modules: (1) Protection of Human Subjects in Biomedical Research and (2) Good Clinical Practice (GCP) ICH E6
 - b. Current basic life support training certificate
 - c. Current International Air Transport Association (IATA) approved training in Shipping & Handling of Dangerous Goods
 - d. When qualified with 2 years' experience: certification in coordination of clinical research from accredited professional research organization: SOCRA or ACRP. (for example: CCRP, CCRA, and CCRC)
- D. Administrative assistants are required to have:
1. Completion of competency-based department orientation
 2. Completion of annual competency
 3. Completion of computer competency and Microsoft Office Suite
- E. Competency

Staff are required to have research competence in tasks necessary to serve our patient population. The required competency for staff depends primarily on their work areas and duties. Competency is assessed by the manager throughout the year on an as-needed basis, then summarized at the annual employee evaluation. Once a year staff are required to complete the on-line education modules that have been defined by the organization.

During the year, clinical research professional development activities and education are implemented for all department staff. This professional development is in addition to the annual competency assessments. Department personnel who attend educational conferences are strongly encouraged to share pertinent information from the conferences with other staff members at in-services. Additional teleconferences, video conferences, and speakers are scheduled for staff on occasion. Other internal and external continuing education opportunities are communicated to staff members.

F. Identification of Educational Needs

Staff educational needs are identified utilizing a variety of input:

- Employee educational needs assessment at the time of hire and annually as part of developmental planning
- Performance improvement planning, data collections and activities
- Staff input
- Evaluation of patient population needs
- New services/programs/technology implemented
- Change in the standard of practice/care
- Change in regulations and licensing requirements
- Needs assessment completed by Nursing Education

The educational needs of the department are assessed through a variety of means, including:

- STAR Values
- Quality Assessment and Improvement Initiatives
- Strategic Planning (Goals & Objectives)
- New / emerging products and/or technologies
- Changes in Practice
- Regulatory Compliance

Feedback and requests for future topics are regularly solicited from staff via e-mail, surveys, in-service evaluation forms, and in person.

G. Continuing Education

Continuing education is required to maintain licenses / certifications. Additional in-services and continuing education programs are provided to staff in cooperation with the Department of Education.

VIII. STAFFING PLAN

Staffing is adequate to service the customer population. The unit is staffed with a sufficient number of professional, technical and clerical personnel to permit coverage of established hours of care / service, to provide a safe standard of practice and meet regulatory requirements.

General Staffing Plan:

In the event of a severe emergency, the minimum amount of staff required to safely operate this unit is: **zero**

IX. EVIDENCED BASED STANDARDS

The SVH staff will correctly and competently provide the right service, do the right procedures, treatments, interventions, and care by following evidenced based policies and practice standards that have been established to ensure patient safety. Efficacy and appropriateness of procedures, treatments, interventions, and care provided will be demonstrated based on patient assessments/reassessments, state of the art

practice, desired outcomes and with respect to patient rights and confidentiality.

The SVH staff will design, implement and evaluate systems and services for care / service delivery which are consistent with a "Patient First" philosophy and which will be delivered:

- With compassion, respect and dignity for each individual without bias.
- In a manner that best meets the individualized needs of the patient.
- In a timely manner.
- Coordinated through multidisciplinary team collaboration.
- In a manner that maximizes the efficient use of financial and human resources.

SVH has developed administrative and clinical standards for staff practice and these are available on the internal intranet site.

X. CONTRACTED SERVICES

- A. Contracted services under this Scope of Service are maintained in Salinas Valley Health's electronic contract management system.
- B. Research financial and accounting support, statistician support, and other operational support may be acquired from time to time via professional services agreements with external vendors.

XI. PERFORMANCE IMPROVEMENT AND PATIENT SAFETY

The Clinical Research Program supports SVHMC's commitment to continuously improving the quality of patient care to the patients we serve and to an environment which encourages performance improvement within all levels of the organization. Performance improvement activities are planned in a collaborative and interdisciplinary manner, involving teams/committees that include representatives from other hospital departments as necessary. Participation in activities that support ongoing improvement and quality care is the responsibility of all staff members. Improvement activities involve department specific quality improvement activities, interdisciplinary performance improvement activities and quality control activities.

Systems and services are evaluated to determine their timeliness, appropriateness, necessity and the extent to which the care / service(s) provided meet the customers' needs through any one or all of the quality improvement practices / processes determined by this organizational unit.

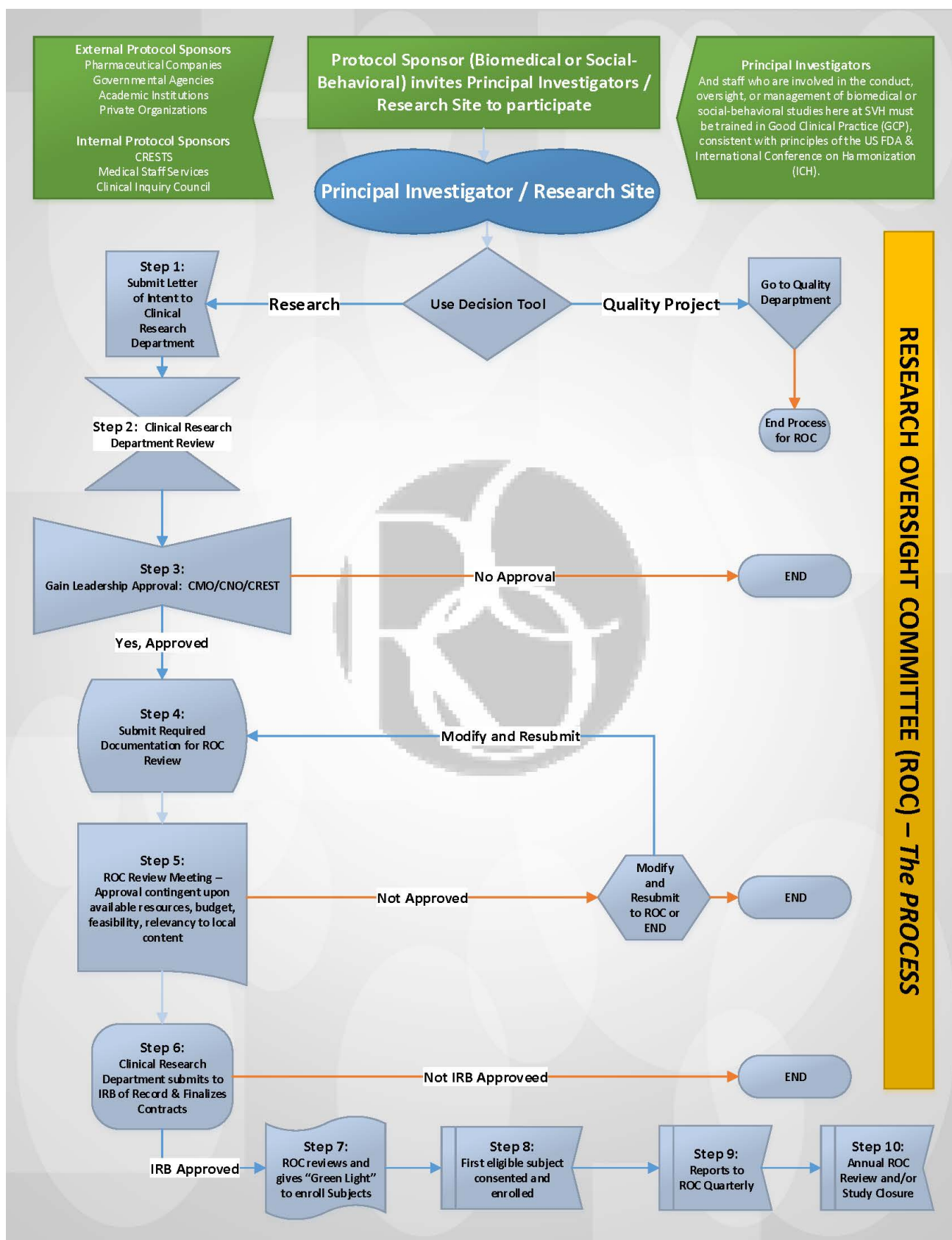
In addition to the overall SVHMC Strategic initiatives and in concert with the Quality Improvement Plan and the Quality Oversight Structure, the Clinical Research Program will develop measures to direct short-term projects and deal with problem issues evolving out of quality management activities.

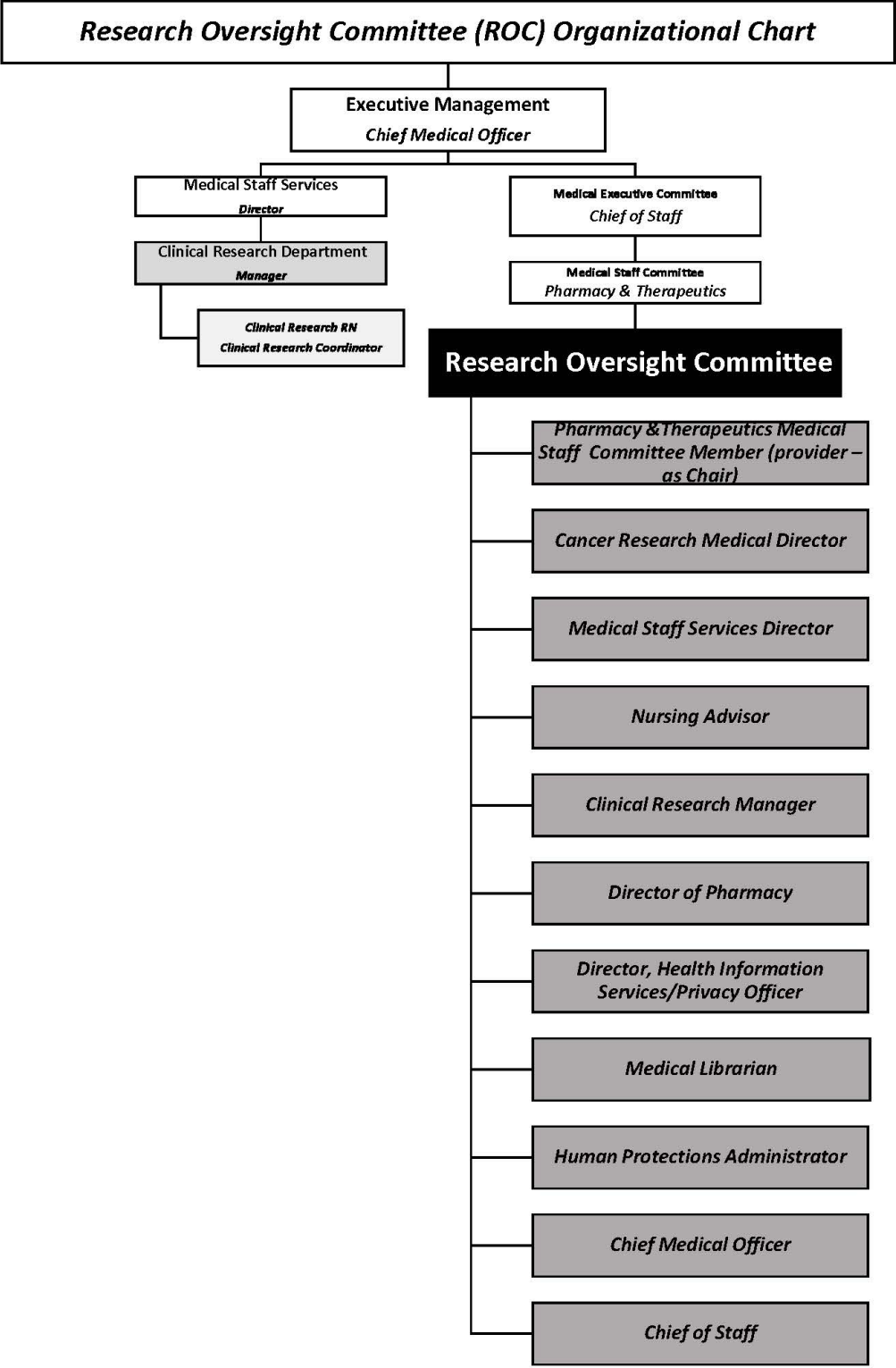
Unit based measurement indicators are found within the Quality dashboard folder.

References:

1. FDA Guidance document: "Using a Centralized IRB Review Process in Multicenter Clinical Trials," accessed on May 22, 2018: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm127004.htm>

2. AAHRPP Level 0 criteria.
 - a. Accessed at: <https://www.aahrpp.org/>
3. U.S. Food and Drug Administration. 2017. Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors – FDA Inspections of Clinical Investigators. <https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm>
4. ECOG-ACRIN Manual of Operations, v.6.2
 - a. The ECOG-ACRIN Cancer Research Group is a multidisciplinary, membership-based scientific organization that designs and conducts biomarker-driven cancer research involving adults who have or are at risk of developing cancer. ECOG-ACRIN has been awarded a grant by the National Cancer Institute as a member of NCI Clinical Trials Network (NCTN).
 - b. SVH has a master agreement with ECOG-ACRIN that allows our organization to open NCI-sponsored cancer protocols in Salinas, as an aligned affiliate of the Stanford Cancer Institute, an NCI Main Institution and grant awardee.
5. NCI Guidelines For Auditing Clinical Trials for the NCI National Clinical Trials Network (NCTN) Program, Community Clinical Oncology Program (CCOP) / NCI Community Oncology Research Program (NCORP) and Research Bases, v. 13
 - a. See link: <https://ctep.cancer.gov/branches/ctmb/>
6. Research advisory for California law: see Health & Safety Code Section 24172 (Calif. Experimental Subject's Bill of Rights), California Civil Code Section 56.11 (Font size requirement for HIPAA Authorization language must be 14 pt.). Accessed on May 24 2018 at: http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=24172.&lawCode=HSC
7. Office for Human Research Protections. Frequently Asked Questions (FAQs). Accessed June 2018 from: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/index.html>
8. American College of Surgeons Commission on Cancer (ACS CoC) 2020 Standards for Accreditation - Optimal Resources for Cancer Care. Accessed on March 18, 2024 at: <https://www.facs.org/quality-programs/cancer-programs/commission-on-cancer/standards-and-resources/>





Attachments

 [Categories of Research that may be Exempt under 45 CFR 46.101\(b\)](#)

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
ELG	Rebecca Alaga: Regulatory/ Accreditation Coordinator	10/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	09/2025
Policy Owner	Terri Nielsen: Manager Clinical Research	09/2025

Standards

No standards are associated with this document



Origination 07/2022
Last Approved N/A
Next Review 3 years after approval

Owner Carla Spencer:
Chief Nursing
Officer
Area Patient Care

Sedation for the Mechanically Ventilated Adult

I. POLICY STATEMENT

A. N/A

II. PURPOSE

A. To guide the staff in providing the appropriate level of sedation for patients requiring mechanical ventilation.

III. DEFINITIONS

- A. RASS: Richmond Agitation Sedation Scale. An evidence based scale to quantify the patient's level of sedation
- B. NIF: Negative Inspiratory Force
- C. Yang-Tobin Index: Weaning parameter calculating by dividing Respiratory Rate by Tidal Volume (in Liters)

IV. GENERAL INFORMATION

A. Daily sedation vacation will be performed as long as exclusion criteria are not met for the measurement of ventilator weaning parameters.

V. PROCEDURE

- A. Pain and sedation should be assessed together (refer to: [PAIN MANAGEMENT](#)), using appropriate pain scale. Treat patient's pain as prescribed.
- B. Use RASS scale to determine level of sedation. Determine if level of sedation is within the target range specified by physician (refer to physician order for target RASS goal).
 - 1. RASS Score is documented every four hours and with every sedation medication titration for patients receiving continuous sedation.
 - 2. First observe patient. If patient is alert, restless, or agitated, score is 0 to +4 (see

Attachment)

3. If not alert, state patient's name and instruct to open eyes and look at the speaker.
 - a. Patient awakens with sustained eye opening and eye contact (score -1)
 - b. Patient awakens with eye opening and eye contact, but not sustained (score -2)
 - c. Patient has any movement in response to voice but no eye contact (score -3)
 4. When no response to verbal stimulation, physically stimulate patient by shaking or sternal rub.
 - a. Patient has any movement to physical stimulation (score-4)
 - b. Patient has no response to any stimulation (score -5)
- C. Titration of sedation agents is done according to orders and titration guidelines. (Attachment A)
- D. Daily Sedation Vacation
1. The patient is evaluated daily for Inclusion Criteria and RASS score to determine if they are eligible for the Sedation Vacation.
 2. Inclusion criteria are:
 - a. MAP greater than 60 and/or SBP greater than 90, regardless of any vasopressor support
 - b. HR greater than 50 and less than 130
 - c. Temperature less than 38.3 C
 - d. FiO2 less than or equal to 50%
 - e. PEEP less than 8
 - f. Not on Pressure Control
 3. Establish baseline RASS:
 - a. If RASS less than or equal to (-1) Hold sedation for 30 minutes
 - b. If agitation results prior to 30 minutes off sedation, resume prior sedation rate
 - c. After 30 minutes off sedation, determine RASS score
 - d. If RASS is (+1) to (-1), perform NIF and Yang-Tobin Index
- E. Documentation: Findings are documented in Electronic Medical Record.
- F. **This table is to be used as a guide:**

Drug Name	Class	SVH Standard Concentration	SVH Dosing Units	Bolus	Usual Effective Dosing Range	Titration goal & frequency	Special considerations
Dexmedetomidine	Sedatives	400 mcg/100 mL NS (premix) = 4 mcg/mL	mcg/kg/hr	-	Cont infusion: 0.2-1.5 mcg/kg/hr Max= 1.5 mcg/kg/hr Titrate- 0.1-0.2 mcg/kg/hr Obesity dosing: BMI>=30 use adjusted or ideal body weight is preferred	RASS Q30min*	Monitor for bradycardia, sinus arrest and hypotension
Ketamine Infusion (ICU vented pts only)	analgesia/ sedation/ agitation	1,000 mg/500 mL DSW or NS = 2 mg/mL 2,000 mg/1000 mL DSW or NS = 2 mg/mL 500 mg/250 mL DSW or NS = 2 mg/mL	mg/kg/hr	Bolus: 0.1-0.5 mg/kg Max: 2.5mg/kg/Hr	Cont infusion: 0.2-0.5 mg/kg/hr For mechanically ventilated patients in the ICU Obesity dosing: BMI>=40 use adjusted or ideal body weight is preferred	Sedation (RASS and/or vent synchrony) Q5min*	Titration based on MD order ONLY

LORazepam	Sedative	25 mg/250 mL D5W = 0.1 mg/mL	mg/hr	+	Cont infusion: 0.5-10 mg/hr Titrate 0.5mg/min Max= 10 mg/hr	RASS Q10min*	-Use low absorption tubing and 0.2 micron filter - Use Non-PVC container
Midazolam	Sedative	100 mg/100 mL NS (premix) Conc: 1 mg/mL	mg/hr	+	Cont infusion: 1-8 mg/hr Titrate: 0.5mg/hr Max= 8 mg/hr For RASS that exceeds goals, hold until RASS reached then resume at 50% previous rate	RASS Q10min*	May be given in non-monitored unit for End of Life care
Propofol	Sedative	1,000 mg/100 mL (premix) = 10 mg/mL	mcg/kg/min	+	Cont infusion: 5-50 mcg/kg/min Titrate: 5-15 mcg/kg/min Max: 60 to 80 mcg/kg/min Obesity dosing: BMI >=30 use adjusted or ideal body weight is preferred	RASS Q5min*	Must be intubated Monitor for bradycardia and hypotension Hypertriglyceridemia onset 2-4 days, especially if >50 mcg/Kg/min for > 2 days -Propofol-related infusion syndrome (PRIS) – rare but high mortality rate

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed

VII. REFERENCES

- Caitlin Brown, Pasquale Joseph Marotta, Richard R. Riker, Ashley D. Eldridge, Gilles L. Fraser, Teresa L. May; Prospective Validation of Sedation Scale Scores That Identify Light Sedation: A Pilot Study. *Am J Crit Care* 1 May 2022; 31 (3): 202–208. doi: <https://doi.org/10.4037/ajcc2022437>
- Freeman CL, Evans CS, Barrett TW. Managing sedation in the mechanically ventilated emergency department patient: a clinical review. *J Am Coll Emerg Physicians Open*. 2020 Apr 10;1(3):263-269. doi: 10.1002/emp2.12045. PMID: 33000041; PMCID: PMC7493591.
- Jenna S. Carraway, Michael W. Carraway, Christopher A. Truelove, Nursing implementation of a validated agitation and sedation scale: An evaluation of its outcomes on ventilator days and ICU length of stay, *Applied Nursing Research*, Volume 57, 2021, 151372, ISSN 0897-1897, <https://doi.org/10.1016/j.apnr.2020.151372>.

Attachments

 [Image 1](#)

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending

Critical Care Director	Carla Spencer: Chief Nursing Officer	09/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	09/2025
Policy Owner	Carla Spencer: Chief Nursing Officer	09/2025

Standards

No standards are associated with this document

BOARD MEMBER COMMENTS

AND REFERRALS

(VERBAL)

*QUALITY AND EFFICIENT
PRACTICES COMMITTEE*

*Minutes of the
Quality and Efficient Practices Committee
will be distributed at the Board Meeting*

(CATHERINE CARSON)

*PERSONNEL, PENSION & INVESTMENT
COMMITTEE*

*Minutes of the
Personnel, Pension & Investment Committee
will be distributed at the Board Meeting*

*Background information supporting the
proposed recommendation from the
Committee is included in the Board Packet*

(CATHERINE CARSON)

Board Paper: Personnel, Pension and Investment Committee

Agenda Item: **Consider Recommendation for Board Approval of (i) Findings Supporting Recruitment of Martin Kamper, MD, (ii) Contract Terms for Dr. Kamper's Recruitment Agreement, and (iii) Contract Terms for Dr. Kamper's Pulmonary and Critical Care Professional Services Agreement**

Executive Sponsor: Tim Albert, MD, Chief Clinical Officer
Molly Heacox, Director of Clinic Services

Date: October 6, 2025

Executive Summary

In consultation with members of the medical staff, Salinas Valley Health (SVH) executive management has identified the recruitment of physicians specializing in **pulmonary and critical care** as a recruiting priority for SVH's service area. Based on the Medical Staff Development Plan, completed by ECG Management Group in January 2023, the specialty of pulmonary and critical care was recommended as a priority for recruitment.

The recommended physician, **Martin Kamper, MD**, received his Doctor of Medicine degree in 2018 from the University of Missouri – Columbia School of Medicine. Following Dr. Kamper's Internal Medicine residency at Loyola University Medical Center, he completed his Pulmonary and Critical Care Fellowship at Hofstra University in New York. After completing his training, Dr. Kamper joined Zucker School of Medicine at Hofstra/Northwell Health in New York as an Assistant Professor. He is triple Board certified in Internal Medicine, Pulmonary Medicine, and Critical Care Medicine. Dr. Kamper speaks conversational Spanish and plans to relocate to the community with his fiancé, a Gastroenterology Fellow. He plans to join SVH Clinics in May 2026.

Terms and Conditions of Agreements

The proposed physician recruitment requires the execution of two types of agreements:

1. **Professional Services Agreement**. Essential Terms and Conditions:

- **Professional Services Agreement (PSA)**. Physician will be contracted under a PSA with Salinas Valley Health and a member of Salinas Valley Health Clinics. Pursuant to California law, the physician will not be an employee of SVH or SVH Clinics but rather a contracted physician.
- **Term**: PSA is for a term of two years, with annual compensation reported on an IRS W-2 Form.
- **Full-Time Schedule**. Physician will be scheduled to provide physician services to clinic patients on a full-time basis, forty-six weeks per year.
- **Compensation**. Physician will earn \$525,000 per year base compensation plus the opportunity for a productivity incentive. Physician will be eligible for additional compensation for shifts in excess of the schedule set forth below; subject to the needs for coverage by SVH. Such coverage will be compensated on a prorated shift basis.
- **Schedule**. Physician shall provide services to patients on a full-time basis in the clinic, hospital intensive care unit, or on hospital rounds on a rotating basis forty-six weeks per year.
- **Annual Incentive Plan**. Physician will be eligible to participate in an Annual Performance Incentive Bonus Plan with the opportunity to earn up to \$15,000 annually.
- **Professional Liability Insurance**. Professional liability is provided through BETA Healthcare Group.

- **Benefits.** Physician will be eligible for standard SVH Clinics physician benefits:
 - ❖ Access to SVH Health Plan for physician and qualified dependents. Premiums are projected based on 15% of SVH cost.
 - ❖ Access to SVH 403(b) and 457 retirement plans. Five percent base contribution to 403(b) plan that vests after three years. This contribution is capped at the limits set by Federal law.
 - ❖ Six work weeks of time off each calendar year, accruing equally throughout the year.
 - ❖ Continuing Medical Education (CME) annual stipend in the amount of \$2,400 paid directly to physician and reported as 1099 income.

2. **Recruitment Agreement** that provides a recruitment incentive of \$50,000, which is structured as forgivable loan over two years of service.

Meeting our Mission, Vision, Goals

Strategic Plan Alignment

The recruitment of Dr. Kamper is aligned with our strategic priorities the service, quality, and growth pillars. We continue to develop Salinas Valley Health Clinics infrastructure that engages our physicians in a meaningful way, promotes efficiencies in care delivery and creates opportunities for expansion of services. This investment provides a platform for growth that can be developed to better meet the needs of the residents of our District by improving access to care regardless of insurance coverage or ability to pay for services.

Pillar/Goal Alignment:

☒ **Service** ☐ **People** ☒ **Quality** ☐ **Finance** ☒ **Growth** ☐ **Community**

Financial/Quality/Safety/Regulatory Implications

The addition of Dr. Kamper to Salinas Valley Health Clinics has been identified as a need for recruitment while also providing additional resources and coverage for the pulmonary and critical care service line.

The compensation proposed in these agreements have been reviewed against published industry benchmarks to confirm that the terms contemplated are fair market value and commercially reasonable.

Recommendation

Salinas Valley Health Administration requests that the Salinas Valley Health Board of Directors approve of the following:

1. **The Findings Supporting Recruitment of Martin Kamper, MD:**
 - That the recruitment of pulmonary and critical care physician to Salinas Valley Health Clinics is in the best interest of the public health of the communities served by the District; and
 - That the recruitment benefits and incentives the hospital proposes for this recruitment are necessary in order to attract and relocate an appropriately qualified physician to practice in the communities served by the District;
2. **The Contract Terms of the Recruitment Agreement for Dr. Kamper; and**
3. **The Contract Terms of the Pulmonary and Critical Care Professional Services Agreement for Dr. Kamper.**

Attachments

Curriculum Vitae for Martin Kamper, MD

- **Benefits.** Physician will be eligible for standard SVH Clinics physician benefits:
 - ❖ Access to SVH Health Plan for physician and qualified dependents. Premiums are projected based on 15% of SVH cost.
 - ❖ Access to SVH 403(b) and 457 retirement plans. Five percent base contribution to 403(b) plan that vests after three years. This contribution is capped at the limits set by Federal law.
 - ❖ Six work weeks of time off each calendar year, accruing equally throughout the year.
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Meeting our Mission, Vision, Goals

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The addition of Dr. Kamper to Salinas Valley Health Clinics has been identified as a need for recruitment while also providing additional resources and coverage for the pulmonary and critical care service line.

The compensation proposed in these agreements have been reviewed against published industry benchmarks to confirm that the terms contemplated are fair market value and commercially reasonable.

Recommendation

Salinas Valley Health Administration requests that the Salinas Valley Health Board of Directors approve of the following:

1. **The Findings Supporting Recruitment of Martin Kamper, MD:**
 - That the recruitment of pulmonary and critical care physician to Salinas Valley Health Clinics is in the best interest of the public health of the communities served by the District; and
 - That the recruitment benefits and incentives the hospital proposes for this recruitment are necessary in order to attract and relocate an appropriately qualified physician to practice in the communities served by the District;
2. **The Contract Terms of the Recruitment Agreement for Dr. Kamper; and**
3. **The Contract Terms of the Pulmonary and Critical Care Professional Services Agreement for Dr. Kamper.**

Attachments

Curriculum Vitae for Martin Kamper, MD

MARTIN J KAMPER

TRAINING AND EDUCATION

Hofstra University, Long Island Jewish and North Shore University Hospital, NY
Pulmonary Critical Care Fellowship
July 2021-July 2024

Loyola University Medical Center, Maywood, IL
Internal Medicine Residency
June 2018-June 2020

University of Missouri- Columbia, School of Medicine- M.D.
Doctor of Medicine
August 2014-May 2018

University of Alabama
Bachelor of Science Biology, Bachelor of Science, Spanish
August 2010-December 2013

QUALITY IMPROVEMENT

Effect of Bolus Doses Prior to Up-Titration of Continuous Infusions of Fentanyl or Midazolam
for Sedation in the Medical Intensive Care Unit
North Shore University Hospital 7/2022-7/2023

*Assisted with data collection for a study examining the safety and efficacy of a protocol
of bolus doses of fentanyl and midazolam prior to up-titration of continuous infusions in
mechanically ventilated patients in the medical intensive care unit.*

Quality Improvement Research Scholar
Loyola University Medical Center, May 2020-July 2021

*Title indicating acceptance for dedicated research time to work on and complete a
quality improvement project with the expectation to submit this project to both a national
conference as well as Loyola University Medical Center's Resident Research Quality
Improvement Day in Spring 2021*
May 2020-July 2021

Improving safety during intra-hospital transport of critically ill patients at Loyola University Medical Center-Quality Improvement Project
Loyola University Medical Center

Developed a tool to risk stratify patients being considered for intra-hospital transport for procedures/imaging studies in addition to a checklist for such transport events to reduce adverse events occurring.

May 2020-July 2021

Quality Improvement and Patient Safety Curriculum

Loyola University Medical Center,

Complete a focused curriculum on healthcare quality improvement and concepts in patient safety.

June 2018-June 2020

RESEARCH/ABSTRACT SUBMISSIONS

Christine Esposito, **Martin Kamper**, Jessica Trentacoste, Susan Galvin, Halie Pfister, Janice Wang. Advances in the Cystic Fibrosis Drug Development Pipeline. Article. Life Journal. Submission received May 5, 2023.

Carlos Rabascall, Becky Lou, Sean Dhar, Zubair Hasan, Craig Fryman, Stephanie Izard, Mina Makaryus, Sudeep Acharya, Fiore Mastroianni, **Martin Kamper**, Sean Duenas, Jonathan Gong, Dimple Shah, Sameer Khanijo, Daniel Ying, Junaid Habibullah, Dae Hyeon Kim, Ryan Butzko, Margarita Oks, Brian Birnbaum, Jonathan Moore, Anup K Sing, Luis Quintero, Michael Lau, Jared Honigman, Ayelet Hilewitz, Kruti Shah, Joseph Simonson, Abhinav Agrawal, Matthew Frank, Adey Tsegaye, Mangala Narasimhan, Harly Greenberg, Stella S Hahn. Randomized Open Investigation Determining Steroid Dose in Severe COVID-19: The ROIDS-Dose Clinical Trial. <https://pubmed.ncbi.nlm.nih.gov/36475114/>. Published 11/4/2022.

M. Kamper, A. Hukku, D. Colon Hidalgo, G. Si, K.P. Simpson. Risk Factors and Outcomes of Unplanned Intensive Care Unit Transfers Within 24 Hours of Admission. Poster. ATS International Conference. May 17, 2020. Poster #1113

Academic Research Curriculum, Loyola University Medical Center

June 2018-July 2021

Completed over 30 hours of small group didactic curriculum focusing on the study of research design and methods in the setting of journal article review with research faculty.

O'Shields, B, McArthur AG, Holowiecki, A, **Kamper, M**, Tapley J, Jenny MJ Inhibition of Endogenous MTF-1 Signaling in Zebrafish Embryos Identified Novel Roles for MTF-1 in Development doi: 10.1016/j.bbamcr.2014.04.015. April 18, 2014

SCHOLARLY PRESENTATIONS

Pulmonary Hemosiderosis

Case Conference, Long Island Jewish Medical Center
September 2023

Pulmonary Physiology Grand Rounds: Asthma

Long Island Jewish Medical Center
August 2023

Patient Information Lecture: Cystic Fibrosis

Northwell Health Physician Partners Pulmonary and Sleep Medicine
June 2023

IgG-4 Related Lung Disease

Case Conference: Long Island Jewish Medical Center
April 2023

Liberation from Mechanical Ventilation

Afternoon Conference, Long Island Jewish Medical Center
January 2022

Pulmonary Transplant Conference

Northwell Lung Institute, Long Island Jewish Medical Center
December 2022

A Case of Resistant Pseudomonal Pneumonia

Autopsy Conference, Edward Hines Jr. Veterans Administration Hospital
April 2020

Updates on Prophylaxis in HIV, Kamper, M

Morning Report, Loyola University Medical Center
September 2019

Severe Dysphagia Secondary to Cervical Osteophytes: A Case Report. Kamper, M

Morning Report, Edward J Hines Veterans Administration Hospital
February 2019

CERTIFICATIONS AND PROCEDURAL COMPETENCIES

Board Certification: Critical Care Medicine
Board Certification: Pulmonary Medicine
Testamur Status: Advanced Critical Care Echocardiography
Board Certification: Internal Medicine
BLS-Basic Life Support
ACLS-Advanced Cardiac Life Support
CITI- Collaborative Institutional Training Institute
Ultrasound guided central venous catheter insertion
Ultrasound guided thoracentesis
Ultrasound guided arterial catheter insertion
Ultrasound guided large volume and diagnostic paracentesis
Chest Tube Placement
Lumbar Puncture
Advanced Critical Care Echocardiography
Critical Care Ultrasound
Bronchoscopy
Transbronchial Biopsy
Video Laryngoscopy/Endotracheal Intubation

TEACHING EXPERIENCE

Center for Learning and Innovation Point of Care Ultrasound Course Instructor
September 26-27, 2022,
May 8, June 4-5, 2024
Provided instruction for medical professionals including attending physicians, nurse practitioners and physician assistants in basic ultrasound techniques with a primary focus on image acquisition

Patient Centered Medicine Mentor
June 2019-Present
Served as a clinical mentor for second year medical students and assessed their ability to perform physical exams as well as elicit medical history from patients. Provided feedback regarding student's typed history and physical exam

PROFESSIONAL ORGANIZATIONS

American College of Physicians
American Thoracic Society

EMPLOYMENT

Zucker School of Medicine at Hofstra/Northwell Health:	
Assistant Professor, Department of Medicine:	July 2024-Present
University of Missouri-Infectious Disease Summer Extern	2015
PSIA Level 1 Certified Ski Instructor for Vail Resorts	2014
Washington University in St. Louis Siteman Cancer Center Summer Research Intern	2013
PSIA Level 1 Certified Ski Instructor for Peak Resorts	2010-2013
Chess Coach for Knight School, Tuscaloosa, Alabama	2012-2013
Howard Hughes Undergraduate Research Intern	2012-2013

SERVICE

Volunteer for Food Bank for Central and Northeast Missouri	2016
Medical Student Volunteer for MedZou Community Health Clinic	2014-2016
ESL Tutor for Tuscaloosa Public Schools	2012-2013

ACTIVITIES AND LEADERSHIP

MU School of Medicine Student Ambassador	2014-2016
Diabetes Case Manager for Medzou Community Health Clinic	2014-2015
Logistics Coordinator for Students Interested in Global Healthcare (SIGHT)	
Trip to Nicaragua	2014-2015
Students Interested in Global Healthcare for Tomorrow	2014

LANGUAGES SPOKEN

English-Fluent
Spanish- Conversational

HOBBIES

Skiing, travelling, mountain biking, cooking, reading, writing, running.

FINANCE COMMITTEE

*Minutes of the Finance Committee
will be distributed at the Board Meeting*

*Background information supporting the
proposed recommendations from the
Committee is included in the Board Packet*

(VICTOR REY, JR.)

Board Paper: Finance Committee

Agenda Item: Consider Recommendation to the Board of Directors Approval to Award Construction Contract to C. Overaa & Co. for the Salinas Valley Health X-Ray Room 1 & 2 Equipment Replacement Project

Executive Sponsor: Clement Miller, Chief Operating Officer
Brad McCoy, Vice President of Facilities, Construction and Real Estate
John Kazel, Director of Imaging Services

Date: October 23, 2025

Executive Summary

Salinas Valley Health is pursuing the replacement and modernization of x-ray equipment in X-Ray Room 1 and X-Ray Room 2. This project upgrades Salinas Valley Health's capabilities to the latest standards in radiology. This investment is to address escalating risks and limitations associated with two existing Siemens x-ray systems, which are considered outdated due to their antiquated computer processing, software radiation dose efficiency, and image quality. The replacement of the Siemens x-ray equipment with Philips' advanced systems will mitigate the risk of equipment failure and enhance diagnostic capabilities, improve patient safety, and increase operational efficiency. This upgrade is essential for maintaining top-tier medical care and meeting the latest standards in medical imaging technology. In August of 2024, the Finance Committee and Board approved the project for planning, design, medical equipment, and construction.

Background/Situation/Rationale

The project involves the phased replacement and improvements of X-Ray Room 1 and X-Ray Room 2. To minimize disruption to clinical operations, the work is carefully staggered, ensuring that only one room is non-operational at any given time. The modernization includes necessary architectural, structural, and electrical upgrades to achieve full compliance with current building codes, as well as coordinated enhancements to the existing nurse call system. Salinas Valley Health will manage all necessary HCAI approvals required to execute the work.

A public request for bids was advertised on September 10, 2025, in the Californian and Central Coast Builder's Exchange, along with an outreach effort to local and regional qualified contractors (Attachment 1). At close of bid on October 7, 2025, five (5) responsive bids were received and publicly opened (Attachment 2). A competitive bidding process was followed, utilizing our standard, legally approved bidding procedures. Following staff review of the submitted bid packages, C. Overaa & Co. was identified as the lowest responsible, responsive bidder (Attachment 3). This contract amount is under the allocated budget approved for this project.

Materials Management facilitated negotiations with Philips Healthcare to secure contracts for capital equipment. This process included a thorough due diligence review, ensuring that the obtained pricing was at or below industry standards.

Timeline/Review Process

September 2025 – Bid process & contractor selection

October 2025 – Award and execute construction contract

November 2025 – Issue notice to proceed to contractor (dependent on HCAI permit issuance)

December 2025 – Commence X-Ray Room 2 construction activities

February 2026 – Complete X-Ray Room 2 construction activities and commence X-Ray Room 1 construction activities

April 2026 – Complete X-Ray Room 1 construction activities

Pillar/Goal Alignment

☒ Service ☐ People ☒ Quality ☒ Finance ☒ Growth ☐ Community

Financial/Quality/Safety/Regulatory Implications

Key Contract Terms	Contractor: C. Overaa & Co.
1. Proposed effective date	Issuance of Notice to Proceed anticipated on November 3, 2025
2. Term of agreement	115 calendar days
3. Renewal terms	Not Applicable
4. Termination provision(s)	Bid Specifications: Section 00 70 00 – Part 12
5. Payment Method	Lump Sum
6. Compensation	\$499,750
7. Cost over life agreement	Not Applicable
8. Budgeted (Indicate yes/no)	Yes. Project funding is included in Fiscal Year 2026 Routine Capital Project. The allocated construction budget of \$897,356 is expected to be fully spent out within FY 2026.

Recommendation

Consider recommendation to Board of Directors to award the construction contract to C. Overaa & Co. for the Salinas Valley Health X-Ray Room 1 & 2 Equipment Replacement project in the total amount of \$499,750.

Attachments:

- Attachment 1: Proof of Publication of Advertisement for Bids September 10, 2025
- Attachment 2: Bid Results Summary October 7, 2025
- Attachment 3: C. Overaa & Co. Bid Forms
- Attachment 4: Contract for Construction



Salinas Californian
GANNETT

PO Box 631437 Cincinnati, OH 45263-1437

AFFIDAVIT OF PUBLICATION

Accts Payable
Salinas Valley Memorial/Legals
450 E Romie Ln
Salinas CA 93901-4029

STATE OF WISCONSIN, COUNTY OF BROWN

The Salinas Californian, a newspaper published in the city of Salinas, Monterey County, State of California, and personal knowledge of the facts herein state and that the notice hereto annexed was Published in said newspapers in the issue:

SCA Salinas Californian 09/10/2025
SCA thecalifornian.com 09/10/2025

and that the fees charged are legal.
Sworn to and subscribed before on 09/10/2025

Legal Clerk

Notary, State of WI, County of Brown

My commission expires

Publication Cost:	\$788.24	
Tax Amount:	\$0.00	
Payment Cost:	\$788.24	
Order No:	11599862	# of Copies:
Customer No:	1252807	0
PO #:	LYRK0357008	

THIS IS NOT AN INVOICE!

Please do not use this form for payment remittance.

VICKY FELTY
Notary Public
State of Wisconsin

ADVERTISEMENT FOR BIDS

Sealed proposals will be received by Salinas Valley Memorial Healthcare System ("SVMHS") operating as Salinas Valley Health located in Salinas, California, for the furnishing of all labor, materials, equipment and services to SVMHS necessary for and incidental to the construction of:

SALINAS VALLEY HEALTH X-RAY ROOM 1 & 2 EQUIPMENT REPLACEMENT

General Description. Salinas Valley Health (SVH) is pursuing equipment replacement activities within its Diagnostic Imaging Department. This initiative focuses on X-Ray Room 1 and X-Ray Room 2, both located on the first level of the Original Building. The work involves replacing the existing Siemens X-ray systems, that have reached the end of their useful life, with new Philips X-ray systems. To facilitate this upgrade, renovations to the existing imaging rooms are required. These include, but are not limited to, necessary architectural modifications, including ceilings, walls, and flooring, structural improvements, installations, and anchorage to support new equipment and associated systems, and upgrades to electrical, low voltage, and nurse call systems.

Bids. Sealed bids will be received by SVMHS at the Construction Office located at 535 E Romie Lane, Suite 6, Salinas, California, until 2:00 p.m. on **October 7, 2025**, at which time all bids will be publicly opened. Bids will be referred to a subsequent SVMHS Board of Directors meeting for appropriate action. All Bid Proposals shall be submitted on forms furnished by SVMHS. Bid Proposals must conform with, and be responsive to, the Bid and Contract Documents, copies of which may be obtained from SVMHS as indicated below. Only Bid Proposals submitted to SVMHS prior to the date and time set forth above for the public opening and reading of Bid Proposals shall be considered. Note: Bids submitted orally or by telephone, electronic transmission (email) or facsimile will be considered invalid and will not be accepted. Each Bid Proposal shall be accompanied by:

1. Bid Letter (including acknowledgement of receipt of Addenda)
2. List of Subcontractors
3. Statement of Bidder's Qualifications
4. Compliance with Immigration Reform and Control Act of 1986
5. Bidder's Guaranty: Bidder's Bond or Irrevocable Standby Letter of Credit
6. Non-Collusion Certification

All information and responses of a Bidder in its Bid Proposal, and other documents accompanying the Bid Proposal, shall be complete, accurate and true. Incomplete, inaccurate, or untrue responses or information provided by a Bidder shall be grounds for SVMHS to reject such Bidder's Bid Proposal as nonresponsive.

Pre-Bid Conference. There will be a non-mandatory pre-bid conference held prior to the date of bid. The conference will take place on **September 18, 2025**, from 10:30 a.m. - 12:00 p.m., in the SVMHS Construction Office located at **535 E. Romie Lane, Suite 6, Salinas, California 93901**. Request to access the hospital for site investigation shall be coordinated through dsullivan@bogardconstruction.com. Bidders and their subcontractors are encouraged to investigate the existing conditions prior to close of the bidding period.

Questions. All requests for interpretation of the drawings and specifications or other questions regarding this project during the bidding process shall be submitted to SVMHS in writing by email with the original copy to follow by mail. No telephone questions will be accepted. All written requests for interpretation (RFIs) or correction of the Contract Documents must be received within ten (10) days of close of bid. Send all pre-bid questions and requests for interpretation to SVMHS via email at: dsullivan@bogardconstruction.com.

Bid and Contract Documents. Requests for digital versions of the Documents shall be addressed to Salinas Valley Memorial Healthcare System, Attn: Dave Sullivan (dsullivan@bogardconstruction.com). The Central Coast Builder's Exchange has all bid documents available for Bidders (Visit URL: <http://www.ccbabuilds.com/>).

Labor & Material Payment and Performance Bonds. The successful bidder will be required to furnish a labor & material payment bond and performance bond equal to one hundred percent (100%) of the Contract Price. Each bond must meet the statutory requirements for a public construction project as set forth in California Civil Code Section 3248. The bonds shall be secured through a surety company approved by SVMHS and paid for by the Prime Contractor.

Bid Acceptance/Rejection. SVMHS reserves the right to reject any or all bids and to waive any informalities in the bidding, or in any bid received. The Contract for the Work, if awarded, will be by action of the SVMHS Board of Directors to the responsible Bidder submitting the lowest responsive Bid Proposal. If Alternate Bid Items are included in the bidding, the lowest priced Bid Proposal will be determined on the basis of the Base Bid Proposal or on the Base Bid Proposal and the combination of Alternate Bid Items selected in accordance with the applicable provisions of the Instructions for Bidders. No bid shall be withdrawn for a period of ninety (90) calendar days subsequent to the opening of bids without the consent of SVMHS.

Contractor License Classification. In accordance with the provisions of California Public Contract Code §3300, SVMHS requires that Bidders have a valid and current class B California Contractors License. Bidders must be properly licensed at the time that the Contract for the Work is awarded and at all times during the Work. Any Bidder not so duly and properly licensed shall be subject to all penalties imposed by law. No payment shall be made for work, labor, materials or services provided under the Contract for the Work unless and until the Registrar of Contractors verifies to SVMHS that the Bidder awarded the Contract is properly and duly licensed to perform the Work.

Prevailing Wage. Minimum prevailing wage rates are required to be paid for each craft, classification, or type of worker needed to execute the Contract. Copies of such minimum rates are on file at the Administration office of SVMHS, and are available to any interested party upon request. See Labor Code Section 1773 et seq.

Dated: September 10, 2025
Salinas Valley Memorial Healthcare System
A Local Health Care District
September 10 2025
LYRK0357008

SALINAS VALLEY MEMORIAL HEALTHCARE SYSTEM
 450 E Romie Lane, Salinas, CA 93901
 HCAI Facility No. 10348
 HCAI Project No. S251154-27-00 AND S251153-27-00
 CIP 01.1250.3770 AND 01.1250.3775

BID OPENING: 10/07/2025 @ 2:00 PM

BID OPENING LOCATION: 535 E Romie Lane, Suite 6, Salinas CA 93901

BID RESULT SUMMARY

	Contractor	Contact	Email Address	Phone Number	Base Bid + Allowances	Comments
1	C. Overaa & Co	Danny Sawyer	dannys@overaa.com	510-719-3925	\$ 499,750	**
2	Tombleson, Inc.	Amy Abbott	amya@tomblesoninc.com	831-422-9696	\$ 532,500	
3	SSB Construction, Inc	Joseph Darpli	jdarpli@ssbconstruction.com	831-737-0638	\$ 723,600	
4	Colin Construction Company, Inc	Mark Ennis	marke@colincc.com	530-272-3357	\$ 702,217	
5	FTG Builders, Inc	Pedro Becerra	pedro@ftgbuilders.com	928-503-9235	\$ 681,036	
	** Apparent Low Bidder					

SVMHS reserves the right to reject any or all bids and to waive any informalities in the bidding, or in any bid received.

	Documents Acompanying Bid	Contractor 1 **	Contractor 2	Contractor 3	Contractor 4	Contractor 5
A	Bid Letter	X	X	X	X	X
B	Addenda (A, B, and C)	X	X	X	X	X
C	List of Subcontracotrs	X	X	X	X	X
D	Disqualification Questionnaire	X	X	X	X	X
E	Insurance Requirements	X	X	X	X	X
F	Bid Bond	X	X	X	X	X
G	Non-Collusion Affidavit	X	X	X	X	X

**BID LETTER
FOR THE SALINAS VALLEY HEALTH
X-RAY ROOM 1 AND 2 EQUIPMENT REPLACEMENT**

Pursuant to the Notice Inviting Bids, the undersigned bidder herewith submits a bid on the Bid Forms attached hereto and made a part hereof, and binds itself on award by the Salinas Valley Memorial Healthcare System operating as Salinas Valley Health (hereinafter "SVH") under this bid to execute a Contract in accordance with its bid and the Contract Documents.

The Notice Inviting Bids, Instructions to Bidders, General Requirements, Supplementary Conditions, Technical Specifications, Appendices, Contract Drawings, and Addenda, if any, are made part of this bid and all provisions thereof are hereby accepted, and all representations and warranties required thereby are hereby affirmed.

This offer shall be irrevocable for a period of ninety (90) days after the date on which bids are opened.

The undersigned bidder understands that any clarification made to the above or any new and different conditions or information submitted on or with its Bid Forms, other than that requested, may render the bid non-responsive.

The undersigned, as bidder, declares that the only persons or parties interested in this bid as principals are those named herein; that this bid is made without collusion with any other person, firm or corporation and in submitting this bid, that it has carefully examined the location of the proposed work, the attached proposed form of contract, and the plans, specifications and the other Contract Documents; and agrees if this bid is accepted, that it will contract with SVH, on the form of contract included with these specifications, to provide all necessary labor, materials, equipment, machinery, apparatus and other means of construction, and to do all the work specified in the Contract Documents, in the manner and time therein prescribed, and according to the requirements of the Owner's Designated Representative as therein set forth, and that he will accept all full payment therefore based on the item prices set forth in its Schedule of Bid Prices.

The prices included within the Schedule of Bid Prices include all costs for labor, materials, tools, equipment, services, subcontractors, suppliers, taxes, insurance, shipment, delivery, overhead, profit and all other costs necessary to perform the work in accordance with the Contract Documents.

The undersigned bidder acknowledges receipt, understanding, and full consideration of the following addenda to the Contract Documents:

ADDENDA NOS. (if none, so state): A, B, C

Name of Bidder: C. Overaa & Co.

Business Address: 200 Parr Blvd., Richmond, CA 94801

Phone: 510-234-0926 Fax: 510-237-2435

Contractor's License No. 106793

License Expiration Date 5/31/2027

Classification Type A, B

SALINAS VALLEY MEMORIAL HEALTHCARE SYSTEM

SALINAS VALLEY HEALTH

Salinas, California

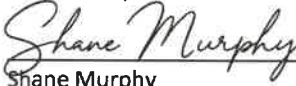
ADDENDUM A TO THE BID DOCUMENTS FOR SALINAS VALLEY HEALTH X-RAY ROOM 1 & 2 EQUIPMENT REPLACEMENT

ISSUED: September 19, 2025

This Addendum A must be signed by the bidder and included in the bid documents submitted for this Project. Salinas Valley Memorial Healthcare System operating as Salinas Valley Health (hereinafter "SVH") reserves the right to disregard any bid, which does not include this Addendum A. Salinas Valley Memorial Healthcare System may waive this requirement at its sole discretion.

SEE ATTACHED ADDENDUM ITEMS

Prepared By:


Shane Murphy
SVH Designated Representative

BIDDER'S CERTIFICATION

I acknowledge receipt of this Addendum A and accept all conditions contained herein.


Bidder's Signature

10/3/2025
Date

C. Overaa & Co.
Name of Company

Please return this signed page to Shane Murphy at SVH as soon as possible to confirm receipt of this addendum. Please email as a PDF to smurphy@bogardconstruction.com.

SALINAS VALLEY MEMORIAL HEALTHCARE SYSTEM

SALINAS VALLEY HEALTH

Salinas, California

**ADDENDUM B
TO THE BID DOCUMENTS FOR
SALINAS VALLEY HEALTH X-RAY ROOM 1 & 2 EQUIPMENT REPLACEMENT**

ISSUED: September 26, 2025

This Addendum B must be signed by the bidder and included in the bid documents submitted for this Project. Salinas Valley Memorial Healthcare System operating as Salinas Valley Health (hereinafter "SVH") reserves the right to disregard any bid, which does not include this Addendum B. Salinas Valley Memorial Healthcare System may waive this requirement at its sole discretion.

SEE ATTACHED ADDENDUM ITEMS

Prepared By:



Shane Murphy

SVH Designated Representative

BIDDER'S CERTIFICATION

I acknowledge receipt of this Addendum A and accept all conditions contained herein.



Bidder's Signature

10/3/2025

Date

C. Overaa & Co.

Name of Company

Please return this signed page to Shane Murphy at SVH as soon as possible to confirm receipt of this addendum. Please email as a PDF to smurphy@bogardconstruction.com.

SALINAS VALLEY MEMORIAL HEALTHCARE SYSTEM

SALINAS VALLEY HEALTH

Salinas, California

ADDENDUM C

TO THE BID DOCUMENTS FOR

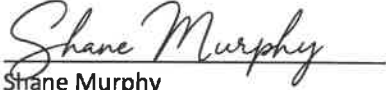
SALINAS VALLEY HEALTH X-RAY ROOM 1 & 2 EQUIPMENT REPLACEMENT

ISSUED: October 1, 2025

This Addendum C must be signed by the bidder and included in the bid documents submitted for this Project. Salinas Valley Memorial Healthcare System operating as Salinas Valley Health (hereinafter "SVH") reserves the right to disregard any bid, which does not include this Addendum C. Salinas Valley Memorial Healthcare System may waive this requirement at its sole discretion.

SEE ATTACHED ADDENDUM ITEMS

Prepared By:



Shane Murphy

SVH Designated Representative

BIDDER'S CERTIFICATION

I acknowledge receipt of this Addendum C and accept all conditions contained herein.



Bidder's Signature

10/3/2025

Date

C. Overaa & Co.

Name of Company

Please return this signed page to Shane Murphy at SVH as soon as possible to confirm receipt of this addendum. Please email as a PDF to smurphy@bogardconstruction.com.

LIST OF SUBCONTRACTORS

The Bidder is required to furnish the following information in accordance with the provisions of Sections 4100 to 4114, inclusive, of the Public Contract Code of the State of California. This list and information shall include all subcontractors that will perform work, provide labor or render services to the Bidder in connection with the project in an amount in excess of one-half of one percent of the total amount of Bidder's Grand Total Bid Price.

Do not list alternative subcontractors for the same work. Use additional sheets if necessary.

NAME OF SUBCONTRACTOR	LICENSE NUMBER AND DIR REG NO.	LOCATION OF/ PLACE OF BUSINESS	PORTION OF WORK
1. ~~BATE~~ CO	~~887811~~ CO 1000002993	~~OAKLAND, CA~~ CO	~~ELECTRICAL~~ CO
CO 2. ~~VALDEZ~~			~~PAINT~~ CO
3. HARRY L. MURPHY	145985 1000004204	SAN JOSE, CA	FLOORING
4. IRONWOOD	895364 1000004603	Concord, CA	DRYWALL
5. JANUS	572682 1000000894	CONCORD, CA	DEMOLITION
6. CAL WEST	320029 1000006938	UNION CITY, CA	CORING
7. ~~WMB SALEM~~ CO	~~465016~~ CO 1000010542	~~MONTEREY, CA~~ CO	~~PAINT~~ CO
8. SATELLITE	563898 1000028304	SAN JOSE, CA	PAINT
9. JMELECTRIC	376938 1000000800	SALINAS, CA	ELECTRICAL
10.			
11.			
12.			
13.			
14.			
15.			

END LIST OF SUBCONTRACTORS

DISQUALIFICATION QUESTIONNAIRE

The Bidder shall complete, under penalty of perjury, the following questionnaire:

Has the Bidder, any officer of the Bidder, or any employee of the Bidder who has proprietary interest in the Bidder, ever been disqualified, removed, or otherwise prevented from bidding on, or completing a federal, state, or local government project because of a violation of law or a safety regulation?

Yes _____ No X

If the answer is yes, explain the circumstances in the following space.

NAME OF BIDDER: C. Overaa & Co.

NOTE: This questionnaire constitutes a part of the Bid, and signature on the portion of this Bid shall constitute signature on this questionnaire.

END OF DISQUALIFICATION QUESTIONNAIRE

ACKNOWLEDGEMENT OF INSURANCE REQUIREMENTS

Included in the Bid Price is full compensation for the requirements set forth in Section 00 86 00, INSURANCE REQUIREMENTS of the Contract Documents, including:

- a) Workers' Compensation (per statutory requirement).
Policy shall include a waiver of subrogation.
- b) Employer's Liability coverage.
Two Million Dollars (\$2,000,000) per accident; and
Two Million Dollars (\$2,000,000) each employee by disease.
- c) Commercial General Liability coverage (including but not limited to premises and operations; contractual liability; personal and advertising injury; explosion, collapse, and underground coverage; products and completed operations, and; broad form property damage) of not less than:
Two Million Dollars (\$2,000,000) combined single limit per occurrence or claim; and
Two Million Dollars (\$2,000,000) general aggregate.
Policy shall include a Waiver of Subrogation and Additional Insured endorsement. Policy will also contain either a Cross Liability endorsement or Severability of Interests Clause.
- d) Business Automobile Liability Insurance coverage of not less than:
Two Million Dollars (\$2,000,000) combined single limit occurrence.
Policy shall include a Waiver of Subrogation and Additional Insured endorsement.

	President	October 3, 2025
Signature of Bidder/Title		Date

END OF ACKNOWLEDGEMENT OF INSURANCE REQUIREMENTS

BIDDER'S BOND

KNOW ALL PERSONS BY THESE PRESENTS:

That C. Overaa & Co., as Principal, and Travelers Casualty and Surety Company of America, as Surety, are held and firmly bound unto the Salinas Valley Memorial Healthcare System, operating as Salinas Valley Health (hereinafter called SVH), in the sum of (\$ see below), *being at least ten percent (10%) of the total amount of the bid, for the payment of which sum in lawful money of the United States of America to SVH we bind ourselves, our heirs, executors, administrators, successors and assigns, jointly and severally, firmly by these presents.

* Ten Percent (10%) of Total Amount of Bid

The condition of the above obligation is such that, whereas the Principal has submitted said bid to SVH;

NOW, THEREFORE, if the principal is awarded a Contract by SVH and, within the time and in the manner required by the Specifications, enters into a written Contract with SVH and furnishes the requisite bond or bonds and insurance certificates, then this obligation shall become null and void, otherwise to remain in full force and effect.

In the event suit is brought upon this bond by SVH and judgment is recovered, the Surety shall pay all costs incurred by SVH in such suit, including a reasonable attorneys fee to be fixed by the Court.

Dated September 26, 2025

TO BE CONSIDERED COMPLETE, BOTH THE PRINCIPAL AND SURETY MUST SIGN THIS BIDDER'S BOND. IN ADDITION, THE SURETY'S SIGNATURE MUST BE NOTARIZED AND A COPY OF THE SURETY'S POWER OF ATTORNEY MUST BE ATTACHED.

C. Overaa & Co.

Principal

By: Carl Overaa

Travelers Casualty and Surety Company of America

Surety

By: Nerissa S. Bartolome

Nerissa S. Bartolome, Attorney-in-Fact

100 California St., Suite 725, San Francisco, CA 94111

Address of Surety

END OF BIDDERS BOND

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

CIVIL CODE § 1189

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California)

County of San Francisco)

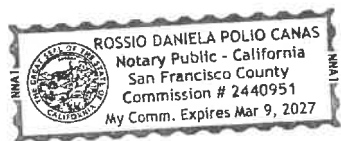
On 09/26/2025 before me, Rossio Daniela Polio Canas, Notary Public,
Date Here Insert Name and Title of the Officer

personally appeared Nerissa S. Bartolome
Name(s) of Signer(s)

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.



Signature [Signature]
Signature of Notary Public

Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____ Document Date: _____

Number of Pages: _____ Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: Nerissa S. Bartolome

- ☐ Corporate Officer — Title(s): _____
☐ Partner — ☐ Limited ☐ General
☐ Individual ☒ Attorney in Fact
☐ Trustee ☐ Guardian or Conservator
☐ Other: _____

Signer Is Representing: _____

Signer's Name: _____

- ☐ Corporate Officer — Title(s): _____
☐ Partner — ☐ Limited ☐ General
☐ Individual ☐ Attorney in Fact
☐ Trustee ☐ Guardian or Conservator
☐ Other: _____

Signer Is Representing: _____



**Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company**

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Nerissa S Bartolome** of **SAN FRANCISCO, California**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April, 2021**.



State of Connecticut

City of Hartford ss.

By: 
Robert L. Raney, Senior Vice President

On this the **21st** day of **April, 2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**




Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

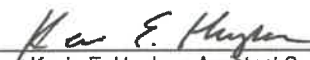
FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **26th** day of **September**, **2025**




Kevin E. Hughes, Assistant Secretary

**To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.**

**NON-COLLUSION AFFIDAVIT TO BE EXECUTED
BY BIDDER AND SUBMITTED WITH BID**

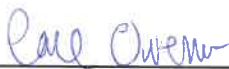
The undersigned declares:

I am the President of C. Overaa & Co., the party making the foregoing bid.

The bid is not made in the interest of, or on behalf of, any undisclosed person, partnership, company, association, organization, or corporation. The bid is genuine and not collusive or sham. The bidder has not directly or indirectly induced or solicited any other bidder to put in a false or sham bid. The bidder has not directly or indirectly colluded, conspired, connived, or agreed with any bidder or anyone else to put in a sham bid, or to refrain from bidding. The bidder has not in any manner, directly or indirectly, sought by agreement, communication, or conference with anyone to fix the bid price of the bidder or any other bidder, or to fix any overhead, profit, or cost element of the bid price, or of that of any other bidder. All statements contained in the bid are true. The bidder has not, directly or indirectly, submitted his or her bid price or any breakdown thereof, or the contents thereof, or divulged information or data relative thereto, to any corporation, partnership, company association, organization, bid depository, or to any member or agent thereof to effectuate a collusive or sham bid, and has not paid, and will not pay, any person or entity for such purpose.

Any person executing this declaration on behalf of a bidder that is a corporation, partnership, joint venture, limited liability company, limited liability partnership, or any other entity, hereby represents that he or she has full power to execute, and does execute, this declaration on behalf of the bidder.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this declaration is executed on 10/3/2025 [date], at Richmond [city], California [state]."


Signature of Bidder

President

Title

10/3/2025

Date

END OF NON-COLLUSION AFFIDAVIT

SECTION 00 41 00

SCHEDULE OF BID PRICES

1.01 GENERAL INSTRUCTIONS

- A. Bidders are directed to submit a lump sum price for all Work set forth in the Contract Documents in the space for the "Base Bid" amount in the Schedule of Bid Prices. This lump sum shall include all costs for labor, materials, tools, equipment, services, subcontractors, suppliers, taxes, insurance, shipment, delivery, overhead, profit and all other costs necessary to perform the Work in accordance with the Contract Documents. ***Contractor should assume that activities associated with utility shutdowns (mechanical, electrical, plumbing and technology) will be required during off-hours throughout the course of the Project. Any overtime costs arising in conjunction with these activities are included in the Contractor's Base Bid.***
- B. Unit prices and lump sum prices must be entered in the appropriate spaces provided in the Schedule. Unit prices shall be multiplied by the Quantities shown, and the total shall be inserted in the AMOUNT column. In the event of any error or discrepancy between the Unit Price and the calculated AMOUNT, the Unit Price shall govern. Owner may correct any mathematical errors apparent on the face of the bid.

**SALINAS VALLEY HEALTH
X-RAY ROOM 1 AND 2 EQUIPMENT REPLACEMENT
SCHEDULE OF BID PRICES**

BASE BID ITEM A:

Contractor shall provide any and all materials, labor, tools, equipment and superintendence necessary to complete this project for the following amount. Contractor shall provide Contractor's profit and overhead for all allowance items identified below in the Base Bid item "A". If costs incurred exceed allowance item, Contractor shall be allowed to mark up the difference between the allowance and actual by a maximum of 5%. If the actual cost is less than the allowance item, Contractor shall credit the Owner the difference, including profit and overhead added to item "A".

"A" \$ 490,500⁰⁰

COMPENSABLE DELAY AMOUNT:

Contractor shall provide all materials, labor, tools, equipment and superintendence necessary to complete any additional work required as a result of non-Contractor caused delays for the following amount:

\$ 1,850⁰⁰ per day x 5 days delay (est.) =

"B" \$ 9,250⁰⁰

GRAND TOTAL BID PRICE:

Base bid plus total (A + B)

\$ 499,750⁰⁰

END OF SECTION 00 41 00



200 Parr Boulevard
Richmond, CA 94801
Tel 510-234-0926
Fax 510-237-2435

CORPORATE RESOLUTION

Resolved, that Carl Overaa, President of this Corporation, be and is hereby authorized, directed and empowered for and on behalf and in the name of this Corporation to execute bid submittals and/or contract documents on behalf of this Corporation.

Resolved further, that this resolution shall remain in effect until amended or revoked thereof by a resolution duly adopted by the Board of Directors of this Corporation.

I, Erin Overaa Dissman, certify that I am the duly elected and acting Secretary of C. Overaa & Co., a Corporation, duly organized and existing under the laws of the State of California, and that the foregoing is a true and correct copy of a resolution of the Board of Directors of said corporation, duly and regularly passed and adopted at a meeting of the Board of Directors of said corporation which was duly and regularly called and held on the 15th day of March, 2022, at which meeting a quorum of the Board of Directors of said corporation was at all times present and acting.

I further certify that said resolution is in full force and effect and has not been amended or revoked.

IN WITNESS WHEREOF, I have hereunto set my hand as such Secretary and affixed the corporate seal of said corporation this October 2, 2025.


Erin Overaa Dissman, Secretary

RECORDING REQUESTED BY &
WHEN RECORDED MAIL TO:

NO RECORDING FEE REQUIRED

California Government Code Sections 6103 & 27383

SPACE ABOVE THIS LINE FOR RECORDER'S USE

CONTRACT FOR CONSTRUCTION

DIVISION 00 00 00 CONTRACT DOCUMENT
SECTION 00 50 00 CONTRACT FOR CONSTRUCTION

Owner: **SALINAS VALLEY MEMORIAL HEALTHCARE SYSTEM**
A Local Health Care District & Political Subdivision of the State of
California

Contractor: **C. Overaa & Co.**
A California Corporation

Property/Project Location: 450 East Romie Lane
Salinas, California 93901
County of Monterey

Construction Project: PROJECT NUMBERS:
01.1250.3770 and 01250.3775
PROJECT NAME: X-Ray Room 1 & 2
Equipment Replacement

This Construction Agreement is made and entered into on XXX XX, 2025 ("Effective Date"), by and between **Salinas Valley Memorial Healthcare System**, a local health care district organized and operating pursuant to Division 23 of the California Health and Safety Code and political subdivision of the State of California ("Owner"), and **C. Overaa & Co.** a California Corporation ("Contractor"), for the construction of Project Numbers 01.1250.3770 and 01.1250.3775, X-Ray Room 1 & 2 Equipment Replacement.

CONTRACT FOR CONSTRUCTION

Owner and Contractor agree as follows:

1. SCOPE OF WORK. Contractor shall perform all the work, and furnish all the labor, materials, tools, supplies, equipment, supervision and other services required to complete all of the work that is described in the Specifications, Drawings and other documents constituting the Contract Documents for the Project located at the Project Location set forth above. The Contract Documents are defined below in Section 4 of this Construction Agreement.
2. TIME OF COMPLETION. Contractor shall complete all work under the Contract Documents within **one hundred fifteen (115) calendar days** of the effective date of the Notice to Proceed. Contractor shall begin work as of the effective date of the Notice to Proceed, and shall diligently proceed with and prosecute all of the work and comply with all requirements set forth in this Construction Agreement and the Contract Documents. Contractor specifically acknowledges and agrees to Section 00 82 00 Time of Completion, Milestones, Incentives and Liquidated Damage of the Contract Documents regarding the time of completion and liquidated damages.
3. CONTRACT SUM. Contractor shall faithfully perform all of the work under this Construction Agreement for the Grand Total Bid Price accepted by Owner in the amount of Four Hundred Ninety-Nine Thousand, Seven Hundred Fifty Dollars **(\$499,750.00)**, payable by Owner to Contractor at the time and in the manner provided in the Contract Documents.
4. CONTRACT DOCUMENTS. This Construction Agreement shall consist of this document and all of the Contract Documents, which are incorporated into and made a part this Construction Agreement. The Contract Documents include all of the following:

Those documents that form the basis of this Contract for Construction, include, but are not limited to, the Notice Inviting Bids, Instructions to Bidders, Pre-Bid Conference, Bid Form, Schedule of Bid Prices, Form of Agreement, Contract Bonds, General Conditions, and Supplementary Conditions, General Requirements in Division 01, Contract Drawings, Technical Specifications, Appendices, Addenda, permits from other agencies, and all Change Orders issued after the execution of the Contract.
5. PREVAILING WAGE SCALE. Contractor agrees to the requirements regarding the general prevailing wage rates set forth in the Contract Documents. A copy of such rates may be reviewed at Owner's Construction Office. Those rates are hereby specified as the minimum rates of prevailing wage to be paid to workers under this Construction Agreement.
6. APPRENTICESHIP REQUIREMENTS. Contractor and any subcontractor under it shall comply with all provisions of California Labor Code Section 1777.5, pertaining to the employment of apprentices on public works projects, and Contractor shall be responsible for its own and its subcontractors' compliance with this provision.
7. WORKERS' COMPENSATION INSURANCE. In accordance with the provisions of Section 3700 of the California Labor Code, Contractor is required to secure workers' compensation insurance coverage for its employees.

8. SERVICE OF NOTICE. Any notice required or permitted to be given under this Construction Agreement shall be deemed given when personally delivered to recipient thereof or mailed by registered or certified mail, return receipt requested, postage pre-paid, to the appropriate address specified in its proposal, and in the case of Owner, at 450 East Romie Lane, Salinas, California 93901, or at any other address which either party may subsequently designate in writing to the other party.

9. GOVERNING LAW & VENUE. This Agreement shall be governed and construed in accordance with the laws of the State of California. Any action relating to this Construction Agreement shall be instituted and prosecuted in a court of competent jurisdiction in the County of Monterey in the State of California. Each party hereby appoints the party listed opposite its name to act as its initial agent for service of process relating to any such action:

OWNER: Salinas Valley Memorial Healthcare System
Attn: Chief Executive Officer
450 East Romie Lane
Salinas, California 93901
(831) 757-4333

CONTRACTOR: C. Overaa & Co.
Carl Overaa
200 Parr Blvd.
Richmond, CA 94801
(510) 234-0926

Each such agent is hereby authorized and directed to accept service of process in any such action on behalf of his principal until such time as his successor shall have been appointed by his principal and notice has been delivered to the other party as provided herein.

Owner and Contractor hereby execute this Construction Agreement to be effective as of the Effective Date first set forth above.

OWNER

Salinas Valley Memorial Healthcare System
A California Local Health Care District

By: _____
Allen Radner, MD, President/CEO

Date

CONTRACTOR

C. Overaa & Co.
A California Corporation

By: _____
Carl Overaa, President

Date

Board Paper: Finance Committee

Agenda Item: Consider Recommendation for Board Approval of Purchase of Seven (7) Canon Ultrasound Units and Associated forty-eight month Service Agreement for Salinas Valley Health Clinics Imaging and Salinas Valley Health Obstetrics & Gynecology

Executive Sponsor: Timothy Albert, MD, MHCM, Chief Clinical Officer

Date: October 20, 2025

Executive Summary

Background/Situation

Salinas Valley Health Clinics' (SVHC) Imaging and Obstetrics & Gynecology practices are requesting the replacement of the departments' ultrasound equipment. The Imaging department currently operates with five units, and Obstetrics & Gynecology with two units. All seven units have exceeded their original equipment manufacturer's recommended service life, limiting reliability, service support, and the ability to provide patients with the highest standard of diagnostic imaging. To address these challenges, SVHC is seeking approval to replace the existing ultrasound fleet with a standardized, state-of-the-art platform.

Canon was selected as the preferred vendor following a comprehensive evaluation of performance, image quality, and clinical functionality. These ultrasound units are consistent with the models currently in use at SVH Medical Center, with minor system configuration adjustments to accommodate the specific operational needs of our clinic sites. The proposal was obtained through our GPO, Vizient, and the ECRI Proposal Analysis specifically connected to the quote shows a discount of 64% for the capital items and is consistent with the highest discount offered on similar purchases of this equipment. GPO pricing insures FMV compliance.

Timeline/Review Process to Date

September 2025: Received quotes for consideration
 October 2025: Request for purchase
 November 2025: Anticipated Implementation

Strategic Plan Alignment

In order to serve our patients efficiently with timely, high-quality care, the new equipment will ensure that we obtain reliable diagnostic images and that the department can operate at full capacity to meet patient demand.

Pillar/Goal Alignment

☒ **Service** ☐ **People** ☒ **Quality** ☐ **Finance** ☐ **Growth** ☐ **Community**

Financial/Quality/Safety/Regulatory Implications

Key Contract Terms	Vendor: Canon Medical Systems USA, Inc.
1. Proposed effective date	November 1, 2025
2. Service Agreement Term	Forty-eight (48) month service agreement, \$252,000 or \$63,000 annually. Service agreement begins after one year warranty.
3. Renewal terms	One-time purchase of Equipment; Renewable Service Agreement
4. Payment Terms	Cash – 0% down payment, 80% upon shipment net 45 days, 20% net 30 days upon completion of installation and / or availability for first use, whichever is earlier.
5. Annual cost	One-time purchase—Aplio i-Series i700 \$770,904 for the purchase of seven (7) ultrasound units Annual service fee: \$63,000
6. Budgeted (indicate y/n)	Yes

Recommendation

Consider recommendation for Board of Directors to approve the terms presented for purchasing the ultrasound equipment for Salinas Valley Health Imaging and Obstetrics & Gynecology from Canon in the amount of \$770,904 and for a forty-eight month service agreement in the amount of \$252,000.

*TRANSFORMATION, STRATEGIC PLANNING
AND GOVERNANCE COMMITTEE*

*Minutes of the
Transformation, Strategic Planning and
Governance Committee
will be distributed at the Board Meeting*

(VICTOR REY, JR.)

Medical Executive Committee Summary – October 9, 2025

Items for Board Approval

Credentials Committee

Initial Appointments:

APPLICANT	SPECIALTY	DEPT	PRIVILEGES
Amin, Amar, MD	Radiology	Surgery	Salinas Valley Health Remote Radiology Salinas Valley Health Advanced Imaging
Carrasco, Victor, MD	Family Medicine	Medicine	Adult Hospitalist
Friedricks, Natalie, MD	Ob/Gyn	Ob/Gyn	Obstetrics and Gynecology Robotic Surgery
Hayrapetian, Artineh, MD	Radiology	Surgery	Salinas Valley Health Nancy Ausonio Breast Health Center Salinas Valley Health Remote Radiology Salinas Valley Health Advanced Imaging
Manning, Conrad, MD	Neurology	Medicine	Tele-Neurology
Ramirez, Jessica, MD	Internal Medicine	Medicine	Adult Hospitalist
Shander, Ellyn, MD	Psychiatry	Medicine	Tele-Psychiatry
Singh, Asha, MD	Neurology	Medicine	Tele-Neurology

Reappointments:

APPLICANT	SPECIALTY	DEPT	PRIVILEGES
Edwards, Mark, MD	Neurology	Medicine	Tele-Neurology
German, Michael, MD	Otolaryngology	Surgery	Otolaryngology
Heide, Aaron, MD	Neurology	Medicine	Tele-Neurology
Hershey, Allen, MD	Orthopedic	Surgery	Orthopedic Surgery Robotic Surgery Taylor Farms Family Health & Wellness Center
Kim, Kyong-Mee MD	Pediatrics	Family Medicine Pediatrics	Remote Pediatric Cardiology
Li, Victor, MD	Pain Medicine	Medicine	Medicine – Active Community
Lo, Jennifer, DDS	Dentistry	Surgery	Dentistry
Mrelashvili, Davit, MD	Neurology	Medicine	Tele-Neurology
Navarro, Misty, MD	Emergency Medicine	Emergency Medicine	Emergency Medicine
Numair, Osman, MD	Allergy/Immunology	Family Medicine Pediatrics	Pediatrics – Active Community
Rapaport, Yul, DO	Neurology	Medicine	Tele-Neurology
Sandhu, Simranjit, DPM	Podiatry	Surgery	Podiatry Salinas Valley Health Wound Healing Clinic
Tull, Blair, MD	Ob/Gyn	Ob/Gyn	Obstetrics and Gynecology
Tung, Christie, MD	Psychiatry	Medicine	Tele-Psychiatry

Modification of Privileges:

NAME	SPECIALTY	NEW PRIVILEGE
Ajam, Firas, MD	Electrophysiology	Use of Fluoroscopy
Dejanovic, Ilja, MD	Interventional Cardiology	Use of Fluoroscopy
Gali, Helena, MD	Ophthalmology	Cryotherapy for retinal tears or uncontrolled painful glaucoma

Kishore, Divya, MD	Radiology	Use of Fluoroscopy
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Staff Status Modifications:

NAME	SPECIALTY	STATUS CHANGE
Kramer, Erik, MD	Emergency Medicine	Leave of Absence effective 10/7/2025
Hindi, Yousef, MD	Cardiology	Leave of Absence effective 9/30/2025
Taich, Lior, MD	Urology	Advancement to Active Staff.
Alapati, Sampath, MD	Tele-Radiology	Resignation effective 9/18/2025
Ford, Kimberly MD	Tele-Psychiatry	Resignation effective 9/18/2025
Nezamabadi, Aryan, MD	Internal Medicine	Resignation effective 10/15/2025
Ruiz, James, MD	Ob/Gyn	Resignation effective 9/3/2025

Temporary/Locum Tenens Privileges:

NAME	SPECIALTY	DATES
Ngo, Tam, MD	Family Medicine	9/13/2025 – 10/12/2025 10/13/2025 – 11/11/2025

Interdisciplinary Practice Committee

Initial Appointments:

APPLICANT	PRIVILEGES	DEPT	COLLABORATING/SUPERVISING PHYSICIAN(S)
Battle, Hailey, PMHNP	Psychiatric Mental Health Nurse Practitioner Tele-Psychiatry	Medicine	Yingying Rezmovits, MD
Cash, Taaka, PMHNP	Psychiatric Mental Health Nurse Practitioner Tele-Psychiatry	Medicine	Nagib Chowdhury, MD
Grant, Carla PMHNP	Psychiatric Mental Health Nurse Practitioner Tele-Psychiatry	Medicine	Nagib Chowdhury, MD
Schrodetzki, Candice, PMHNP	Psychiatric Mental Health Nurse Practitioner Tele-Psychiatry	Medicine	Nagib Chowdhury, MD
Victor, Stephanie, PMHNP	Psychiatric Mental Health Nurse Practitioner Tele-Psychiatry	Medicine	Nagib Chowdhury, MD

Reappointments:

APPLICANT	PRIVILEGES	DEPT	COLLABORATING/SUPERVISING PHYSICIAN(S)
Berenji, Tyler, PA-C	Cardiology Cardiology Ambulatory Care CDOC and CADI	Medicine	Christopher Oh, MD

Modification of Privileges:

NAME	SPECIALTY	PRIVILEGE
Ajam, Firas, MD	Electrophysiology	Addition: Use of Fluoroscopy

Policies and Plans:

1. Aerosol Transmitted Diseases Exposure Control Plan
2. Bioterrorism Readiness Plan
3. Laboratory Critical Call Values
4. Respiratory Virus-Influenza-Pandemic Plan

Informational Items:

I. Committee Reports:

- a. Credentials Committee
- b. Interdisciplinary Practice Committee
- c. Quality and Safety Committee
 - CMS Star Rating Action Plan
 - Leapfrog Rate Improvement Plan

II. Other Reports:

- a. Summary of Executive Operations Committee Meetings
- b. Summary of Medical Staff Department/Committee Meetings September 2025
- c. Medical Staff Treasury Report October 3, 2025
- d. Medical Staff Statistics Year to Date
- e. Financial Update August 2025
- f. Executive Updates
- g. HCAHPS Update October 3, 2025

III. Rules and Regulations: Medical Staff Excellence Committee (MSEC) Charter Update (*Attached*) Presented as informational to the Board of Directors prior to a vote of the General Medical Staff.

Medical Staff Excellence Committee (MSEC) Charter

The Medical Staff Excellence Committee (MSEC) is responsible for evaluating and improving Medical Staff and Advanced Practice Provider performance in the following areas:

- Technical Quality: Skill and judgment related to effectiveness and appropriateness in performing the clinical privileges granted
- Patient Safety/Patient Rights: Cooperation with patient safety and rights, rules and procedures
- Resource Use: Effective and efficient use of Hospital resources
- In defining Medical Staff / Advanced Practice Provider indicators the following processes will be evaluated:
 - Patient Care
 - Knowledge based practice
 - Systems based practice
 - Interpersonal
 - Practice based learning
 - Professionalism

The following areas are considered outside the Committee's scope:

- Individual Medical Staff / Advanced Practice Provider member behavior incidents
- Credentialing and privileging recommendations
- System issues or concerns related to Health Information Management, Utilization Management, Blood Management, Medication Formulary and other policies requiring Medical Staff approval.

Responsibilities

Evaluation of Individual Cases

- Perform initial review of all cases requiring Medical Staff / Advanced Practice Provider member peer review. Cases are identified based on review indicators, ongoing Departmental audits or through referrals to Medical Staff Services or directly to MSEC.
- Obtain reviews and recommendations from internal or external specialists when required.
- Communicate with the practitioner involved with the case to obtain input prior to making determinations.
- Make recommendations regarding facility performance improvement (PI) opportunities based on individual case review.

Evaluation of Rate and Rule Indicators

- Perform regular review of adverse patterns, trends and outlier status for rate indicators relevant to all dimensions of practitioner performance. The purpose of this review is to determine if additional analysis or focus reviews are needed. This function may be delegated to an individual member of the committee or to a subcommittee.
- Identify performance improvement opportunities if additional analysis or focus reviews are needed and refer to the appropriate Hospital committee.

External Peer Review

Either the MSEC or MEC will make determinations on the need for external peer review. No practitioner can require the Medical Staff to obtain external peer review if it is not deemed appropriate by the MEC or MSEC. Circumstances for external peer review may include:

- Litigation - when dealing with the potential for a lawsuit.
- Ambiguity - when dealing with vague or conflicting recommendations from internal reviewers or Medical Staff committees and conclusions from this review will directly impact a practitioner's membership or privileges.

- Lack of internal expertise – When no one on the Medical Staff has adequate expertise in the specialty under review;
- When the only practitioners on Medical Staff with that expertise are determined to have a conflict of interest regarding the practitioner under review as describe above. External peer review will take place if this potential for conflict of interest cannot be appropriately resolved by the MSEC, MEC or Board of Directors or adequately mitigated.

The role of the MSEC is to assure that when opportunities for improvement are identified, the appropriate individuals are notified of the issues and a reasonable improvement plan is developed. This will be accomplished through the following:

- Communicate individual improvement opportunities to the appropriate Department Chair, who with the assistance of the MSEC Chair or designee, develops an improvement plan.
- Communicate system improvement opportunities to the appropriate Hospital committee/personnel.
- Track responses and improvement plans as requested/required.
- Report to the MEC regularly regarding actions taken to improve care. If a practitioner does not respond to requests from the MSEC or the Department Chair for meeting or discussion regarding the need for performance improvement, this lack of response will be forwarded to the MEC for further actions. This lack of response will be incorporated in to the final case summary.

Measurement System Management

- Review department specific indicators with Department Chairs at least annually to determine if revisions are necessary. Medical Staff Services reviews and evaluates screening tools and referral systems ongoing for effectiveness in collaboration with the Department Chairs and recommends changes to the MSEC and MEC.
- In coordination with the Department Chairs and Credentials Committee, define the appropriate content and format for performance feedback reports.
- Requests for modification of indicators, criteria or focused studies for evaluating practitioner performance will be submitted to Medical Staff Services who will then submit for MSEC review and approval.

Membership

The Chair of the MSEC will be appointed by the Chief of Staff and approved by the MEC for a term of two years. The Chair may serve an unlimited number of consecutive terms. The Chair will be an ex-officio member of the MEC without vote.

The MSEC will be comprised of the Chair and representatives from each of the following Service Lines:

- 3 Representatives: Medicine and Primary Care Services (Medicine, Cardiology, Family Practice, Emergency Medicine). At least one representative will be from the Hospitalist Service.
- 3 Representatives: Operative and Procedural Services (Surgery, GYN, Gastroenterology, Interventional Cardiology, Anesthesiology, Radiology, Pathology).
- 2 Representatives: Women's and Children's Services (Obstetrics, Pediatrics, Family Medicine with OB and/or Pediatric privileges).
- Three additional at large representatives, one of which will be an Advanced Practice Provider practitioner, will be appointed to enhance the specialty balance and expertise available to the committee. Medical Staff members from other specialties may be requested to review cases and be invited to the meeting as needed when the committee does not have the Medical Staff expertise with current members.

Ex-officio members of the MSEC may include the Chief of Staff, Chief Clinical Officer, and Medical Staff Services support staff, without voting rights.

The MSEC members will be recommended by the Chief of Staff in consultation with the MSEC Chair and Department Chairs and approved by the MEC. Voting members are appointed from the active, provisional or consulting staff categories and will serve for a three-year term.

Committee members who wish to be removed will send a written request to their respective Department Chair or to the MSEC Chair. The Department Chair or MSEC Chair will notify the Chief of Staff with recommendations for replacement.

Committee members will be expected to attend at least two thirds of the committee meetings over a twelve-month period to maintain membership and to participate in educational programs to increase their knowledge and skills in performing the Committee's responsibilities.

Meetings

The committee will meet at least 10 times per year with a summary of the meeting reported to the MEC. A quorum for purposes of making case determinations will be based on the presence of 50% of the voting seated committee members for which there are filled seats.

Reporting

The MSEC will report to Medical Executive Committee.

Attachment C: Case Review Process

Action	Case Review Process	Timeline - Guidelines
Case Identification	Screening Worklists: Patient case review worklists for appropriate review are obtained from a Hospital database system. Referrals: Referrals from occurrence reports, Case Management, patient relations, or other formal or informal requests for review are preliminarily screened to determine if they qualify for case review based on Medical Staff review indicators.	Worklists are run by the Medical Staff Services Department (MSS) for discharges occur within a given month within 3 weeks after the end of that month. Cases referred within 2 days of receipt of referral by the appropriate department and are preliminarily screened within 2 working days of receipt.
Case Screening	Cases are reviewed to determine if peer review is required. If peer review required, the MSS completes the initial section of the case review form, including providing the reviewer with a brief case summary of key clinical milestones and identification of key questions for the reviewer. If the MSS needs clarification of the Medical Staff review criteria, it will contact the MSEC Chair or designee. If the Chair feels a case does not meet current review indicator criteria but is of sufficient concern, the Chair will present the issue to the MSEC which will determine whether the case qualifies for review.	MSS will perform the initial screen and determine the need for peer review following identification of or receipt of a case referral. Potential cases for review not meeting current review indicators will be presented at the next MSEC meeting to determine if the issue qualifies for case review and whether a new or modified review indicator should be adopted to handle similar cases in the future.
MSEC Reviewer Assignment	Cases will be assigned for initial review as appropriate by the MSS. Whenever possible, the number of cases to be reviewed will be equally distributed among all MSEC members.	MSS will assign the initial reviewer at the time of screening when case is determined to require MSEC review. Committee members are informed of their case reviews approximately two weeks prior to the scheduled committee meeting.
MSEC Review	The assigned MSEC reviewer will review the case and complete required sections of the peer review module for the individual whose care is being reviewed. If the review is not completed, the MSS will contact the reviewer to obtain the additional information.	MSEC review will be completed within 14 days of assigning case to the reviewer. If the assigned reviewer is unable to perform the review within 14 days, the reviewer will contact the MSS within 1 week of the assignment.
Additional Review Needed	If the initial reviewer determines the case is solely a technical issue outside of the reviewer's expertise, the reviewer will inform the MSS and request the MSEC Chair, or designee to assign an appropriate second reviewer. The second reviewer will be a member of the committee if the committee has a member with the specific expertise without significant conflict of interest.	Second review to be completed within 14 days of assigning chart unless difficulty is encountered obtaining 2nd reviewer.

Action	Case Review Process	Timeline - Guidelines
Completed Case Review	Completed reviews will be submitted to the MSS by the MSEC reviewer immediately upon completion. Only completed peer review will be placed on the MSEC agenda. Late or incomplete reviews will be deferred to the next meeting.	Case reviews completed by MSEC reviewers submitted to the MSS department past the required 14 day completion timeframe (less than two business days/end of business on Friday before the Tuesday committee meeting prior to the MSEC) will be reported to the MSEC Chair. Late completion will be tracked.
Initial Reviews Rated Quality of Care Appropriate	Reviews indicating appropriate provider care are reported to the MSEC for summary approval. The MSEC Chair will review the summary of these cases with the peer review support staff prior to the committee meeting. If there are any concerns with the scoring, the chair will discuss the case with the reviewer. If any concerns still exist, the case will be presented to the MSEC for discussion.	Reviews indicating appropriate physician care are approved at the meeting.
Initial Reviews Rated Opportunity for Improvement, Inappropriate Care or Reviewer Uncertain	Reviews indicating potential inappropriate care or reviewer uncertain and desires committee input are presented to the MSEC for discussion and confirmation or change in preliminary scoring. If the committee feels that care may be inappropriate or an opportunity for improvement exists, it will communicate with the involved practitioner(s) via secure email. The involved physician or advanced-practice provider is informed of the key questions regarding the case and asked to respond in writing only.	Individual under review will respond to committee within 2 weeks. If no response, the provider will be notified (rule violation for non-response to MSEC request) and the committee will finalize rating based on the available information. The MSS department will contact the provider by phone if failed to respond to determine if provider was unavailable due to special circumstances.
Additional Clarification from the Provider	If after the initial written response, the MSEC determines it needs further clarification, it may request the practitioner for a second written response.	Clarification responses will be provided by the next MSEC meeting or the MSEC may finalize rating based on the available information.
Committee Final Disposition for Cases with Inquiry Letters	Following receipt of the provider's response or, if the response timeframe has lapsed, the MSEC will make the final determination of the overall provider care and, if the care is rated outside of current practice standards, identify the provider care issues. The MSEC will also determine whether the communication back the individual provides sufficient education for improvement. If additional education is deemed necessary, MSEC will involve the Department Chair as described below.	Final case determinations will be made by collective agreement of the MSEC members.
Communicating Findings to Individuals	Reviewed physicians or Advanced Practice Providers are informed of the decision by send secure email.	Outcome letters are sent to physician or Advanced Practice Provider within 30 days of the MSEC meeting.

Action	Case Review Process	Timeline - Guidelines
Tracking Review Findings	The MSS Department will enter the results of all final review findings into the database for tracking.	Case outcomes are tracked in individual physician/Advanced Practice Provider report cards in the peer review database.
Improvement Plan Development	If the results of either case reviews or analysis of rate or rule indicator trends indicate a need for individual provider performance improvement, the issue will be referred to the appropriate Department Chair. The MSEC Chair and the Department Chair, and if requested, the CMO, will work together to create and implement the improvement action plan.	The Department Chair and the MSEC Chair will create and implement the improvement plan within 30 days of the MSEC decision, or as soon as reasonably possible. When requested by the committee, the MSS Department will track the improvement implementation and the date implemented and will report back to the MSEC. A 6-month follow up will be sent from MSEC to the Department Chair to determine if further action is needed or if the event that triggered the action plan has been resolved.
Medical Executive Committee involvement	If MSEC Chair or Department Chair need assistance with the improvement, they will discuss the issue with the MEC Chair for resolution. Recommendations that may result in “adverse action” (e.g., restriction of privileges or membership) will be addressed in accordance with procedures in the Medical Staff Bylaws and Rules. For those cases determined to have potential opportunities for improving system performance or potential issues with nursing care, the MSEC Chair will communicate the issue to the appropriate Hospital committee or person.	The MSEC Chair will discuss any need for assistance with the MEC Chair within 30 days of the MSEC decision.
Referrals to Quality and Safety Committee	For cases meeting the organizations sentinel event criteria, timely processing of practitioner-specific information is necessary to ensure patient safety. Sentinel Events requiring peer review, will have immediate review by the MSEC Chair or designee. Additional information (such as a literature search, second opinion, or external peer review) may be necessary before making a decision on action.	The Hospital committee or person receiving the referral will discuss the issue and communicate action plan to the MSEC committee.
High-Risk Cases		Initial MSEC review will be performed within three (3) working days of case identification, with committee discussion at the next MSEC meeting or within 30 days of the event if there is not regularly scheduled meeting within 30 days. If additional information is needed, the timelines may be extended after approval from the Governing Body or its designee or the MEC.

Medical Staff Excellence Committee (MSEC) Charter

Goals

~~To maintain a centralized committee for evaluating and/or improving Medical Staff / Advanced Practice Provider member performance on an individual and aggregate level to accomplish the following:~~

- ~~1. Improve patient outcomes by pursuing and maintaining excellence in medical staff / Advanced Practice Provider member performance.~~
- ~~2. Create a culture with a positive approach to medical staff / Advanced Practice Provider member peer review.~~
- ~~3. Promote efficient use of Medical Staff Services staff.~~
- ~~4. Provide accurate and timely performance data for medical staff / Advanced Practice Provider member feedback, Ongoing and Focused Professional Practice Evaluation and reappointment.~~
- ~~5. Support medical staff / Advanced Practice Provider educational goals to improve patient care.~~
- ~~6. Provide mechanism to assure responsiveness to system improvement opportunities identified by the medical staff / Advanced Practice Provider.~~
- ~~7. Obtaining data for Focused Professional Practice Evaluation (FPPE) obtained via the Ongoing Professional Practice Evaluation (OPPE) process.~~

Scope

The ~~Medical Staff~~Medical Staff Excellence Committee (MSEC) is responsible for evaluating and improving ~~Medical Staff~~Medical Staff / ~~and~~ Advanced Practice Provider ~~member~~ performance in the following areas:

- Technical Quality: Skill and judgment related to effectiveness and appropriateness in performing the clinical privileges granted
- ~~Service Quality: Ability to meet the customer service needs of patients and other care caregivers~~
- Patient Safety/Patient Rights: Cooperation with patient safety and rights, rules and procedures
- Resource Use: Effective and efficient use of ~~hospital~~Hospital ~~clinical~~ resources
- In defining ~~medical staff~~Medical Staff / Advanced Practice Provider indicators the following processes will be evaluated:
 - Patient Care
 - Knowledge based practice
 - Systems based practice
 - Interpersonal
 - Practice based learning
 - Professionalism

The following areas are considered outside the Committee's scope:

- Individual ~~medical staff~~Medical Staff / Advanced Practice Provider member behavior incidents
- ~~Routine concurrent aspects of medical staff / Advanced Practice Provider member resource use~~
- Credentialing and privileging recommendations
- System issues or concerns related to Health Information Management, Utilization Management, Blood Management, Medication Formulary and other policies requiring ~~medical staff~~Medical Staff approval.

Responsibilities

Evaluation of Individual Cases

- Perform initial review of all cases ~~of sufficient complexity of management or seriousness of outcome~~ requiring ~~medical staff~~ Medical Staff / Advanced Practice Provider member peer review. Cases are identified based on review indicators, ongoing ~~D~~departmental audits or through referrals to ~~Medical Staff~~ Medical Staff Services ~~or directly to MSEC~~.
- Obtain reviews and recommendations from internal or external specialists ~~on the medical staff or from external specialists~~ when required.
- Communicate with the ~~medical staff / Advanced Practice Provider member~~ practitioner involved with the case to obtain input prior to making determinations ~~when opportunities for improvement may exist~~.
- Make recommendations regarding facility performance improvement (PI) opportunities based on individual case review.

Evaluation of Rate and Rule Indicators

- Perform regular review of ~~adverse outliers from aggregated results of rule indicators and of~~ adverse patterns, trends and outlier status for rate indicators relevant to all dimensions of ~~medical staff / Advanced Practice Provider member practitioner~~ performance ~~within the scope of the committee~~. The purpose of this review is to determine if additional analysis or focus reviews are needed. This function may be delegated to an individual member of the committee or to a subcommittee.
- Identify ~~P~~performance improvement opportunities ~~for improvement and determine~~ if additional analysis or focus reviews are needed and refer to the appropriate ~~hospital~~ Hospital committee.

External Peer Review

Either the MSEC or MEC will make determinations on the need for external peer review. No practitioner can require the Medical Staff to obtain external peer review if it is not deemed appropriate by the MEC or MSEC. Circumstances for external peer review may include:

- Litigation - when dealing with the potential for a lawsuit.
- Ambiguity - when dealing with vague or conflicting recommendations from internal reviewers or Medical Staff committees and conclusions from this review will directly impact a practitioner's membership or privileges.
- Lack of internal expertise – When no one on the Medical Staff has adequate expertise in the specialty under review;
- When the only practitioners on Medical Staff with that expertise are determined to have a conflict of interest regarding the practitioner under review as describe above. External peer review will take place if this potential for conflict of interest cannot be appropriately resolved by the MSEC, MEC or Board of Directors or adequately mitigated.

Oversight of Other Medical Staff / Advanced Practice Provider Member Performance Evaluation Committees

~~Although the vast majority of initial review of individual cases, along with rule and rate indicator results, will be performed by Medical Staff Services Peer Review support staff, under the MSEC, medical staff departments or committees may perform some of these functions either as a quality control mechanism or as a multi-disciplinary educational process. Such proceedings are considered part of the medical staff quality function and are protected from discovery as long as the appropriate policies and procedures of the MSEC are followed and ongoing reports submitted to the MSEC.~~

~~Departmental reviews may be accomplished through the review of either individual cases or through the use of aggregate data. The purpose of this review is to improve individual or aggregate medical staff / Advanced Practice Provider member performance on an informal educational basis. Each Department may perform the initial review of rate and rule data for patterns / trends for medical staff member relevant indicator(s). Cases resulting in misinterpretations or missed findings, significant change in treatment, or adverse outcomes or~~

~~trends or patterns potentially related to medical staff/ Advance Practice Provider member care will be referred to the Medical Staff Services Department for inclusion in the MSEC peer review process. Referred cases will be included in the Electronic Peer Review System.~~

The role of the MSEC is to assure that when opportunities for improvement are identified, the appropriate individuals are notified of the issues and a reasonable improvement plan is developed. This will be accomplished through the following:

- Communicate individual improvement opportunities to the appropriate ~~Department Chair~~Department Chair, who with the assistance of the MSEC Chair or designee, develops an improvement plan.
- Communicate system improvement opportunities to the appropriate ~~hospital~~Hospital committee/personnel.
- Track responses and improvement plans as requested/required.
- ~~Report to the MEC regularly regarding actions taken to improve care, and any cases where action was not taken when requested or actions are perceived to be inadequate.~~
- If a practitioner does not respond to requests from the MSEC or the ~~department chair~~Department Chair for meeting or discussion regarding the need for performance improvement, this lack of response will be forwarded to the MEC for further actions. This lack of response will be incorporated in to the final case summary.

Measurement System Management

- ~~At least biennially~~ Review department specific indicators with ~~Department Chairs~~ Department Chairs at least annually to and determine if revisions are necessary ~~based on previous trends / patterns~~. Medical Staff Medical Staff Services reviews and evaluates screening tools and referral systems ongoing for effectiveness in collaboration with the ~~department chairs~~ Department Chairs and recommends changes to the MSEC and MEC.
- ~~At least every 3 years, i~~ In coordination with the ~~Department Chairs~~ Department Chairs and Credentials Committee, define the appropriate content and format for performance feedback reports ~~(OPPE)~~.
- Requests for ~~addition or deletion to~~ modification of indicators, criteria or focused studies for evaluating practitioner performance will be submitted to ~~Medical Staff~~ Medical Staff Services who will then submit for MSEC review and approval.

Membership

The Chair of the MSEC will be appointed by the Chief of Staff and approved by the MEC for a term of two years. The Chair may serve an unlimited number of consecutive terms. The Chair will be an ex-officio member of the MEC without vote.

The MSEC will be comprised of the Chair and ~~three~~ representatives from each of the following Service Lines:

- 3 Representatives: Medicine and Primary Care Services (Medicine, Cardiology, Family Practice, Emergency Medicine). At least one representative will be from the Hospitalist Service.
- 3 Representatives: Operative and Procedural Services (Surgery, GYN, Gastroenterology, Interventional Cardiology, Anesthesiology, Radiology, Pathology).
- 2 Representatives: Women's and Children's Services (Obstetrics, Pediatrics, Family Medicine with OB and/or Pediatric privileges).
- Three additional at large representatives, one of which will be an Advanced Practice Provider practitioner, will be appointed to enhance the specialty balance and expertise available to the committee. ~~Medical staff~~ Medical Staff members from other specialties may be requested to review cases and be invited to the meeting as needed when the committee does not have the ~~medical staff~~ Medical Staff expertise with current members.

Ex-officio members of the MSEC may include the Chief of Staff, Chief ~~Medical~~ Clinical Officer, and ~~Medical Staff~~ Medical Staff Services support staff, without voting rights.

The MSEC ~~Committee~~ members will be ~~appointed~~ recommended by the Chief of Staff ~~based on~~ in consultation with the MSEC Chair and ~~Department Chair~~ Department Chairs and approved by the MEC. Voting members are appointed from the active, provisional or consulting staff categories and will serve for a three-year term.

Committee members who ~~request wish~~ to be removed ~~as a member of MSEC~~ will send a written notice request, in writing, to their respective ~~Department Chair~~ Department Chair or to the MSEC Chair. The ~~Department Chair~~ Department Chair or MSEC Chair will notify the Chief of Staff with recommendations for ~~committee appointment~~ replacement.

Committee members will be expected to attend at least two thirds of the committee meetings over a twelve-month period to maintain membership. ~~Committee members will be expected and~~ to participate in educational programs to increase their knowledge and skills in performing the Committee's responsibilities.

Meetings

The committee will meet at least 10 times per year with a summary of the meeting reported to the MEC. A quorum for purposes of making case determinations will be based on the presence of 50% of the voting seated committee members for which there are filled seats.

Reporting

The MSEC will report to Medical Executive Committee.

Attachment C: Case Review Process

Action	Case Review Process	Timeline - Guidelines
Case Identification	Screening Worklists: Patient case review worklists for appropriate review are obtained from a ~~hospital~~<u>Hospital</u> database system. Referrals: Referrals from occurrence reports, Case Management, patient relations, or other formal or informal requests for review are preliminarily screened to determine if they qualify for case review based on ~~medical-staff~~<u>Medical Staff</u> review indicators.	Worklists are run by the ~~Medical Staff~~<u>Medical Staff</u> Services Department (MSS) for discharges occur within a given month within 3 weeks after the end of that month. Cases referred within 2 days of receipt of referral by the appropriate department and are preliminarily screened within 2 working days of receipt.
Case Screening	Cases are reviewed to determine if peer review is required. If peer review required, the MSS completes the initial section of the case review form, including providing the reviewer with a brief case summary of key clinical milestones and identification of key questions for the reviewer. If the MSS needs clarification of the ~~medical-staff~~<u>Medical Staff</u> review criteria, it will contact the MSEC Chair or designee. If the Chair feels a case does not meet current review indicator criteria but is of sufficient concern, the Chair will present the issue to the MSEC which will determine whether the case qualifies for review.	MSS will perform the initial screen and determine the need for peer review following identification of or receipt of a case referral. Potential cases for review not meeting current review indicators will be presented at the next MSEC meeting to determine if the issue qualifies for case review and whether a new or modified review indicator should be adopted to handle similar cases in the future.
MSEC Reviewer Assignment	Cases will be assigned for initial review as appropriate by the MSS. Whenever possible, the number of cases to be reviewed will be equally distributed among all MSEC members.	MSS will assign the initial reviewer at the time of screening when case is determined to require MSEC review. Committee members are informed of their case reviews approximately two weeks prior to the scheduled committee meeting.
MSEC Review	The assigned MSEC reviewer will review the case and complete required sections of the peer review module for the individual whose care is being reviewed. If the review is not completed, the MSS will contact the reviewer to obtain the additional information.	MSEC review will be completed within 14 days of assigning case to the reviewer. If the assigned reviewer is unable to perform the review within 14 days, the reviewer will contact the MSS within 1 week of the assignment.
Additional Review Needed	If the initial reviewer determines the case is solely a technical issue outside of the reviewer's expertise, the reviewer will inform the MSS and request the MSEC Chair, or designee to assign an appropriate second reviewer. The second reviewer will be a member of the committee if the committee has a member with the specific expertise without significant conflict of interest.	Second review to be completed within 14 days of assigning chart unless difficulty is encountered obtaining 2nd reviewer.

Action	Case Review Process	Timeline - Guidelines
Completed Case Review	Completed reviews will be submitted to the MSS by the MSEC reviewer immediately upon completion. Only completed peer review will be placed on the MSEC agenda. Late or incomplete reviews will be deferred to the next meeting.	Case reviews completed by MSEC reviewers submitted to the MSS department past the required 14 day completion timeframe (less than two business days/end of business on Friday before the Tuesday committee meeting prior to the MSEC will be reported to the MSEC Chair. Late completion will be tracked.
Initial Reviews Rated Quality of Care Appropriate	Reviews indicating appropriate provider care are reported to the MSEC for summary approval. The MSEC Chair will review the summary of these cases with the peer review support staff prior to the committee meeting. If there are any concerns with the scoring, the chair will discuss the case with the reviewer. If any concerns still exist, the case will be presented to the MSEC for discussion.	Reviews indicating appropriate physician care are approved at the meeting.
Initial Reviews Rated Opportunity for Improvement, Inappropriate Care or Reviewer Uncertain	Reviews indicating potential inappropriate care or reviewer uncertain and desires committee input are presented to the MSEC for discussion and confirmation or change in preliminary scoring. If the committee feels that care may be inappropriate or an opportunity for improvement exists, it will communicate with the involved practitioner(s) via secure email. The involved physician or advanced-practice provider is informed of the key questions regarding the case and asked to respond in writing only.	Individual under review will respond to committee within 2 weeks. If no response, the provider will be notified (rule violation for non-response to MSEC request) and the committee will finalize rating based on the available information. The MSS department will contact the provider by phone if failed to respond to determine if provider was unavailable due to special circumstances.
Additional Clarification from the Provider	If after the initial written response, the MSEC determines it needs further clarification, it may <u>allow request the physician or Advanced Practice Provider/practitioner for to deliver a second written response in writing or in person within a specified timeframe. If the provider chooses to appear in person, the individual will only respond to specific, predetermined questions and not be present for any committee discussion.</u>	Clarification responses will be provided by the next MSEC meeting or the MSEC <u>will may</u> finalize rating based on the available information <u>unless the MSEC requires a personal appearance and the provider has a previous commitment.</u>
Committee Final Disposition for Cases with Inquiry Letters	Following receipt of the provider's response or, if the response timeframe has lapsed, the MSEC will make the final determination of the overall provider care and, if the care is rated <u>less than appropriate/outside of current practice standards</u> , identify the provider care issues. The MSEC will also determine whether the communication back the individual provides sufficient education for improvement, <u>or whether involvement is needed by the Department Chair as described below under Improvement Plan development. If</u>	Final case determinations will be made by <u>majority vote as described in the MSEC Charter. Cases determined to be inappropriate require a unanimous vote of the committee members present. A committee member who is present but wishes to abstain from voting will not affect the unanimous vote of all other committee members present; collective agreement of the MSEC members.</u>

Action	Case Review Process	Timeline - Guidelines
	additional education is deemed necessary, <u>MSEC will involve the Department Chair as described below.</u>	Outcome letters are sent to physician or Advanced Practice Provider within 30 days of the MSEC meeting.
Communicating Findings to Individuals	Reviewed physicians or Advanced Practice Providers are informed of the decision by send secure email.	
Physician's Right to Appeal	~~If a provider disagrees with the final determination of the MSEC, an appeal may be made to the involved Department Chair. No further appeals may be made to the MSEC. In the event that the Department Chair disagrees with the MSEC decision, the decision of the Department Chair prevails.~~	~~In order to be considered, an appeal must be submitted by the involved provider to their Department Chair no later than 30 days following provider receipt of the outcome notification.~~
Tracking Review Findings	The MSS Department will enter the results of all final review findings into the database for tracking.	Case outcomes are tracked in individual physician/Advanced Practice Provider report cards in the peer review database.
Improvement Plan Development	If the results of either case reviews or analysis of rate or rule indicator trends indicate a need for individual provider performance improvement, the issue will be referred to the appropriate ~~Department Chair~~ <u>Department Chair</u> . The MSEC Chair and the ~~Department Chair~~ <u>Department Chair</u> , and if requested, the CMO, will work together to create and implement the improvement action plan.	The ~~Department Chair~~ <u>Department Chair</u> and the MSEC Chair will create and implement the improvement plan within 30 days of the MSEC decision, or as soon as reasonably possible. When requested by the committee, the MSS Department will track the improvement implementation and the date implemented and will report back to the MSEC. A 6-month follow up will be sent from MSEC to the ~~Department Chair~~ <u>Department Chair</u> to determine if further action is needed or if the event that triggered the action plan has been resolved.
Medical Executive Committee involvement	If MSEC Chair or ~~Department Chair~~ <u>Department Chair</u> need assistance with the improvement, they will discuss the issue with the MEC Chair for resolution. Recommendations that may result in "adverse action" (e.g., restriction of privileges or membership) will be addressed in accordance with procedures in the ~~Medical Staff~~ <u>Medical Staff</u> Bylaws and Rules.	The MSEC Chair will discuss any need for assistance with the MEC Chair within 30 days of the MSEC decision.
Referrals to Quality and Safety Committee	For those cases determined to have potential opportunities for improving system performance or potential issues with nursing care, the MSEC Chair will communicate the issue to the appropriate ~~hospital~~ <u>Hospital</u> committee or person.	The ~~hospital~~ <u>Hospital</u> committee or person receiving the referral will discuss the issue and communicate action plan to the MSEC committee.

Action	Case Review Process	Timeline - Guidelines
High-Risk Cases	For cases meeting the organizations sentinel event criteria, timely processing of practitioner-specific information is necessary to ensure patient safety. Sentinel Events requiring peer review, will have immediate review by the MSEC Chair or designee. Additional information (such as a literature search, second opinion, or external peer review) may be necessary before making a decision on action.	Initial MSEC review will be performed within three (3) working days of case identification, with committee discussion at the next MSEC meeting or within 30 days of the event if there is not regularly scheduled meeting within 30 days. If additional information is needed, the timelines may be extended after approval from the Governing Body or its designee or the MEC.
Precautionary or Summary Suspensions	~~The processes and time frames in this document do not apply to precautionary suspensions or summary suspensions under the Medical Staff Bylaws and Rules.~~	~~Refer to the Medical Staff Bylaws and Rules.~~



Origination 01/2022
Last Approved N/A
Next Review 1 year after approval

Owner **Melissa Deen:**
Manager
Infection
Prevention
Area **Plans and
Program**

Aerosol Transmitted Diseases Exposure Control Plan

I. SCOPE

- A. An aerosol-transmissible disease (ATD) is a disease that is transmitted either by inhalation of infectious particles/droplets or direct contact with the particles/droplets with mucous membranes in the respiratory tract or eyes. Salinas Valley Health Medical Center (SVHMC) employees may have occupational exposure to ATDs in the course of conducting their job duties. Following California Code of Regulations, title 8, section [5199](#), Aerosol Transmissible Diseases, SVHMC has implemented this written exposure control plan to reduce employees' risk of contracting these infections, so that SVHMC may respond in an appropriate and timely manner when exposure incidents occur.

II. DEFINITIONS

- A. For purposes of this plan, the term "employee" represents all persons who engage in or affect patient care.
- B. **Aerosol transmissible disease (ATD) or aerosol transmissible pathogen (ATP):** A disease or pathogen for which droplet precautions or airborne isolation are recommended.
- C. **Aerosol transmissible pathogen – laboratory (ATP-L):** A disease or pathogen for which droplet precautions or airborne isolation are required (refer to Appendix B).
- D. **Airborne infection isolation (AII):** Infection control procedures as described in Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings. These procedures are designed to reduce the risk of transmission of airborne infectious pathogens and apply to patients known or suspected to be infected with epidemiologically important pathogens that can be transmitted by the airborne route.
- E. **Airborne infection isolation room or area (AIIR):** A room, area, booth, tent, or other enclosure that is maintained at negative pressure to adjacent areas in order to control the spread of aerosolized *M. tuberculosis* and other airborne infectious pathogens and that meets the requirements stated in engineering controls of this plan.

- F. **Airborne infectious disease (AirID):** Either: (1) an aerosol transmissible disease transmitted through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the disease agent for which the CDC or CDPH recommends All, or (2) the disease process caused by a novel or unknown pathogen for which there is no evidence to rule out with reasonable certainty the possibility that the pathogen is transmissible through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the novel or unknown pathogen.
- G. **Airborne infectious pathogen (AirIP):** Either: (1) an aerosol transmissible pathogen transmitted through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the infectious agent, and for which the CDC or CDPH recommends All, or (2) a novel or unknown pathogen for which there is no evidence to rule out with reasonable certainty the possibility that it is transmissible through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the novel or unknown pathogen.
- H. **Droplet precautions:** Infection control procedures as described in CDC Guideline for Transmission-based Precautions designed to reduce the risk of transmission of infectious agents through contact of the conjunctivae or the mucous membranes of the nose or mouth of a susceptible person with large-particle droplets (larger than 5 µm in size) containing microorganisms generated from a person who has a clinical disease or who is a carrier of the microorganism
- I. **Electronic Health Record (EHR)**
- J. **Exposure incident:** An event in which all of the following has occurred: (1) An employee has been exposed to an individual who is a case or suspected case of a reportable ATD, or to a work area or to equipment that is reasonably expected to contain ATPs associated with a reportable ATD; and (2) The exposure occurred without the benefit of applicable exposure controls required by this section, and (3) It reasonably appears from circumstances of the exposure that transmission of disease is sufficiently likely to require medical evaluation.
- K. **Guideline for Isolation Precautions:** The Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, June 2007, CDC
- L. **Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health- Care Settings:** The Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, December 2005, CDC
- M. **Health care provider:** A physician and surgeon, a veterinarian, a podiatrist, a nurse practitioner, a physician assistant, a registered nurse, a nurse midwife, a school nurse, an infection control practitioner, a medical examiner, a coroner, or a dentist
- N. **Health care worker:** A person who works in a health care facility, service or operation
- O. **High hazard procedures:** Procedures performed on a person who is a case or suspected case of an aerosol transmissible disease or on a specimen suspected of containing an ATP-L, in which the potential for being exposed to aerosol transmissible pathogens is increased due to the reasonably anticipated generation of aerosolized pathogens. Such procedures include, but are not limited to, sputum induction, bronchoscopy, aerosolized administration of pentamidine or other medications, and pulmonary function testing. High Hazard Procedures also include, but are not limited to, autopsy, clinical, surgical and laboratory procedures that may aerosolize pathogens

- P. **Individually identifiable medical information** means medical information that includes or contains any element of personal identifying information enough to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity
- Q. **Infection Preventionist (IP):** An infection control professional who is knowledgeable about infection control practices, including routes of transmission, isolation precautions and the investigation of exposure incidents
- R. **Infectious:** Having the ability to transmit TB or ATD/ATP to other people via respiratory droplet nuclei, fomites, or during autopsy
- S. **Initial treatment:** Treatment provided at the time of the first contact a health care provider has with a person who is potentially an AirID case or suspected case. Initial treatment does not include high-hazard procedures
- T. **Laboratory:** A facility or operation in a facility where the manipulation of specimens or microorganisms is performed for the purpose of diagnosing disease or identifying disease agents, conducting research or experimentation on microorganisms, replicating microorganisms for distribution or related support activities for these processes
- U. **Local health officer:** The health officer for the local jurisdiction responsible for receiving and/or sending reports of communicable diseases, as defined in Title 17, CCR
**NOTE: Title 17, Section 2500 of CCR requires that reports be made to the local health officer for the jurisdiction where the patient resides.*
- V. **M. tuberculosis (TB or M. tb) means Mycobacterium tuberculosis:** The scientific name of the bacterium that causes tuberculosis
- W. **Negative pressure:** The relative air pressure difference between two areas. The pressure in a containment room or area that is under negative pressure is lower than adjacent areas, which keeps air from flowing out of the containment room or area and into adjacent rooms or areas
- X. **NIOSH:** The National Institute for Occupational Safety and Health
- Y. **Novel or unknown ATP:** A pathogen capable of causing serious human disease meeting the following criteria:
 - 1. There is credible evidence that the pathogen is transmissible to humans by airborne and/or droplet transmission and;
 - 2. The disease agent is:
 - a. A newly recognized pathogen, or
 - b. A newly recognized variant of a known pathogen and there is reason to believe that the variant differs significantly from the known pathogen in virulence or transmissibility, or
 - c. A recognized pathogen that has been recently introduced into the human population, or
 - d. A not yet identified pathogen
- Z. **NOTE: Variants of seasonal influenza virus that typically are not considered novel or unknown ATPs. Pandemic influenza strains that have not been fully characterized are novel pathogens.*

- AA. **Occupational exposure:** Exposure from work activity or working conditions that is reasonably anticipated to create an elevated risk of contracting any disease caused by ATPs if protective measures are not in place. In this context, "elevated" means higher than what is considered ordinary for employees having direct contact with the general public outside of the facilities, service categories and operations listed in subsection (a)(1) of this standard. Occupational exposure is presumed to exist to some extent in each of the facilities, services and operations listed in subsection (a)(1)(A) through (a)(1)(H) of the California Code of Regulations, Title 8, Section 5199, Aerosol Transmissible Diseases. Whether a particular employee has, occupational exposure depends on the tasks, activities, and environment of the employee, and therefore, some employees of a covered employer may have no occupational exposure. For example, occupational exposure typically does not exist where a hospital employee works only in an office environment separated from patient care facilities or works only in other areas separate from those where the risk of ATD transmission, whether from patients or contaminated items, would be elevated without protective measures. It is the task of employers covered by this standard to identify those employees who have occupational exposure so that appropriate protective measures can be implemented to protect them as required. Employee activities that involve having contact with or being within exposure range of cases or suspected cases of ATD, are always considered to cause occupational exposure. Similarly, employee activities that involve contact with, or routinely being within exposure range of, at-risk populations are considered to cause occupational exposure. Employees working in laboratory areas in which ATP are handled or reasonably anticipated to be present are also considered to have occupational exposure
- AB. **Physician or other licensed health care professional (PLHCP)** means an individual whose legally permitted scope or practice (i.e., license, registration, or certification) allows him or her to independently provide, or be delegated the responsibility to provide, some or all health care services required by this section.
- AC. **PPD (Purified Protein Derivative):** The substance used in a skin test to determine presence of hypersensitivity to tuberculin protein, signifying exposure to the organism
- AD. **IGRA (Interferon Gamma Release Assay):** A blood test that screens for tuberculosis (TB) bacteria
- AE. **Referral:** The directing or transferring of a possible ATD case to another facility, service or operation for the purposes of transport, diagnosis, treatment, isolation, housing or care.
- AF. **Reportable aerosol transmissible disease (RATD):** A disease or condition which a health officer, in accordance with Title 17 CCR, Division 1, Chapter 4, and which meets the definition of an aerosol transmissible disease (ATD)
- AG. **Respirator:** A device which has met the requirements of 42 CFR Part 84, has been designed to protect the wearer from inhalation of harmful atmospheres, and has been approved by NIOSH for the purpose for which it is used
- AH. **Respiratory Hygiene/Cough Etiquette in Health Care Settings: Respiratory Hygiene/Cough Etiquette in Health Care Settings,** CDC, November 4, 2004, which is hereby, incorporated by reference for the sole purpose of establishing requirements for source control procedures
- AI. **Risk:** The likelihood of an individual acquiring or having acquired TB by virtue of behavior, underlying medical condition, occupation, international travel, personal contact or

socioeconomic conditions

- AJ. **Screening (health care provider):** The initial assessment of persons who are potentially AirID or ATD cases by a health care provider in order to determine whether they need airborne infection isolation or need to be referred for further medical evaluation or treatment to make that determination. Screening does not include diagnostic testing
- AK. **Screening (non-health care provider):** The identification of potential ATD cases through readily observable signs and the self-report of patients or clients. Screening does not include diagnostic testing
- AL. **Significant exposure:** An exposure to a source of ATPs or ATP-L in which the circumstances of the exposure make the transmission of a disease sufficiently likely that the employee requires further evaluation by a PLHCP
- AM. **Source control measures:** The use of procedures, engineering controls, and other devices or materials to minimize the spread of airborne particles and droplets from an individual who has or exhibits signs or symptoms of having an ATD, such as persistent coughing
- AN. **Surge:** A rapid expansion beyond normal services to meet the increased demand for qualified personnel, medical care, equipment, and public health services in the event of an epidemic, public health emergency, or disaster
- AO. **Susceptible person:** A person who is at risk of acquiring an infection due to a lack of immunity as determined by a PLHCP in accordance with current CDC or California Department of Health guidelines
- AP. **Suspected case:** Either of the following:
 - 1. A person whom a health care provider believes, after weighing signs, symptoms, and/or laboratory evidence to probably have a disease or condition listed in Section
 - a. IV. A. 6 of the California Code of Regulations, Title 8, Section 5199, Aerosol Transmissible Diseases
 - 2. A person who is considered a probable case, or an epidemiologically- linked case, or who has supportive laboratory findings under the most recent communicable disease surveillance case definition established by CDC and published in the Morbidity and Mortality Weekly Report (MMWR) or its supplements as applied to a particular disease or condition listed in Section IV. A. 6 of the California Code of Regulations, Title 8, Section 5199, Aerosol Transmissible Diseases
- AQ. **TB or M. tb:** The organism *Mycobacterium tuberculosis*, the causative agent of the infection which leads to disease of people infected
- AR. **TB conversion:** A change from negative to positive as indicated by TB test results, based upon current CDC or California Department of Public Health guidelines for interpretation of the TB test
- AS. **TB transmission:** The spread of TB from one person to another. This occurs via the airborne route by inhalation of droplet nuclei, small (1-5 micron) residual of aerosols suspended in air exhaled by a person with active disease. Most TB is transmitted by patients not known to have active disease, but who in fact have cavitary, pulmonary, laryngeal disease, by coughing, speaking, singing, or spitting. Individuals with exposure to air contaminated in such a way have a risk of acquisition of organisms proportionate to the degree of contamination of the air and

the total volume of that air inhaled. Highest risk of acquisition is in household settings, or enclosed locations of poor ventilation, such as shelters, aircraft or older engineered facilities

- AT. **Treatment:** The use of chemotherapy to kill ATD in patients or employees with disease, including chemoprophylaxis
- AU. **Test for Tuberculosis Infection (TB Test):** Any test, including the tuberculin skin test (TST) and blood assays for *M. Tuberculosis* (BAMT) such as interferon gamma release assays (IGRA) which: (1) has been approved by the Food and Drug Administration for the purposes of detecting tuberculosis infection, and (2) is recommended by the CDC for testing for TB infection in the environment in which it is used, and (3) is administered, performed, analyzed and evaluated in accordance with those approvals and guidelines
- AV. **Tuberculosis (TB or *M. tb*):** A disease caused by *M. tuberculosis*

III. PLAN MANAGEMENT

A. Plan Elements

1. LIST OF ALL HIGH HAZARD PROCEDURES AND JOB CLASSIFICATIONS

- a. High hazard procedures are procedures performed on an ATD case or suspected case where the potential for being exposed to an aerosol transmissible pathogen (ATP) is increased due to the reasonably anticipated generation of aerosolized pathogens. A procedure is also considered high hazard if generation of aerosolized pathogens is reasonably anticipated when performed on a laboratory specimen suspected of containing an aerosol transmissible pathogen-laboratory (ATP-L).
 - i. A Powered Air Purifying Respirator (PAPR) is required upon entering an airborne isolation room (AIIR) for high hazard procedures with patients with suspected or confirmed diseases transmitted via the airborne route
 - ii. PAPR, eye protection (per employee preference), gloves, fluid resistant gown hand hygiene and an AIIR room* are required during a high hazard procedure on a patient with a suspected or confirmed aerosol transmissible infectious disease (AirID). Where no AIIR room or area is available and the treating physician determines that it would be detrimental to the patient's condition to delay performing the procedure, high hazard procedures may be conducted in other areas. In that case, employees working in the room or area where the procedure is performed shall use all necessary personal respiratory protection and personal protective equipment. The physician's determination shall be documented and reviewed annually.
Reference/link: [Aerosol Transmitted Diseases Pathogens list](#)
Reference/ link: [ISOLATION - STANDARD AND TRANSMISSION BASED PRECAUTIONS](#)
- b. SVHMC has compiled a list of all high hazard procedures performed at

this facility, conducted a risk assessment for these high hazard procedures, analyzed job classification and job tasks that employees perform and operations with potential exposure, including required PPE for each task, see table below:

c.

High Hazard Procedure	Job Classifications & Operations With Potential Exposure	Required PPE
Endotracheal Intubation/Extubation	Physicians, Nursing, Respiratory Therapy, Phlebotomy, Diagnostic Imaging	PAPR or higher (AirID)
Airway Surgeries (e.g., ENT, thoracic, transsphenoidal surgeries)	Physicians, Nursing, Respiratory Therapy, Cardiac Perfusionist	PAPR or higher (AirID)
Chest Compressions	Physicians, Nursing, Respiratory Therapy, Phlebotomy	PAPR or higher (AirID)
Nebulization	Physicians, Respiratory Therapy, Nursing	PAPR or higher (AirID)
High Flow oxygen, including nasal cannula at >6L or 15L	Physicians, Respiratory Therapy, Nursing	PAPR or higher (AirID)
Non-invasive positive pressure ventilation (e.g. CPAP, BiPAP)	Physicians, Respiratory Therapy, Nursing	PAPR or higher (AirID)
Oscillatory ventilation	Physicians, Nursing, Respiratory Therapy	PAPR or higher (AirID)
Bronchoscopy	Endoscopy/ OR Clinical Staff, Physicians, Nursing, Respiratory Therapy	PAPR or higher (AirID)
Sputum Induction	Physicians, Respiratory Therapy, Nursing	PAPR or higher (AirID)
Open suctioning of tracheostomy or Endotracheal tube	Physicians, Respiratory Therapy, Nursing	PAPR or higher (AirID)
Manual ventilation (e.g. bag-mask ventilation before intubation) and Ventilator circuit manipulation	Physicians, Nursing, Respiratory Therapy	PAPR or higher (AirID)

Disconnecting patient from ventilator	Physicians, Nursing, Respiratory Therapy	PAPR or higher (AirID)
Upper endoscopy (including transesophageal echocardiogram)	Endoscopy/ OR Clinical Staff, Diagnostic Imaging Clinical Staff, Physicians, Nursing, Respiratory Therapy	PAPR or higher (AirID)
Endoscopy	Endoscopy/ OR Clinical Staff, Diagnostic Imaging Clinical Staff, Physicians, Nursing, Respiratory Therapy	PAPR or higher (AirID)
Venturi mask with cool aerosol humidification	Physicians, Nursing, Respiratory Therapy	PAPR or higher (AirID)
<i>All other surgical, lab or clinical procedure that aerosolizes pathogens</i>		
The following are not considered aerosol-generating: • Non-rebreather, face mask, or face tent up to 15L • Humidified trach mask up to 20L with in-line suction • Routine trach care (e.g., replacing trach mask, changing trach dressing) • In-line suctioning of endotracheal tube • Routine Venturi mask without humidification • Coughing • Suctioning of oropharynx • Tracheostomy change • Cesarean delivery, post-partum hemorrhage, second stage of labor • Nasopharyngeal swab • Proning is not inherently aerosol-generating but aerosols are possible if the endotracheal tube becomes disconnected during the proning process		

B. Plan Management

1. LIST OF ALL ASSIGNMENTS OR TASKS REQUIRING PERSONAL OR RESPIRATORY PROTECTION

- a. SVHMC utilizes feasible engineering controls and work practice controls to reduce employee exposure to aerosol transmissible pathogens. However, when those controls are not sufficient, SVHMC provides personal protection or respiratory protection to the employees performing those tasks. In some cases, the minimum requirement of an N95 respirator is

sufficient, but in other cases, higher-level protection is required, such as a powered air-purifying respirator (PAPR).

- b. SVHMC requires employees to wear personal or respiratory protection when conducting certain assignments or tasks in certain SVHMC Staff Roles for protection against ATD.

Reference/link: [SVHMC Job Titles 2024-2025](#)

2. METHODS OF IMPLEMENTATION

- a. SVHMC's methods of implementing requirements for engineering and work practice controls, PPE, respiratory protection, medical services, training, and record-keeping are described below.

- b. **Engineering and Work Practice Controls, and PPE**

- i. The best method to control employee exposure to ATPs is to use engineering controls and work practice controls. If those do not provide sufficient protection, then SVHMC provides personal protective equipment (PPE) and/or respiratory protection and ensures that employees use them. For some tasks, use of both respiratory protection and engineering or work practice controls may be required.

- ii. Work practices will be implemented in accordance with Appendix A of section 5199, which categorizes pathogens as requiring airborne and/or droplet precautions. Where Appendix A does not address the exposure, SVHMC will use protections in accordance with the CDC Guideline for Isolation Precautions for droplet and contact precautions. For airborne precautions, procedures will be in accordance with the CDC Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings.

Reference/link: [CDC Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings.](#)

- iii. SVHMC uses the following types of engineering and work practice controls to protect employees from ATD exposures: use of AIIR rooms and converting standard patient rooms to an AIIR by installing a portable HEPA filter device, and balancing the HVAC airflow to achieve negative pressure, when necessary.

Reference/link: [ISOLATION - STANDARD AND TRANSMISSION BASED PRECAUTIONS](#)

- iv. When working with an AirID or suspected AirID patient, employees will properly wear personal protective equipment. Job classifications are categorized into three categories (see **SVHMC Job Titles 2024-2025** for a table of job classifications in which an occupational exposure for occupational exposure to ATD):

- a. **CATEGORY I – HAVE EXPOSURE:** Job classifications in which **ALL** employees have potential occupational

exposure to ATD/ATP

- b. **CATEGORY II – POTENTIAL EXPOSURE:** Job classifications in which **SOME** employees have potential occupational exposure to ATD/ATP
- c. **CATEGORY III – NO EXPOSURE:** Job classifications in which **NO** employees have occupational exposure to ATD/ATP. Job classifications not listed are considered to be category III.

- i. **Reference/link:** [SVHMC Job Titles 2024-2025](#)

- v. Surfaces may become contaminated with ATPs after contact with individuals with AirID. Contaminated surfaces enable the spread of infectious disease agents and can be a source of infection to employees until they are cleaned and disinfected. SVHMC ensures that employees use appropriate EPA-registered disinfectant(s) to clean and disinfect the following surfaces, including equipment as soon as feasible after contact with infectious persons (*include types of surfaces and equipment to be disinfected, and the period*):

Reference/link:

- a. [MEDICAL EQUIPMENT CARE, CLEANING AND MAINTENANCE](#)
 - b. [SPECIAL PROCEDURES ROOMS/AREAS - PROCEDURE](#)
 - c. [STEP BASE CLEANING PROCEDURE](#)
 - d. [TERMINAL CLEANING OF SURGICAL SUITES PROCEDURE](#)
 - e. [PATIENT ROOM CLEANING - DISCHARGE/TRANSFER PROCEDURE](#)
 - f. [PATIENT ROOM CLEANING - OCCUPIED PROCEDURE](#)
 - g. [PATIENT ROOM ISOLATION PROCEDURE](#)
 - h. [PEDIATRIC DEPARTMENT CLEANING PROCEDURE](#)
 - i. [PERSONAL PROTECTION EQUIPMENT - CARE & USE PROCEDURE](#)

c. Engineering Controls

- i. AirID cases or suspected cases shall be identified and these individuals shall be:
 - a. Provided with disposable tissues and hand hygiene materials and masked or placed in such a manner that contact with employees who are not wearing respiratory protection is eliminated or minimized until transfer or placement in an All room or area can be

- accomplished and;
- b. Placed in an All room or area or transferred to a facility with All rooms or areas.
 - ii. If admission is required, the transfer to an airborne infection isolation room or other suitable area within the facility shall occur within 5 hours of identification.
 - iii. If Airborne Infection Isolation Rooms (AIIR)s are not available to accommodate a transfer in the facility, SVHMC will follow our procedures to transfer AirID cases and suspected cases to an AIIR at another facility. The procedures are described in detail in the "Referral and Transfer of AirID Cases" section of this program.
 - iv. Exceptions:
 - a. Where it is not feasible to provide All rooms or areas to individuals suspected or confirmed to be infected with, or carriers of novel or unknown ATPs, then SVHMC shall provide other effective control measures to reduce the risk of transmission to employees, which shall include the use of respiratory protection.
 - b. Where the treating physician determines that transfer would be detrimental to a patient's condition, the patient need not be transferred. In that case, the facility shall ensure that employees use respirator protection when entering the room or area housing the individual. The patient's condition shall be reviewed at least every 24 hours to determine if transfer is safe, and the determination shall be recorded. Once transfer is determined to be safe, transfer must be made within the time period set forth above.
 - v. High hazard procedures shall be conducted in All rooms or areas, such as a ventilated booth or tent. Persons not performing the procedures shall be excluded from the area, unless they use the respiratory and personal protective equipment required for employees performing these procedures.
 - a. Exception- Where no All room or area is available and the treating physician determines that it would be detrimental to the patient's condition to delay performing the procedure, high hazard procedures may be conducted in other areas. In that case, employers working in the room or area where the procedure is performed shall use respiratory protection and all necessary personal protective equipment.

- vi. **The location(s) of airborne infection isolation rooms:** 329, 429, 529, 537
- vii. Airborne infection isolation rooms must be kept at a negative pressure (at least -0.01"H₂O) to prevent pathogens from escaping to the adjacent hallway or other rooms. The ventilation rate will be 12 air changes per hour (ACH). If AIIRs are unable to actually supply 12 ACH so SVHMC attains the required ventilation rate by using a ventilation rate of minimum of 6 or 12 ACH supplemented by the following additional air cleaning technology. Portable ventilation unit with HEPA filtration. If an AIIR is capable of switching between negative pressure mode and normal ventilation mode, SVHMC will ensure that it is switched to negative pressure mode before transferring an AirID patient to the room.
- viii. **Reference/link:**
 - a. [Air Exchange Process](#)
 - b. [TUBERCULOSIS \(TB\) PREVENTION AND CONTROL](#)
- ix. During the time that an AIIR is used for airborne infection isolation, the doors and windows will be kept closed except when the doors are opened for entering and exiting the room to achieve the required level of negative pressure.
- x. During the time that an AIIR is being used for isolation of an AirID patient, SVHMC performs daily checks of the airflow using a vaneometer or other equally effective method to ensure that the room is under negative pressure. To accomplish this, SVHMC uses the following procedure:
- xi. If using an electronic device to conduct the visual check, SVHMC ensures that it shows the direction of airflow at the required level (at least -0.01" H₂O). SVHMC also calibrates the instrument annually. This is done only for our permanently dedicated AIIRs.
- xii. Siemens Building Technologies Division I Fire Life Safety performs inspection and maintenance on our airborne infection isolation rooms monitors. This includes monitoring the performance of the system, including exhaust, recirculation filter loading, and leakage. This is performed at least annually, whenever filters are changed, and more often if necessary to maintain effectiveness.
- xiii. If any problems are found, SVHMC ensures that they are corrected in a reasonable period of time. If the problem(s) prevent the room from providing effective airborne infection isolation, then SVHMC will not use the room for that purpose until the condition is corrected.
- xiv. If HEPA filters are used, SVHMC change the filters on the

following schedule:

xv. **Reference/link:**

a. [ENGINEERING/BIOMEDICAL MAINTENANCE WORK ORDERS PROCEDURE](#)

b. [SCOPE OF SERVICE: BIOMEDICAL SERVICES](#)

xvi. SVHMC also ensures that the AIIR and accompanying ductwork are installed in a manner consistent with requirements so that the equipment run properly and the air exhausts properly, away from people and HVAC air intakes, so to not inadvertently expose more people to contaminants.

xvii. When an AirID case or suspected case vacates an AIIR room or area, SVHMC will ensure that the AIIR is ventilated for the minimum amount of time required for 99.9% of potential airborne contaminants to be exhausted or filtered from the air prior to allowing anyone to enter without respiratory protection. At 12 air changes per hour, this requires running the ventilation system with no one in the room for a minimum of 30 minutes prior. Our policy is to ventilate the AIIR for 30 to 60 minutes.

xviii. **Reference/Link:**

a. [TUBERCULOSIS \(TB\) PREVENTION AND CONTROL](#)

b. [CDC Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings](#)

d. **Respiratory Protection**

i. When employees must wear respiratory protection to guard against aerosol transmissible pathogens, SVHMC ensures that they only use NIOSH-certified respirators that are approved for that purpose in accordance with the Respiratory Protection Program.

Reference/link: [HEALTHCARE WORKER RESPIRATORY PROTECTION PROGRAM](#)

ii. In most situations where respiratory protection is needed, SVHMC will ensure that employees use a respirator at least as protective as an N95 filtering face piece respirator. However, for high hazard procedures (aerosol-generating procedures) performed on AirID cases or suspected cases, SVHMC will utilize PAPRs with high-efficiency particulate air (HEPA) filters or equivalent or better unless SVHMC determines that this would interfere with the success of the procedure or task.

iii. If SVHMC determines that use of a PAPR would interfere with the success of a particular procedure or task, SVHMC will conduct a risk assessment to document this determination. Each case will be determined on a case-by-case basis in

collaboration with Environmental Health & Safety Manager, Infection Prevention/Infectious Diseases, and Employee Health Director. The case reviews will be maintained in accordance with the CHA Records Retention Schedule.

- iv. All determinations will be reviewed during the annual ATD exposure control plan review; this will be performed through the Environment of Care Committee (EOCC).
- v. SVHMC stays apprised of current recommendations for specific diseases, such as Ebola and makes respiratory controls available as appropriate to the disease.
- vi. SVHMC provides N95 and/or PAPR for employees during high hazard procedures performed on patients requiring droplet precautions.
- vii. The diseases requiring droplet precautions use of respiratory protection when conducting high hazard procedures includes (this is a dynamic list and other will be included as necessary: **Reference/Link:** [Aerosol Transmitted Diseases, Pathogens List](#)
- viii. SVHMC provides N95 and/or PAPR for employees during high-hazard procedures performed on airborne infectious disease cases or suspected cases.
- ix. SVHMC requires employees to wear respirators at least as effective as N95 filtering facepiece respirators when conducting certain procedures on or around ATD patients, as required by section 5199. Even when that standard does not require a respirator, such as in the case of high-hazard procedures performed on patients requiring droplet precautions, SVHMC evaluates each situation, including the pathogens, to determine whether to require respiratory protection. The following represents the types of respirators available to employees when required.

Procedure	Type(s) of Respiratory Protection Used
x. Entering AIIR in use for airborne infection isolation	PAPR preferred, N95 if PAPR not available or impedes patient care.
Being present during the performance of procedures or services for an AirID case or suspected case	PAPR preferred, N95 if PAPR not available or impedes patient care
Repairing, replacing, or maintaining air systems or equipment that may	PAPR preferred, N95 if PAPR not available

contain or generate aerosolized pathogens	or impedes patient care
Working in an area occupied by an AirID case or suspected case	PAPR preferred, N95 if PAPR not available or impedes patient care
Decontaminating an area after an AirID case or suspected case has left the area or being present during the decontamination	PAPR preferred, N95 if PAPR not available or impedes patient care
Entering an AIIR while it is being ventilated after an AirID case or suspected case has vacated	PAPR preferred, N95 if PAPR not available or impedes patient care
Working in a residence where an AirID case or suspected case is known to be present	PAPR preferred, N95 if PAPR not available or impedes patient care
Being present during the performance of aerosol generating procedures on cadavers that are suspected of, or confirmed as, being infected with aerosol transmissible pathogens	PAPR preferred, N95 if PAPR not available or impedes patient care
Transporting an AirID case or suspected case within the facility.	PAPR preferred, N95 if PAPR not available or impedes patient care

- xi. SVHMC does not require or permit employees to wear a respirator when operating a vehicle if the respirator may interfere with the safe operation of the vehicle. SVHMC will provide these other means of protection where feasible (e.g., barriers or source control measures): N95
- xii. Before having our employees, use a respirator, SVHMC will provide them with a no-cost medical evaluation designed to determine if they are medically capable of SVHMC wearing a respirator without overburdening them. This will be completed before the employee is fit tested.

e. Medical Evaluations for Respirator Use

- i. For employees who will wear respirators (minimum of N95 or PAPR) solely for protection against aerosol transmissible pathogens, SVHMC provides the medical evaluation to employees by using the Respirator Medical Evaluation

Questionnaire completed through Employee Health electronic health record.

- ii. SVHMC will have the medical evaluation questionnaire reviewed by a licensed health care provider (PLHCP) in Employee Health or other designated PLHCP (RN, Nurse Practitioner, MD) If employees need a follow-up examination based on the questionnaire responses, SVHMC will request follow up with their primary care physician or SVHMC occupational health provider.

f. FIT Tests

- i. SVHMC conducts fit testing for employees before they are required to wear a respirator. An employee's fit testing will be performed using the same size, make, model, and style of respirator that the employee would actually wear. The fit test will be performed under the supervision of Employee Health:
- ii. Fit testing at SVHMC is performed using a qualitative method. If fit testing single use respirators for multiple employees, SVHMC will ensure that each employee is fit tested using a new respirator.
- iii. SVHMC conducts fit tests for each employee according to the following schedule:
 - a. At the time of initial fitting;
 - b. When a different size, make, model, or style of respirator is used;
 - c. At least annually thereafter; and
 - d. When the employee reports, or when SVHMC, a physician or other licensed health care provider (PLHCP), supervisor, or program administrator makes visual observations of changes in the employee's physical condition that could affect respirator fit, such as facial scarring, dental changes, cosmetic surgery, or obvious change in body weight.
- iv. If, after passing a fit test, an employee reports, that the respirator is not acceptable, SVHMC will evaluate with the employee to determine the most acceptable respirator.
- v. SVHMC provides employees with training on the following topics:
 - a. Why the respirator is necessary and how improper fit, usage, or maintenance can compromise the protective effect of the respirator.
 - b. What the limitations and capabilities of the respirator are.

- c. How to use the respirator effectively in emergencies, including situations in which the respirator malfunctions.
 - d. How to inspect, put on and remove, use, and check the seals of the respirator.
 - e. What the procedures are for maintenance and storage of the respirator.
 - f. How to recognize medical signs and symptoms that may limit or prevent the effective use of respirators.
 - g. Information on vaccinations.
 - h. N95 respirator vs. surgical mask
 - i. Respiratory re-use
- vi. This training is provided to employees if required to wear a respirator initially and annually thereafter. SVHMC retrain employees as necessary but at least if changes in the workplace or the initial type of respirator is obsolete.

g. Laboratory Operations

- i. SVHMC employees engaged in laboratory operations that include procedures that may aerosolize transmissible pathogens-laboratory (ATP-L) follow [LABORATORY AEROSOL TRANSMISSIBLE PATHOGENS POLICY - OSHA](#).
- ii. SVHMC has conducted a risk assessment in accordance with the Bio-Safety in Microbiological and Biomedical Laboratories (BMBL).

h. Summary of Control Measures

- i. The table in [Attachment C \(Matrix of Department related Tasks & Procedure Involving Occupational Exposure & Exposure Controls for Aerosol Transmitted Diseases\)](#) summarizes the control measures we use in each operation or work area in which occupational exposures may occur.

i. Source Control Measures

- i. Early identification of ATD cases or suspected cases is critical to ensure that employees have as little unprotected contact as possible, thereby reducing the risk of becoming infected.
- ii. If SVHMC observes respiratory infection symptoms in a patient or other person, utilize source control measures to protect our employees from contracting the illness. These include a combination of engineering controls, such as placing the patient in a separate room or area; procedures, such as providing and having the suspected ATD case wear a surgical mask; and work practice controls, such as limiting contact with the suspected

ATD person.

- iii. SVHMC is a fixed-site health care facility, and has incorporated the recommendations contained in the CDC's Respiratory Hygiene/Cough Etiquette in Health Care Settings.
Reference/link: [Respiratory Hygiene/Cough Etiquette in Health Care Settings.](#)
- iv. SVHMC utilizes the following source control measures to prevent the spread of aerosol-transmissible pathogens:
 - a. Visual alerts (*e.g., signs telling people to cover their cough*):
 - i. Posters at major entry points, respiratory hygiene stations, and station signs throughout high traffic areas in the facility.
 - ii. Signage at the entrances requesting patients and persons accompanying them to inform the receptionist if they have a persistent cough.
 - b. SVHMC place the visual alerts at the following entrances and other locations (list locations if applicable): Hospital Main Lobby/waiting area, ED entrance/waiting area, Out-patient surgery waiting area, all waiting rooms for out-patient testing (Lab, Diagnostic imaging, etc.) and off-site locations waiting areas (Sleep Center, Wound Care Center, Infusion Center, CDOC, Cardiac Rehabilitation, Mammography, Taylor Farms)
 - c. Tissues provided in waiting areas, waste receptacle in waiting areas, handwashing facilities including soap and water accessible to patients and visitors, and alcohol-based hand sanitizer or other antiseptic hand wash in waiting areas.
 - d. Provide individuals exhibiting symptoms of aerosol transmissible disease with a surgical or procedure mask, instruct them in proper use, and limit contact with said individuals.
 - e. Separate symptomatic individuals from others in the same room by distance (at least 3 to 6 feet away from others).
- v. SVHMC ensures the concierge staff, and reception staff who may be the first employees to encounter a patient or other person entering the facility, are knowledgeable in observing for signs and symptoms of ATD.
- vi. Other source control methods / procedures include the following

policies and/or procedures:

- a. [VISITOR POLICY](#)
- b. [Hospital Screening/Visitor Management Process](#)

j. Contract Employees

- i. SVHMC is required to provide information about infectious disease hazards to contractors who provide us with temporary or contract employees who may be reasonably anticipated to have occupational exposure so that these employers may take precautions to protect their employees. The electronic Vendor software system is utilized to assure contractors / vendors have review the required documents and upload vaccination status.
Reference/link: [VENDOR, CONTRACTOR, AND AGENT PARTICIPATION IN HOSPITAL COMPLIANCE PROGRAM](#)

k. Referral and Transfer of AirID Cases to Airborne Infection Isolation Rooms (AIIR) or Facilities

- i. In order to best protect employees from contracting infections from AirID or suspected persons, SVHMC strives to identify these individuals as quickly as possible.
- ii. After identifying an individual as an AirID or suspected, SVHMC will continue to use the previously described source control measures and isolate the patient by masking them or placing them in a location where they will not contact employees who are not wearing respiratory protection until they can be transferred to an airborne infection isolation room (AIIR).
- iii. SVHMC takes the following measures to reduce the risk of ATD transmission to our employees. This includes constant observation of standard precautions as well as other protective measures.
- iv. In the Emergency Department, SVHMC temporarily isolates the person requiring airborne isolation in rooms 19 and 20, which are equipped with a large industrial Hepa filter that vents outside. Once admitted, SVHMC places the individual in an airborne infection isolation room or area as soon as one of the following inpatient rooms are available: 329, 429, 529, and 537.
- v. SVHMC employees wear NIOSH-certified N95 filtering face piece or PAPR hood with P100 filter when entering the room.
- vi. If an Airborne Infection Isolation Room (AIIR) is not available, SVHMC assesses current occupancy and transfers a non-infectious patient to a non AIIR. If no AIIR is available, the patient will be placed in a private room with a HEPA filter. If SVHMC has maximized resources and has no other available AIIR or HEPA filters, then a request for transfer to another facility will be initiated.

- vii. The goal is to transfer to another facility within 5 hours of identification, unless SVHMC documents, at the end of the 5 hour period and at least every 24 hours thereafter, the following:
 - a. Case Management, or designee, will facilitate the transfer of the patient and documents:
 - i. There are no All room or area available within that jurisdiction.
 - ii. Reasonable efforts have been made to contact establishments outside of the jurisdiction.
 - iii. All applicable measures recommended by the local health officer or the Infection Control PLHCP have been implemented.
 - b. All personnel who enter the room or area housing the individual are provided with, and use, appropriate personal protective equipment and respirator protection.
 - c. In the event that there are no available accepting facilities, then SVHMC will continue to arrange transfers until successful or patient condition changes.
 - d. SVHMC will document and maintain a transfer attempt in the Electronic Medical Record and/or All-scripts.
- viii. The Administrative Supervisor contacts the Infection Prevention Department or designee for any Airborne Infectious Disease (AirID) suspected case. Infection Prevention will contact the local health officer.
 - a. The phone number for the local health officer is 831-755-4521
- ix. These are the names and contact information for facilities with AIIR or areas within the local area that will be contacted in the event of referral

x. Facility	Contact Information
Natividad Medical Center	Transfer Center (855) 445-7872
Hazel Hawkins	ED: 831-636-2640
	Hazel Hawkins House Supervisor (Inpt Transfers): 831-902-0482
CHOMP	831-624-5311 (Ask for House Supervisor)
Mee Memorial	ED: 831-385-7220

	Mee Memorial House Supervisor (Inpt Transfers): 831-821-1634
Dominican Hospital	Transfer Center 855-455-7872

- xi. These are the names and contact information for facilities with AIIR or areas outside the local jurisdiction that will be contacted in the event of referral and no All rooms are available within our local jurisdiction.

xii.	Facility	Contact Information
	UCSF Transfer Center	415-353-9166
	Stanford Transfer Center	800-800-1551
	Santa Clara VMC Transfer Center	408-885-4495

- xiii. **There are two exceptions to the requirement to transfer an AirID patient to an AIIR:**

- a. Where it is not feasible to provide All rooms or areas to individuals suspected or confirmed to be infected with or carriers of novel or unknown aerosol transmissible pathogens (ATPs), the employer must provide other effective control measures to reduce the risk of transmission to employees, which must include the use of respiratory protection in accordance with [subsection \(g\) and section 5144, Respiratory Protection](#).
- b. Where the treating physician determines that transfer would be detrimental to a patient's condition, the patient need not be transferred. In that case, the facility must ensure that employees use respiratory protection when entering the room or area housing the patient. The patient's condition must be reviewed at least every 24 hours to determine if transfer is safe, and the determination must be recorded as described in the Plan, in accordance with subsection (d)(2)(G). Once transfer is determined to be safe, transfer must be made within the time period set forth in subsection (e)(5)(B).
 - i. Decisions not to transfer a patient for All
 - i. SVHMC will maintain records of any decisions not to transfer a patient to another facility for All for medical reasons. The following will be documented in the patient's chart:

- i. Name of the physician determining that the patient was not able to be transferred.
 - ii. Date and time of the initial decision.
 - iii. Date and time of each daily review and identity of the person(s) who performed them.
 - iv. This summary record will not include a patient's individually identifiable medical information. SVHMC will retain these records according to the [Records Retention Policy](#).
- xiv. All transfers to external facilities will be completed in compliance with the following policies/procedures:
 - a. [INTRAFACILITY TRANSPORT - NEWBORN CLINICAL PROCEDURE](#)
 - b. [MATERNAL TRANSPORT-TERTIARY CARE AND TRANSFER OF PATIENT](#)
 - c. [NICU TRANSPORT: CARE PRACTICES FOR TRANSPORT](#)
 - d. [EMTALA](#)

I. Medical Services

- i. SVHMC provides employees with no cost medical services in-house, that include vaccinations, TB testing, and post-exposure medical services and follow-up. Employees will be sent to:
 - a. Employee Health Services or Administrative Nursing Supervisor, Emergency Department, other designated care provider. Details about the medical services related to ATDs that SVHMC offers to employees are in the "Medical Services" section of this written plan.
 - b. **Reference/link:**
 - i. [EMPLOYEE HEALTH SERVICES](#)
 - ii. [EMPLOYEES EXPOSURES & PREVENTION PLANS: SPECIFIC DISEASE EXPOSURES AND WORK RESTRICTIONS](#)

iii. HEALTHCARE WORKER IMMUNIZATIONS & IMMUNITY REQUIREMENTS

- ii. SVHMC provides medical services at no cost to our employees who have occupational exposure to aerosol transmissible disease. These medical services, including vaccinations, tests, examinations, evaluations, determinations, procedures, and medical management and follow-up, will meet the following conditions:
- a. Performed by or under the supervision of a physician or other licensed health care provider (PLHCP).
 - b. Provided according to applicable public health guidelines.
 - c. Provided in a manner that ensures the confidentiality of employees and patients.
 - d. Notification to employees who had significant exposure of the date(s), time and nature of the exposure.

iii. **Vaccinations**

- a. Vaccination is a safe, effective, and reliable method of controlling the spread of infectious diseases where a vaccine is available. When the number of susceptible health care workers is decreased by vaccination, it also helps to prevent transmission of illness to patients and others. Therefore, vaccinations are available to employees at no cost during their work hours and encourages employees to receive them.
- b. Employees are not required to participate in a prescreening serology program prior to receiving a vaccine unless applicable public health guidelines recommend prescreening prior to administration of the vaccine. Vaccinations are available to employees after they receive training and within 10 working days of initial assignment unless one of the following conditions exists:
 - i. The employee has previously received the recommended vaccination(s) and is not due to receive another vaccination dose.
 - ii. A PLHCP has determined that the employee is immune in accordance with applicable public health guidelines.
 - iii. The vaccine(s) is contraindicated for medical reasons.

iv.	Vaccine	Schedule
	Influenza	One dose annually
	Measles	Two doses
	Mumps	Two doses
	Rubella	One dose
	Tetanus, Diphtheria, and Acellular Pertussis (Tdap)	One dose, booster as recommended
	Varicella-zoster (VZV)	Two doses
	COVID-19	Schedule per CDC/CDPH guidelines

v. **Reference/link:** [HEALTHCARE WORKER IMMUNIZATIONS & IMMUNITY REQUIREMENTS](#)

- c. SVHMC shall make additional vaccine doses available to employees within 120 days of the issuance of new applicable public health guidelines recommending the additional dose.
- d. SVHMC shall not make participation in a prescreening serology program a prerequisite for receiving a vaccine, unless applicable public health guideline recommends this prescreening prior to administration of the vaccine.
- e. If the employee initially decline a vaccination but, at a later date, while still covered under 8 CCR 5199, decides to accept the vaccination, then SVHMC shall make the vaccination available within 10 working days of receiving a written request from the employee.
- f. SVHMC shall ensure that employees who decline to accept a recommended and offered vaccination sign the declination statement for each offered vaccine.
- g. SVHMC requests the PLHCP administering a vaccination for determining immunity to provide only the following information to the employee:
 - i. The employee's name and employee identifier.
 - ii. The date of the vaccine dose or determination of immunity.
 - iii. Whether the employee is immune to the

disease, and whether there are any specific restrictions on the employee's exposure or ability to receive the vaccine.

- iv. Whether an additional vaccination dose is required, and if so, the date the additional vaccination dose should be provided.
- h. EXCEPTION: Where SVHMC cannot implement these procedures because of the lack of availability of vaccine, then SVHMC shall document efforts made to obtain the vaccine in a timely manner and inform employees of the status of the vaccine availability, including when the vaccine is likely to become available. SVHMC shall check on the availability of the vaccine every 60 calendar days and inform employees when the vaccine becomes available.
- i. EHS manages all employee vaccinations, including declinations, with information maintained in the EHS electronic medical record system. Employees receiving vaccinations at another facility will be requested to supply vaccination records and may be required to complete the SVHMC Declination form

iv. **LTBI Assessment**

- a. A latent tuberculosis infection (LTBI) is a condition when the individual infected with the M. tuberculosis bacteria does not exhibit symptoms and cannot spread the infection to others. However, approximately 5 to 10% of these people will develop active, potentially contagious TB disease if untreated. LTBI screening helps to ensure that employees are provided with appropriate treatment for new TB infections and to identify previously unidentified occupational exposures.
- b. Latent TB infection screening (the TB skin test, TB blood test, and TB screening questionnaire) is offered annually to all employees with reasonably foreseeable occupational exposures to ATD, including those whose occupational exposure risk is greater than that of employees in public contact operations that are not included within the scope of the ATD standard.
- c. Employee Health Services, in collaboration with Infection Diseases is responsible for implementing the TB screening procedures.
- d. Employees with a baseline positive TB test will receive an annual symptom screening questionnaire. If

questionnaire results indicate further testing is needed, SVHMC offers that employee a follow up screening (PPD or chest x-ray) using the following procedures:

- i. If an employee experiences a TB conversion, SVHMC refers them to the following:
 - i. PLHCP knowledgeable about TB for evaluation, which may include SVHMC occupational health provider, an infectious disease provider or their primary care physician.
- ii. In the event of a TB conversion, EHS will:
 - i. Provide the PLHCP employee's TB test records. If EHS / Infection Prevention has identified the source of the infection, the PLHCP will be provided available diagnostic test results including drug susceptibility patterns relating to the source patient.
 - ii. The PLHCP, with the employee's consent, performs any necessary diagnostic tests and informs the employee about appropriate treatment options.
- iii. The PLHCP determines if the employee is an active TB case or suspected case, and to do all of the following, if the employee is a case or suspected case:
 - i. Inform the employee and the local Health Officer in accordance with title 17.
 - ii. Consult with the local Health Officer to define infection control recommendations related to the employee's activity in the workplace, including precautionary removal. SVHMC complies with local Health Officer Recommendations for additional testing as applicable. Informs EHS of the recommendations.
 - iii. The person who will receive

information from the PLHCP regarding infection control recommendations related to employees who are TB cases or suspected cases is Employee Health leadership/designee and/or Infection Prevention Manager/designee, who will then communicate the recommendations to the following managers or staff members, if applicable:

- i. All clinical and non-clinical Directors/Managers, will communicate to the employees in their department.
- iv. In the event of a TB conversion, SVHMC will also record the case on the Cal/OSHA Form 300 Log of Work-Related Injuries and Illnesses by placing a check in the "respiratory condition" column and entering "privacy case" in the space normally used for the employee's name. SVHMC will also investigate the circumstances of the conversion and correct any deficiencies in the procedures, engineering controls, or PPE.
- iv. List the job titles and roles of staff involved in investigating the circumstances of the conversion and correcting deficiencies that may have led to the conversion: ATD Exposure Control Plan administrator(s), infection prevention manager/officer, employee health leader/coordinator, environmental health & safety manager; Clinical and non-clinical Directors and Managers will interview the employee(s), and review relevant patient records.
 - i. SVHMC will also document the investigation using the following

procedure: See below section for exposure incidents.

- v. For all RATD and ATP-L exposure incidents, the written opinion will consist of only the following information:
 - i. The employee's test status or applicable RATD test status for the exposure of concern.
 - ii. The employee's infectivity status.
 - iii. A statement that the employee has been informed of the results of the medical evaluation and has been offered any applicable vaccinations, prophylaxis, or treatment.
 - iv. A statement that the employee has been told about any medical conditions resulting from exposure to RATD, or ATP-L that requires further evaluation and/or treatment and that the employee has been informed of treatment options.
 - v. Any recommendations for precautionary removal from the employee's regular assignment.

3. EXPOSURE INCIDENTS

- a. In the event of an exposure incident, it is critical to inform exposed employees quickly and provide medical services in a timely manner to mitigate the severity of illness and limit the spread of infection.
- b. An exposure incident is defined in this plan as an event where all of the following have occurred:
 - i. An employee has been exposed to an individual who is a case or suspected case of a reportable ATD (RATD) or to a work area or equipment that is reasonably expected to contain an aerosol transmissible pathogen associated with a reportable ATD.
 - ii. The exposure occurred without the benefit of applicable exposure controls required by the ATD standard.
 - iii. It reasonably appears from the circumstances of the exposure that transmission of disease is sufficiently likely to require medical evaluation.
 - iv. A reportable ATD (RATD) is an aerosol transmissible disease

that a health care provider is required to report to the local health officer.

Reference/Link: [Aerosol Transmitted Diseases Pathogens List](#)

- c. In the context of this plan, a "health care provider" is a physician, a nurse practitioner, a physician assistant, a registered nurse, a nurse midwife, an infection control practitioner, a medical examiner, or a dentist.
 - i. The California Department of Public Health, Division of Communicable Disease Control home page includes the current list of RATDs. Contact information for the local health departments are also available on the CDPH page for the California Conference of Local Health Officers.
 - ii. SVHMC is a health care provider. Therefore, when SVHMC determines that a person is an RATD case or suspected case, SVHMC will report the case to the local health officer, in accordance with title 17, observing the different time deadlines for different diseases.
 - iii. Person responsible for reporting cases to the local health officer:
 - a. Infection Prevention Manager/Director and/or Infection Prevention Coordinator.
 - b. Contact information for the local health officer:
831-755-4521
 - iv. SVHMC is required to notify our own employees who had significant exposure to the ATD case or suspected case. First, SVHMC conduct an analysis of the exposure scenario to determine which of our employees had significant exposure. This analysis will be completed within a time frame reasonable for the specific disease, but no later than 72 hours after either our report to the local health officer or our receipt of notification internally from SVHMC employee/department, or from another facility or local health officer of the exposure.
 - v. The person responsible for conducting this analysis is:
 - a. Infection Prevention Manager/Director in collaboration with Employee Health Manager/Director. Reviewed with Medical Director(s) of Infection Prevention and/or Employee Health.
 - vi. Our procedures for conducting this analysis are as follows:
 - a. Send an email to department leadership of affected departments and have each leader identify all the employees in their department(s) who may have been exposed;
 - b. Leader(s) review records to see which employee(s)

- had contact with the ATD case or suspected case;
 - c. Leader interviews employee(s), then submits line listing of exposed employees to Employee Health via email.
 - d. Employee health reviews information from each leader, interviews the employee(s) if needed, determines level of exposure based on leader/employee information, then contacts each employee by email and/or phone, then determines exposure plan for that individual exposed.
 - e. Employee Health will refer an exposed employee based on the determination by PLHCP for testing, treatment and/or monitoring.
- vii. SVHMC will document the analysis, recording the names and any other employee identifier used at the workplace of persons who SVHMC included in the analysis. SVHMC will also document the name of the person who made the determination and the identity of any PLHCP making the determination. This is our procedure for this documentation:
- a. If the analysis determines that neither of the following conditions exist for an employee, then that employee does not require post-exposure follow-up, and SVHMC will also document the basis for the determination:
 - b. The employee did not have significant exposure.
 - c. Physician or other licensed health care provider (PLHCP) determined that the employee is immune to the infection.
- viii. This is our procedure to document any determination that an employee does not require post-exposure follow-up:
- a. Documentation will be in one or more of the following areas depending on if the exposure involves one or a group of employees:
 - i. Documentation of exposure follow up in shared electronic report accessible by Infection Prevention, Employee Health and Infection Prevention MD for review.
 - ii. Documentation in the employee EHR in Employee Health
- ix. SVHMC will make the exposure analysis available to the local health officer upon request.
- x. SVHMC will also determine, to the extent that the information is available in our records, whether any employees of other

employers may have been exposed to the case or suspected case. If so, SVHMC will notify the other employer(s) within a reasonable time-frame but no later than 72 hours after the report to the local health officer. This allows the other employer(s) time to conduct their own analysis to determine which of their employees had significant exposure and to provide their employee(s) with timely, effective medical intervention to prevent disease or mitigate the disease course.

- xi. See the "Communicating with Other Employers Regarding Exposure Incidents" section below for our procedures to notify other employers that their employees may have had significant exposure while working at our facility.
- xii. Upon determining which of our own employees had significant exposure, SVHMC will notify them of the date, time, and nature of their exposure, within a time-frame reasonable for the specific disease but no later than 96 hours of becoming aware of the potential exposure.
- xiii. Notification to our employees who had significant exposure may occur by one or more of the follows communications:
 - a. Department leader's notification to their staff regarding potential exposure and communication pending from Employee Health Services.
 - b. Email notification sent via Employee Health EHR with instructions.
 - c. Phone communication to those determined to have high-risk exposures by Employee Health.
- xiv. As soon as feasible, SVHMC will provide all of our employees who had a significant exposure a post-exposure medical evaluation by a PLHCP knowledgeable about the specific disease, including appropriate vaccination, prophylaxis, and treatment.
- xv. SVHMC will notify employees that they have the right to decline to receive the medical evaluation from us, and SVHMC will ensure that the employee receives post-exposure evaluation and follow-up from an outside PLHCP.
- xvi. SVHMC will send employees to one or more of the following PLHCP for post-exposure medical evaluation and follow-up unless the employee declines Employee Health Services, Administrative Nursing Supervisor, Infection Prevention, Emergency Department, Occupational Health Provider or other designated PLHCP.
- xvii. Employee Health Services RN or other designated healthcare provider will provide the following information to the PLHCP:

- a. A description of the exposed employee's duties as they relate to the exposure incident;
The circumstances under which the exposure incident occurred;
 - b. Any available diagnostic test results, including drug susceptibility pattern or other information relating to the source of exposure that could assist in the medical management of the employee;
 - c. All of the employer's medical records for the employee that are relevant to the management of the employee.
- xviii. SVHMC will request from the evaluating PLHCP an opinion on whether precautionary removal from the employee's regular job assignment is necessary to prevent the employee from spreading the disease agent and what type of alternative work assignment may be provided. SVHMC will request that any recommendation for precautionary removal be made immediately by phone, fax, and secure email and/or in writing.
- xix. The person responsible for requesting and obtaining medical recommendation/opinion is:
 - a. Employee Health Services, or designee
- xx. SVHMC will obtain and provide the employee a copy of the PLHCP written opinion within 15 working days of completion of all required medical evaluations.
- xxi. If the PLHCP or local health officer recommends precautionary removal due to a related ATD exposure:
 - a. Workplace exposure: will follow the workers compensation process.
 - b. Non-work place exposure: will follow SVHMC medical leave process.

4. EVALUATION OF EXPOSURE INCIDENTS

- a. After ensuring that the exposed employees receive required medical evaluations and follow-up, SVHMC will also investigate the exposure incidents to determine the cause and to revise existing procedures in order to prevent recurrence of the incidents.
- b. The person who will conduct the evaluation of exposure incidents is Infection Prevention & Employee Health.
- c. Our procedures to evaluate exposure incidents to determine causation and identify ways to prevent future exposures are as follows (*e.g., interviewing exposed employees, inspecting equipment that may have been involved, reviewing whether procedures SVHMC are followed*):

Reference/link: [OUTBREAK INVESTIGATION](#)

- d. Upon completion of the evaluation, SVHMC will also revise our procedures to ensure that similar exposure incidents do not occur again. These are our procedures to revise our ATD exposure control plan:

- i. [RISK MANAGEMENT PLAN](#)
- ii. [SAFETY MANAGEMENT PLAN](#)

5. PROCEDURES TO COMMUNICATE WITH OUR EMPLOYEES AND OTHER EMPLOYERS REGARDING INFECTIOUS DISEASE STATUS OF PATIENTS

- a. To ensure our employees use appropriate precautions, SVHMC will communicate with them regarding the suspected or confirmed infectious disease status of persons to whom they are exposed in the course of their duties. SVHMC will also communicate this status with other employers whose employees SVHMC are also exposed to the individual, such as those involved with transportation or care of the patient.
- b. To communicate with our own staff, SVHMC use the following procedures:
 - i. Making notes in the patient's chart and maintaining a policy that our employees are to check the patient's chart before proceeding with their tasks.
 - ii. Staff huddle at the start of each shift where patient infectious status will be discussed.
 - iii. When SVHMC place a patient in isolation, SVHMC communicate the isolation status of the patient with employees and visitors by posting a sign at the room. SVHMC also make a note of the isolation precautions in the patient's chart so that if the patient is transferred to another department, such as Radiology, then those employees in the other department will be notified of the extra precautions required.
 - iv. To communicate with other employers regarding the infectious disease status of patients, SVHMC implement the following procedures: Infection Prevention will notify other employers and report to local county public health department.
- c. Communicating with Other Employers Regarding Exposure Incidents
 - i. Upon establishing that a patient is a reportable ATD case or suspected case, SVHMC will determine whether any employees of other employers had contact with the individual, using the following procedure: Department Leaders/Infection Prevention notifies employers
 - ii. Upon making that determination, SVHMC will notify the other employer(s) within a time-frame that will allow reasonable time for them to promptly investigate to identify employees who had significant exposure and for those employee(s) to receive effective medical intervention. SVHMC will make the notification no later than 72 hours after our report to the local health officer.

- iii. Our notification will include the following information:
 - a. Date and time of the potential exposure.
 - b. The nature of the potential exposure.
 - c. Any other information that is necessary for the other employer(s) to evaluate the potential exposure of their employees.
 - d. The contact information for the diagnosing PLHCP.
- iv. The notification will not include the identity of the employee (source) patient due to privacy laws.
- v. Our procedure to notify other employers that their employees may have had contact with an ATD case or suspected case, verbal or written notification based on level of risk, notification is completed by Department Leader and/or Infection Prevention.
- vi. This is our procedure to notify health care providers and receive notification from them regarding the disease status of patients referred or transferred between SVHMC our facilities or care, in accordance with subsection (h) of 8 CCR 5199:
- vii. **Reference/link:**
 - a. [ADMISSION-PATIENT PLACEMENT GUIDELINES](#)
 - b. [TRANSPORT OF PATIENTS TO AND FROM AN EXTERNAL HEALTHCARE FACILITY FOR TREATMENT](#)

6. ENSURING ADEQUATE SUPPLY OF PPE AND OTHER EQUIPMENT

- a. To ensure that employees SVHMC wear the required PPE, such as gowns, gloves, and respiratory protection, SVHMC must ensure that SVHMC have adequate supplies under normal operations and in foreseeable emergencies.
- b. These PPE will be stocked by Materials Management and supplied to our employees using the following procedure: Standard PPE such as Gloves, Gowns, and Eye protection is stocked throughout the hospital by Materials Management. Disease Specific PPE such as Impervious gowns, N95 Respirators, and signage is stocked in Isolation Carts by Materials Management staff and ordered as needed. In the event that bulk product is needed, Materials Management will supply a bulk PPE cart and maintain stock daily.
 - i. **Reference/Link:**
 - a. [ORDERING SUPPLIES FROM MATERIALS MANAGEMENT](#)
 - b. [PURCHASE ORDER AND PURCHASE ORDER REQUISITION](#)
- c. These are our procedures for maintaining adequate supplies of PPE:

Materials Management keeps an average of 7 days on hand of all PPE at the main campus. Materials Management also keep an Emergency Supply of PPE at our off-site warehouse. The amount of PPE at the off-site warehouse meets the standards outlined in AB2537 and SB275.

7. RECORD KEEPING

- a. To ensure that SVHMC are taking all necessary steps to protect our employees, SVHMC are required to keep various records, including employee health records, training records, and other records of implementation of this ATD Exposure Control Plan.
- b. Medical records will be kept confidential. Employees will have access to their own health records. Anyone with written consent of the employee, Cal/OSHA representatives, NIOSH, and the local health officer will also be given access to employee health records in accordance with applicable regulations.
- c. SVHMC will keep all required health records for each employee with occupational exposure, including the following information:
- d. The employee's name and any other employee identifier used at our workplace.
- e. The employee's vaccination status for all vaccines.
- f. All PLHCP's written opinions and results of TB assessments.
- g. A copy of the information regarding an exposure incident that was provided to the PLHCP.
- h. SVHMC will retain these records for the duration of the employee's employment plus 30 years. These records will be kept separately from the employee's non-medical personnel health records. This is how employees may request copies of their records: employees can submit requests in writing to employee health department and/or employees have limited access through the employee health electronic health record. These records are kept separately from their personnel records in Human Resources.
- i. SVHMC maintains records per hospital policy and according to federal, state and local requirements.

j.	Record	Location of Record
	Vaccination status of employees including any signed declinations	EHS EHR
	Employee medical screening/evaluation/results	EHS EHR
	Results of annual employee TB assessments	EHS EHR
	Copies of information regarding exposure incidents provided to	Notifications from IP in share drive; N Drive QMS IP, Exposures

the PLHCP	folder; N
Training records	Health stream (online education), Dept. Records, Education Department, Employee Health EHR
Record of annual review of ATD Exposure Control Plan	Policy Tech by leaders, new hire orientation and annual online education, real-time education by dept. leaders
Records of exposure incidents (exposure analysis; any determinations of no post-exposure follow-up needed)	Kept in shared drive/files for EH, IP, EHS and infectious Disease providers
Records of unavailability of vaccines	Pharmacy
Records of unavailability of All rooms or areas	Administration Supervisors
Records of decisions not to transfer a patient to another facility for All due to medical reasons	EHR of the individual patient(s)
Records of inspection, testing, and maintenance of non-disposable engineering controls including ventilation and other air handling systems, air filtration systems, containment equipment, biological safety cabinets, and waste treatment systems	Facilities/Engineering Department
Records of the respiratory protection program policy and/or program changes	Policy Tech
Determinations that a PAPR would interfere with successful performance of certain high hazard tasks	Occurrence reporting system

k. Vaccination Records

- i. SVHMC is required to keep vaccination records for all employees with occupational exposure. This includes both records of vaccinations that SVHMC provide them and that the employees supplied to employee health prior to employment with our organization. These records also include any signed declination forms for those vaccinations that are not deemed

mandatory by SVHMC, local or federal agencies.

- ii. SVHMC ensure that SVHMC obtain employee ATD vaccination records prior to their employment, all staff are required to provide appropriate documentation of immunizations/immunity status to Employee Health.
- iii. These are our procedures for keeping records of ATD vaccinations that SVHMC provide to our employees, in their employee health EHR.

l. Copy of Information Given to PLHCP Regarding Exposure Incidents

- i. SVHMC will also ensure to keep a copy of the information SVHMC give to the PLHCP related to exposure incidents, following these procedures and storing the records in the following manner:

m. Training Records

- i. SVHMC education department and/or department leader(s) will keep documentation of all trainings provided to our employees regarding ATD. Each training record will include the following information:
 - a. The date(s) of the training.
 - b. The contents or a summary of the training.
 - c. The names and qualifications of persons conducting the training or designee to respond to interactive questions.
 - d. The names and job titles of all persons attending the training.
- ii. SVHMC will retain these records for three years from the date the training occurred.

n. Annual review of our ATD Exposure Control Plan

- i. Records of annual review of the ATD Exposure Control Plan will include the following information:
 - a. Names of the people conducting the review.
 - b. Dates the review was conducted and completed.
 - c. Names and work areas of employees involved.
 - d. Summary of the conclusions.
- ii. SVHMC will retain the record for three years using the following: all information for the above is in our policy management software.

o. Records of Exposure incidents

- i. In addition to maintaining medical records of employees involved in exposure incidents, SVHMC will maintain the following documentation of exposure incidents:
 - a. The date(s) of the exposure incident.
 - b. The names, and any other employee identifiers used in the workplace, of employees who SVHMC are included in the exposure evaluation.
 - c. The disease or pathogen to which employees may have been exposed.
 - d. The name and job title of the person performing the evaluation.
 - e. The identity of any local health officer and/or PLHCP consulted.
 - f. The date of the evaluation.
 - g. The date of contact and contact information for any other employer who either notified the employer or was notified by the employer regarding potential employee exposure.
- ii. SVHMC will maintain these records according to hospital policy and federal, state and local guidelines. Exposure records will be kept separately from human resources and personnel files.

p. Records of Unavailability of vaccines

- i. SVHMC will retain records of the unavailability of vaccines. These shall include the following information:
 - a. Name of the person who determined that the vaccine was not available.
 - b. Name and affiliation of the person providing the vaccine availability information.
 - c. Date of the contact.
- ii. The person responsible for maintaining these records is Pharmacy Department Manager/Director
- iii. SVHMC will retain these records for three years, using the following: All unavailable medications including vaccines are reported to the PT/IC Committee.

q. Records Unavailability of All rooms or areas

- i. Any time SVHMC require an All room or area but are unable to locate an available one, SVHMC will document the unavailability. In these cases, SVHMC will record the following information:
 - a. Name of the person who determined that an All room or area was not available.

- b. Names and the affiliation of persons contacted for transfer possibilities.
 - c. Date of contacting the persons for transfer possibilities.
 - d. Name and contact information for the local health officer providing assistance.
 - e. Times and dates of contacting the local health officer.
 - ii. SVHMC will not record a patient's individually identifiable medical information as a part of this record. SVHMC will retain these records for three years.
- r. **Records of Decisions Not to Transfer a Patient to Another Facility for All for Medical Reasons**
 - i. Records of decisions not to transfer a patient to another facility for All for Medical reasons shall be documented:
 - a. In the patient's EHR
 - b. A summary shall be provided to the plan administrator providing only the name of the physician determining that the patient was not able to be transferred, the date and time of the initial decision and the date, time and identity of the person(s) who performed each daily review.
 - c. The summary record, which shall not contain a patient's individually identifiable medical information, shall be retained for three years.
- s. **Records Inspection, testing, and maintenance of non-disposable engineering controls**
 - i. SVHMC will maintain records of inspection, testing, and maintenance of non-disposable engineering controls, including ventilation and other air handling systems, air filtration systems, containment equipment, biological safety cabinets, and waste treatment systems.
 - ii. SVHMC will maintain these records for a minimum of five years, including the following information:
 - a. Name(s) and affiliation(s) of the person(s) performing the test, inspection or maintenance.
 - b. Date. Any significant findings and actions that SVHMC has taken.
 - iii. SVHMC will use the following procedures to maintain these records: Procedures are defined Preventative Maintenance schedules and assigned Work Orders for repairs. All documentation is inputted into our CMMP (Computerized

Maintenance Management Program) and kept for a minimum of 5 years.

t. Records of Respiratory protection program

- i. SVHMC will establish and maintain records of our respiratory protection program. These include records of employee health evaluations, fit test records, and training records.

Reference/link:

[HEALTHCARE WORKER RESPIRATORY PROTECTION PROGRAM](#)

8. OBTAINING ACTIVE INVOLVEMENT OF EMPLOYEES TO UPDATE THE PLAN

- a. As part of our annual review process to update this ATD Exposure Control Plan, SVHMC obtain the active involvement of employees and not just managers and supervisors. Active involvement means more than merely having a form available that employees can fill out at their leisure.
- b. These are our procedures to obtain the active involvement of employees:
 - i. With respect to the procedures performed in their respective work areas or departments by actively asking employees for input in meetings,
 - ii. Solicit input during annual trainings,
 - a. SVHMC will provide annual employee education of this plan with opportunity for questions and recommendations of this plan by the employees, provided by our online education system.
 - b. These recommendations made by employee (s), will be reviewed and used in the annual review of this plan. Workplace Safety Committee will oversee this process.

9. SURGE PROCEDURES

- a. Our employees will provide services in surge conditions, such as large outbreaks of aerosol transmissible disease or release of a biological agent. When the event arises, SVHMC will implement the surge procedures described below.
- b. When our employees provide services during surge conditions, SVHMC will ensure that the following work practices are followed:
Reference/link: [EMERGENCY OPERATIONS PLAN](#)
- c. During these responses, SVHMC will set up the following kinds of decontamination facilities: SVHMC have a decontamination trailer located outside the ER that can decontaminate up to 3 people at a time.
- d. The decontamination facilities will be located in the following areas: See above answer.
- e. SVHMC will also ensure that our employees have adequate types and supplies of respiratory protection, gloves, shoe covers, Tyvek suits, and

any other PPE:

- i. Materials Management keeps an average of 7 days on hand of all PPE at the main campus. Materials Management also keep an Emergency Supply of PPE at our offsite warehouse.
- ii. The amount of PPE at the offsite warehouse meets the standards outlined in AB2537 and SB275. In addition, SVHMC keep all Class A respirators, Tyvek suits, etc. in our Emergency Management Trailer.

a. **Reference/link:**

- i. [EMERGENCY MANAGEMENT FOR MASS CASUALTY INCIDENTS \(MCI\), INCLUDING DECONTAMINATION](#)
- ii. [BIOTERRORISM READINESS PLAN](#)
- iii. [Infection Prevention Pandemic Plan Emerging Infectious Diseases](#)

- f. Even during periods when there are no surge conditions, SVHMC will implement the following procedures so that if surge conditions do arise, SVHMC will have adequate supplies of all necessary PPE (i.e., stockpiling, procurement methods): Materials Management maintains a 7-day supply of all equipment except for PPE covered by SB275/AB2537 for which they keep a 45-day supply.
- g. The PPE and respiratory protection will be stored in the following areas of our facility:
 - i. Emergency Preparedness Supplies in designated areas.
- h. This is how SVHMC ensure that the protective equipment will be accessible to employees when needed during surge procedures: Generally, they will be retrieved and distributed per the EOP plan (or you could say under the direction of the Incident Command)
- i. Emergency Liaison Officer via our Incident Command Center is in charge of communicating our activities with the local and regional emergency response agencies. These are our procedures for interacting with the local and regional emergency plan: The Incident Commander, or designee, would be in charge of this. SVHMC are members of the Monterey County Healthcare Coalition and SVHMC have a few key communication pathways to rely on:
 - i. Is to call the Monterey County MOHOAC, and
 - ii. SVHMC can use the READYNET portal via the ED Charge Nurses to reach out to the other hospitals and facilities in our county.
 - iii. SVHMC can also communicate with these entities using the 800-megawatt radio system via the ED Charge Nurses.

C. Plan Responsibility

1. Designation of Responsibility

- a. The administrator of the ATD Exposure Control Plan is the Infection Prevention Manager in collaboration with Clinical Leaders, Environmental Health and Safety Officer and Employee Health Manager.

2. POSITION/COMMITTEE RESPONSIBLE	RESPONSIBILITY
SVHMC Executive Leadership	Responsible to assure adequate resources have been designated to implement the ATD Program in accordance with the Plan.
Infection Prevention (IP) Manager	The facility's IP manager is responsible for the establishment, implementation, and maintenance of the ATD plan and infection control and prevention procedures. The administrator has the authority to perform in this role and is knowledgeable in infection control principles and practices. Assist the Education Department with the development of the employee training program In collaboration with the Employee Health and Safety managers, review and revise as necessary Exposure Control Plan (ECP) at least annually.
IP Specialist, Safety Specialist and Employee Health Services (EHS) Staff	Perform risk assessment(s) annually Support Leaders in implementing the plan.
Pharmacy and Therapeutics / IC (IP) Committee	Review and approve ATD Exposure Control Plan
EHS Leadership	The EHS Director has the authority to act on behalf of the IP Manager to administer the plan if the IP Manager is not available Develop and administer the TB screening program for employees and volunteers Support the EHS team on performing respirator fit testing upon hire and thereafter in accordance with OSHA regulations Develop and administer the Vaccination/ Immunization Program for employees and volunteers Maintain employee vaccination, fit testing, medical evaluation and exposure records for the designated period as required.
Environmental Health and Safety Manager	Assures appropriate patient care policies and procedures are developed and implemented. HEALTHCARE WORKER RESPIRATORY

	<u>PROTECTION PROGRAM</u>
Emergency Management Committee	Under the Environmental Health and Safety Manager, administers the Surge Plan, Disaster Plan and disaster training <u>LABORATORY DISRUPTION OF SERVICES/ DISASTER PLAN</u> <u>NUTRITION SERVICES DISASTER PLAN</u> <u>INFORMATION MANAGEMENT DISASTER RECOVERY</u>
Director of Clinical Laboratory	Assures Laboratory Safety Policies & Procedures specific to Aerosolizing Transmitting Procedures are in place and staff have been trained. <u>LABORATORY AEROSOL TRANSMISSIBLE PATHOGENS POLICY - OSHA</u>
Director of Materials Management	Ensure an adequate supply of Personal Protective Equipment) PPE and other equipment necessary to minimize employee exposures in normal operations and in foreseeable emergencies
Human Resources/ Education Department(s)	Provide and document initial ATD education and annual training thereafter. Collaborates with the IP Manager / designee and department leaders for additional education as deemed necessary.
Department Directors /Managers	Monitor compliance with Exposure Control Plan and report compliance issues for resolution.
Respiratory Therapy and Pulmonary Department	Maintains adequate supply of oxygen needed equipment such as, oxygen tubing, face masks, ventilators, etc.
Biomedical Engineering	Maintain PAPRs including checking filters and replacing filters according to manufacturer's specifications,
Engineering / Facilities Department	Ensures facility-engineering controls are in place. Monitor and maintain engineering controls (e.g. negative pressure room alarms and required testing).

3. Employees are considered to have occupational exposure to ATD if their work activity or work conditions are reasonably anticipated to present an elevated risk of contracting these diseases without protective measures in place. "Elevated," means higher than what is considered ordinary for other employees who have direct contact

with the general public in occupations that are not covered under the scope of this standard, such as bus drivers and retail employees.

D. Performance Measurement

1. The performance measurement process is one part of the evaluation of the effectiveness of the Quality and Safety. Performance measures have been established to measure at least one important aspect of the Safety Program. (Add additional information if needed - Do not list performance metrics)
2. On an annual basis, the Environment of Care Committee evaluates the scope, objectives, performance, and effectiveness of the Plan to manage risks to the staff, visitors, and patients at SVHMC.

E. Orientation and Education

1. Orientation, education and/or training is provided on an as needed basis.
2. SVHMC provides training to our employees (based on appropriate content and vocabulary to the education level, literacy and language needs), who have potential for occupational exposure to aerosol transmissible diseases according to the following schedule:
 - a. At the time of initial assignment to tasks where occupational exposure may take place, and annually thereafter.
3. When changes, such as introduction of new engineering or work practice controls, modification of tasks or procedures or institution of new tasks or procedures, affect the employee's occupational exposure or control measures. The additional training may be limited to addressing the new exposures or control measures as necessary.
4. This training may be provided by one or more of the following method(s):
 - a. On-line training with opportunity to ask questions.
 - b. In person training with opportunity for questions and answer.
 - c. Staff Meetings through the department
 - d. 1 to 1 training through individual department
5. SVHMC will train all of our employees who have been determined to have potential occupational exposure to ATPs, as listed at the beginning of this program. This training will be provided to employees in those job categories when they are initially assigned to tasks where they may have occupational exposure and at least annually thereafter.
6. SVHMC ensure employees receive initial training during new employee orientation prior to initial start date.
7. SVHMC ensure employees receive their training on an annual basis through on-line training modules.
8. SVHMC ensures training materials appropriate in content and vocabulary to the educational level, literacy, and language of employees will be used.
9. If employees are absent on the day of their scheduled training, SVHMC use the following procedure to ensure that they receive a make-up training: All employees

are required to complete annual training/competencies within 30 days of returning to work.

10. The trainings will include an opportunity for employees to ask questions:
 - a. The trainings are provided in-person and questions are answered SVHMC during the training by the instructor, who is knowledgeable in the subject matter as it relates to our workplace and who is also knowledgeable in our ATD Exposure Control Plan.
 - b. The trainings are given on-line but SVHMC have ensured that all required topics are covered and that interactive questions are answered SVHMC within 24 hours by a person who is knowledgeable in the subject matter as it relates to our workplace and who is knowledgeable in our ATD Exposure Control Plan.
 - c. The person or department assigned to answer SVHMC questions related to the training is: Nursing Education, and/or Infection Prevention Department and/or Employee Health Department Leader(s).
11. Training includes the following:
 - a. An accessible copy of the regulatory text of this standard and an explanation of its contents.
 - b. A general explanation of ATDs including the signs and symptoms of ATDs that require further medical evaluation.
 - c. An explanation of the modes of transmission of ATDs and applicable source control procedures.
 - d. An explanation of the employer's ATD Exposure Control Plan and/or Biosafety Plan, and the means by which the employee can obtain a copy of the written plan and how they can provide input as to its effectiveness.
 - e. An explanation of the appropriate methods for recognizing tasks and other activities that may expose the employee to ATDs.
 - f. An explanation of the use and limitations of methods that will prevent or reduce exposure to ATDs including appropriate engineering and work practice controls, decontamination and disinfection procedures, and personal and respiratory protective equipment.
 - g. An explanation of the basis for selection of personal protective equipment, its uses and limitations, and the types, proper use, location, removal, handling, cleaning, decontamination and disposal of the items of personal protective equipment employees will use.
 - h. A description of the employer's TB surveillance procedures, including the information that persons who are immune-compromised may have a false negative test for LTBI.
 - i. EXCEPTION: Research and production laboratories do not need to include training on surveillance for LTBI if *M. tuberculosis* containing materials are not reasonably anticipated to be present in the laboratory.

- i. Training meeting the requirements of Section 5144(k) of these orders for employees whose assignment includes the use of a respirator.
- j. Information on the vaccines made available by the employer, including information on their efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge.
- k. An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident, the medical follow-up that will be made available, and post-exposure evaluation.
- l. Information on the employer's surge plan as it pertains to the duties that employees will perform.
As applicable, this training shall cover the plan for surge receiving and treatment of patients, patient isolation
- m. procedures, surge procedures for handling of specimens, including specimens from persons who may have been contaminated as the result of a release of a biological agent, how to access supplies needed for the response including personal protective equipment and respirators, decontamination facilities and procedures, and how to coordinate with emergency response personnel from other agencies.

Reference/link: Emergency Operations Plan

IV. REFERENCES

A. Safety

1. 8 CCR 5199: <https://www.dir.ca.gov/title8/5199.html>
2. [California Code of Regulations, Title 8, Section 5144. Respiratory Protective Equipment](#)
3. The Joint Commission Comprehensive Accreditation Manual for Hospitals
 - Environment of Care Chapter
 - Infection Prevention and Control Chapter

B. Employee Health

1. [CalOSHA](#), COVID-19 Resources

C. Infection Prevention

1. [California Conference of Local Health Officers \(CCLHO\) Contact Information](#)
2. [California Local Health Department Contact Information for Communicable Disease Reporting](#)
3. [CDPH Division of Communicable Disease Control Homepage](#)
4. [CDPH Guide to Respirator Use in Health Care – a Toolkit for Program Administrators](#)
5. [CDPH Healthcare-Associated Infections Program - Effective Cleaning Strategies](#)
6. [CDPH Respirator Use in Health Care – a Toolkit for Program Administrators](#)

7. [CDC Clinical Testing Guidance for Tuberculosis: Tuberculin Skin Test](#)
8. [CDC Guidelines for Environmental Infection Control in Health-Care Facilities](#)
9. [CDC Isolation Precautions Guideline](#)
10. [CDC Tuberculosis Infection Control](#)
11. [CDC "Pink Book" - Epidemiology and Prevention of Vaccine-Preventable Diseases](#)
12. [CDC Recommended Vaccines for Healthcare Workers](#)
13. [CDC Respiratory Hygiene/Cough Etiquette in Healthcare Settings](#)
14. [Selected EPA-registered Disinfectants](#)
15. [OSHA Respiratory Protection Program Toolkit for Hospitals](#)
16. [Title 17 CCR Division 1, Chapter 4, Reporting to the Local Health Authority](#)

Attachments

 [A: COVID Procedure for PAPR Use.docx](#)

 [Attachment A_SVH ATD Job Titles_2024-2025.pdf](#)

 [B: Aerosol Transmitted Diseases Exposure Disease Pathogen List](#)



[C: Matrix of Department Related Tasks & Procedure Involving Occupational Exposure & Exposure Controls for Aerosol Transmitted Diseases](#)

Approval Signatures

Step Description	Approver	Date
Emergency Management	James Hively: Manager Environmental Health & Safety	Pending
Policy Committees	Rebecca Alaga: Regulatory/ Accreditation Coordinator	10/2025
Policy Owner	Melissa Deen: Manager Infection Prevention	10/2025

Standards

No standards are associated with this document



Origination 08/2022
Last N/A
Approved
Next Review 1 year after approval

Owner Melissa Deen:
Manager
Infection
Prevention
Area Plans and
Program

Bioterrorism Readiness Plan

I. SCOPE

- A. Four major agents/diseases potentially encountered in the event of bioterrorism are anthrax, botulism, plague, and smallpox. Additional agents/diseases may include tularemia, brucellosis, Q fever, viral hemorrhagic fevers, viral encephalitis, and staphylococcal enterotoxin B. With the exception of smallpox, these agents are generally not transmitted from person to person, and re-aerosolization of the agents is unlikely.
- B. For Pathology department procedures related to the Laboratory Response Network and recognizing possible bioterrorism agents, see [BIOTERRORISM PREPAREDNESS – PATHOLOGY](#).
- C. Support Policies/Plans:
 - 1. [AEROSOL TRANSMITTED DISEASES EXPOSURE CONTROL PLAN](#)
 - 2. [AEROSOL TRANSMISSIBLE PATHOGENS – PATHOLOGY](#)
 - 3. [ISOLATION - STANDARD AND TRANSMISSION BASED PRECAUTIONS](#)
 - 4. [INFECTIOUS DISEASE REPORTING - PATHOLOGY](#)

II. OBJECTIVES/GOALS

A. Objectives

- 1. To guide the staff in the event Salinas Valley Health Medical Center (SVHMC) provides care/treatment to individuals with illnesses related to suspected or known exposure to bioterrorism agents.

B. Goals

- 1. Summary of the goals for the bioterrorism plan at Salinas Valley Health Medical Center (SVHMC):
 - a. Develop a comprehensive bioterrorism response plan and ensure staff are

- trained.
- b. Enhance surveillance for and rapid diagnosis of bioterrorism-related illnesses.
- c. Respond quickly and appropriately to suspected or confirmed cases, including isolating patients and administering treatment.
- d. Communicate effectively and collaborate with public health authorities.
- e. Minimize the spread of disease within the facility.
- f. Have a plan for returning to normal operations after an event and update the response plan based on lessons learned.

III. DEFINITIONS

- A. Association of Professionals in Infection Control and Epidemiology (APIC)
- B. Centers for Disease Control and Prevention (CDC)
- C. Hospital Infection Control Practices Advisory Committee (HICPAC)
- D. California Department of Public Health (CDPH)

IV. PLAN MANAGEMENT

- A. Plan Elements
 - 1. Reporting Requirements and Contact Information (see Table 1 in Attachments)
 - a. Internal Contacts - Immediately notify the following persons:
 - i. Infection Prevention: (831) 759-1858 SVHMC Operator has after-hours contact information.
 - ii. After hours, contact Administrative Supervisor/ Hospital Operator
 - b. External Contacts
 - i. Monterey County Health Department:(831) 755-4521, after hours: (831) 755-5100
 - ii. State Health Department, defers to local County Public Health; see contact information above
 - c. FBI Field Office (San Francisco): (415) 553-7400
 - d. Bioterrorism Emergency Number, CDC Emergency Response Office: (770) 488-7100
 - e. CDC Hotline 800-232-4636
 - f. California Poison Control Centers: (800) 222-1222
 - g. *Note: Phone numbers listed above were last verified on 02/24/2024*
 - 2. Detection of Outbreaks Caused by Agents of Bioterrorism: Bioterrorism is generally committed as a covert act and persons are unknowingly exposed. An outbreak may

only be recognized if unusual disease clusters or symptoms are recognized. Rapid response is required if bioterrorism related illness is suspected to prevent progression to illness and potential dissemination of these agents through secondary spread of infection.

- a. Recognition of Illness: "Diseases Associated with Bioterrorism" lists the four most common diseases caused by these agents and their characteristic features. These are not easily identified in the absence of an outbreak.
- b. Epidemiologic Criteria for Recognition of Outbreaks: Features that may represent early symptoms of exposure to a bioterrorism agent include:
 - i. A rapidly progressing incidence of disease in a normally healthy population.
 - ii. An epidemic curve that rises and falls during a short period of time.
 - iii. An unusual increase in the number of people seeking care, especially with fever, respiratory, or gastrointestinal complaints.
 - iv. An endemic disease rapidly emerging at an uncharacteristic time or in an unusual pattern.
 - v. Lower attack rates among people who had been indoors, especially in areas with filtered air or closed ventilation systems, compared with people who had been outdoors.
 - vi. Clusters of patients arriving from a single locale.
 - vii. Large numbers of rapidly fatal cases.
 - viii. Any patient presenting with a disease that is relatively uncommon and has bioterrorism potential (e.g., pulmonary anthrax, tularemia, or plague).

3. Surveillance

- a. Reporting & Analysis of Disease – the following may be considered for detection of Bioterrorism-related diseases.
 - i. Laboratory – Laboratories must immediately report cases to the local Health Department. Including SVHMC Infection Prevention and / or Chief Medical Officer/Infectious Disease Medical Director.
 - ii. Radiology Departments – Most cases will not initially be recognized by radiological findings; however, in the presence of an outbreak, Radiologists should be alerted to report suspect findings immediately.
 - iii. Analysis of trends
 - a. Clusters
 - b. Epidemic curves

- iv. Sources of information
 - a. Medical record access
 - b. Coding
 - c. Hospital Information Systems
 - d. Pharmacy records (e.g., high use of amantadine may indicate influenza or other pulmonary illness)
- 4. Community-wide Surveillance—The Health Department, CDC, and the local chapter of the Association of Professionals in Infection Control and Epidemiology (APIC) will alert infection preventionists in Monterey County.
- 5. **Infection Prevention Practices for Patient Management** (See CDC Links in References)
 - a. **Isolation Precautions:**
 - i. Standard Precautions – Agents of bioterrorism are generally not transmitted from person to person. Standard Precautions are recommended for all patients regardless of their diagnosis or presumed infection status.
 - ii. Transmission-Based Precautions
 - a. Suspected or confirmed smallpox - Airborne & Contact Precautions - using a negative pressure room with an anteroom.
 - b. Suspected or confirmed pneumonic plague – Droplet Precautions
 - c. [ISOLATION - STANDARD AND TRANSMISSION BASED PRECAUTIONS](#)
 - b. **Patient Placement:**
 - i. Routine patient placement for Standard or Transmission-based Precautions is generally adequate for small-scale events.
 - ii. If a large-scale event occurs, and existing in-patient facilities are insufficient for the number of patients admitted, the Infection Control Committee will work with the Incident Commander.
 - iii. Patients with similar syndromes may be directly triaged to alternate sites such as a designated clinic, emergency department area, or a designated ward, floor, or separate building, and cohorted and negative air ventilation may be required. Non-emergency services and procedures may need to be canceled.
 - c. **Patient Transport:** Patient movement should be limited. Patients in Airborne Precautions must have procedures done in negative pressure rooms. Transportation outside the facility must be coordinated with the Monterey County Emergency Operations Center.

- d. Cleaning, disinfection, laboratory testing, and sterilization of equipment and environment: Notify Pathology/laboratory and the Medical Examiner of potentially infectious cases during an outbreak before submitting specimens for examination, testing, or disposal.

B. Plan Management

1. Post-exposure Management:

- a. Decontamination is not necessary and should only be considered in instances of gross contamination.
- b. Employee Health and Pharmacy will identify sources of vaccines, immune globulin, antibiotics, and botulinum anti-toxin (with assistance from the local health departments). Current antibiotic prophylaxis for Plague (*Yersinia pestis*) and Anthrax (*Bacillus anthracis*) should be referenced by CDC standards, and the Infectious Disease Medical Director should be consulted.
- c. All in-patients will be evaluated for discharge potential and discharged as early as possible.
- d. Patients treated for a biological event-induced illness and their families will receive discharge instructions applicable to their illness.
- e. The hospital will attempt to reduce the psychological impact of bioterrorism by using on-site clergy, counselors, social workers, and volunteers. Public inquiries will be referred to the Public Information Officer.

C. Plan Responsibility

1. This plan will be utilized by staff as a support document during a bioterrorism event through the facility's HICS System and Incident Command Structure, as outlined in the [EMERGENCY MANAGEMENT PROGRAM PLAN](#).

D. Plan Performance

1. The performance measurement process is one part of evaluating the effectiveness of the Bioterrorism Readiness Plan. Performance measures have been established to measure at least one crucial plan aspect.
2. On an annual basis, the PT/IC Committee evaluates the plan's scope, objectives, performance, and effectiveness to manage risks to the staff, visitors, and patients at SVHMC.

E. Orientation and Education

1. Orientation, education, and/or training are provided on an as-needed basis.
2. Education is provided during general or departmental-specific orientation and periodically as practice or policy changes.

V. REFERENCES

A. Preparation and Planning for Bioterrorism Emergencies.

<https://www.osha.gov/bioterrorism/emergency-response> and <https://www.cdc.gov/orr/index.html>

- B. Laboratory Information for Bioterrorism Emergencies. <https://www.cdc.gov/laboratory-response-network/php/biological/index.html>
- C. CDC Emergency Preparedness and Response, Bioterrorism Agents/Diseases. <https://wwwnc.cdc.gov/eid/article/29/7/22-1769-t1>
- D. **DISEASES ASSOCIATED WITH BIOTERRORISM & Preventable measures:**
 - 1. Anthrax: [Anthrax | CDC](#)
 - 2. Botulism: [Botulism | Botulism | CDC](#)
 - 3. Ebola: [Ebola \(Ebola Virus Disease\) | CDC](#)
 - 4. Plague: [CDC Plague Information | Emergency Preparedness & Response](#)
 - 5. Smallpox: [Smallpox | CDC](#)
 - 6. Tularemia: [CDC Tularemia | Emergency Preparedness & Response](#)
- E. Infectious Disease Disasters: Bioterrorism, Emerging Infections and Pandemics. APIC Text of Infection Control and Epidemiology, updated 2024.

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
MEC	Katherine DeSalvo: Director Medical Staff Services	10/2025
P&T/IP Committee	Genevieve delos Santos: Director Pharmacy	09/2025
P&T/IP Committee	Kiri Golleher: Pharmacy Clinical Coordinator	09/2025
Emergency Management	James Hively: Manager Environmental Health & Safety	07/2025
Policy Committees	Rebecca Alaga: Regulatory/ Accreditation Coordinator	07/2025
Policy Owner	Melissa Deen: Manager Infection Prevention	07/2025

Standards

No standards are associated with this document



Origination 04/2021
Last Approved N/A
Next Review 2 years after approval

Owner Lori Orosco:
Director
Laboratory
Services
Area Laboratory -
General

Laboratory Critical Call Values

I. POLICY STATEMENT

A. N/A

II. PURPOSE

A. The laboratory medical director in consultation with medical staff is responsible for defining critical laboratory values that may be indicative of life-threatening conditions requiring rapid clinical intervention. Designation of critical values by clinical laboratories is required by the Clinical Laboratory Improvement Amendments and regulatory agencies.

III. DEFINITIONS

A. N/A

IV. GENERAL INFORMATION

These Laboratory Urgent Notification / Critical Call Values have been identified and agreed upon by the medical staff. These are values that require immediate notification of the responsible caregiver for timely intervention. Most results must be called directly to the physician and/or the nurse and documented per policy [LABORATORY CRITICAL RESULTS DOCUMENTATION](#).

V. PROCEDURE

A. Notification exceptions are as follows:

1. ER notifications can be done via TigerText to the ordering ER physician and to the designated Charge Nurse.
2. Pathology/Histology results are reported to the physician.

3. Critical results for patients on pharmacy protocol are called to the pharmacist
4. Call ALL **outpatient** critical results (regardless of previous critical result) with the exception of creatinine for renal patients, (Renal patients will be defined as anyone who has had a previous critical creatinine in their medical history.) For all other cases do not use "previous High/Low" as a reason not to call.

B. Chemistry Values

TEST	LOW VALUE	HIGH VALUE	COMMENTS
Ammonia 0-2 day		>169 ug/dL	Initial
Ammonia 3days to 31 days		>129 ug/dL	Initial
Ammonia 1 month and older		>100 ug/dL	Initial
Amylase		>250 IU/L	initial Do not call on ER patients
Blood Gas: pH (venous)	<7.20	>7.60	Initial
HCO ₃	<15 mEq/L	>40 mEq/L	Initial
Bilirubin Total		>9.9 mg/dL	Newborn less than 24hrs
Bilirubin Total		>16.0 mg/dL	2 days old to ≤ 3 months, not for adults
BUN		>100 mg/dL	Do not call on ER patients
Calcium, Total	<6.5 mG/dL	>13.0 mg/dL	Initial
Calcium, ionized	<3.2 nG/dL	>6.3 ng/dL	Initial
CO ₂ , Total (Serum/Plasma) 0-2 days old	<13 mmol/L	>50 mmol/L	Initial
CO ₂ , Total (S/P) 3days old and above	<15 mmol/L	>50 mmol/L	Initial
CKMB		>3.6 ng/ml	Initial only. Do not call on ER patients. Do not call if troponin was called.
CK-IND		>1.8	Initial only. Do not call on ER patients. No need to call if troponin was called.

TEST	LOW VALUE	HIGH VALUE	COMMENTS
Chloride	<80 mmol/L	>120 mmol/L	Initial
Cortisol	<18 uG/dL		Call only if <18 uG/ml following a stimulation dose.
Creatinine ages 0-11		>2.0 mg/ dL	Initial only
Creatinine ages 12-15		>3.0 mg/ dL	Initial only
Creatinine ages 16 and over		>4.0 mg/ dL	Initial only. No call on dialysis patients.
Ethanol		>400 mg/ dL	
Employee Exposure Panel/ Source Patient			Call to Employee Health (call Nursing Supervisor after hours)
Fetal Fibronectin			Call ALL results
Glucose serum/plasma 0-1 day old	<20 mg/ dL	>200 mg/ dL	initial
Glucose serum/plasma 2-6 days old	<30 mg/ dL	>200 mg/ dL	initial
Glucose serum/plasma >6 days old	<50 mg/ dL	>500 mg/ dL	Initial
Glucose CSF	<37 mg/ dL	>440 mg/ dL	
Lactic Acid		>2.0 mMol/L	Initial
Lipase		>159 U/L	Initial
Magnesium 0-6 days old	<0.8 mg/ dL	>5.0 mg/ dL	Initial
Magnesium 7 days and up	<1.0 mG/ dL	>4.9 mg/ dL	Initial
Magnesium OB patient on MG		>9.0 mg/ dL	
NEO-TSH and NEO-FT4			Call all results outside of reference range for < 1mo. olds
Osmolality,Serum/Plasma	<250 mOsm/kg	>326 mOsm/kg	Initial
Phosphorus 0- 9 Days	<1.2 mg/ dL	>10.0 mg/ dL	Initial

TEST	LOW VALUE	HIGH VALUE	COMMENTS
Phosphorous 10 days -11 years	<2.0 mg/dL	>10.0 mg/dL	
Phosphorus 12 Years and Higher	<1.0 mg/dL	>8.9 mg/dL	Initial
Potassium 0 - 12 Months	<2.8	>6.2	
Potassium 1- 13 Years Old	<2.8 mmol/L	>6.0 mmol/L	
Potassium 14 Years and Older	<2.5 mmol/L	>6.0 mmol/L	Initial
Sodium 0-2 Days	<111 mmol/L	>160 mmol/L	Initial
Sodium 2 Days and older	<120 mmol/L	>165 mmol/L	Initial
Troponin I		>180 ng/L	Initial
Uric Acid		>13.0 mg/dL	Initial
THERAPEUTIC DRUGS			
Acetaminophen		>120 ug/ml	
Carbamazepine		>15.0 ug/ml	
Digoxin		>3.0 ug/ml	
Gentamicin (Random/Peak)		>12.0 ug/ml	
Gentamicin (Trough)		>2.5 ug/ml	
Lidocaine		>7.0 ug/ml	
Phenobarbital		>55.0 ug/ml	
Phenytoin		>30.0 ug/ml	
Salicylate		>30 mg/dL	
Theophylline		>25.0 ug/ml	
Tobramycin (Random/Peak)		>12.0 ug/	

TEST	LOW VALUE	HIGH VALUE	COMMENTS
		ml	
Tobramycin (Trough)		>2.5 ug/ml	
Valproic Acid		>100 ug/ml	
Vancomycin (Random/Trough)		>30 ug/ml	

C. Immunochemistry

TEST	LOW VALUE	HIGH VALUE	COMMENTS
HIV Antibody/Antigen		Preliminary Reactive	• Call ALL reactives to MD. • If OB inpatient, call nonreactives to RN and reactives to MD
Hepatitis C-Employee Health only		Positive	Report to Employee Health

D. Reference Lab

TEST	LOW VALUE	HIGH VALUE	COMMENTS
Serotonin Release Assay			Positives only
Tacrolimus (Prograf)		>20 mcg/L	
Cocci Serology			First positive

E. Hematology

TEST	LOW VALUE	HIGH VALUE	COMMENTS
WBC	<2,000 cu/mm	>37,000 cu/mm	
HGB	<7 g/dl	>18 g/dL	
HEPARIN ANTI-XA		>1.0 IU/mL	Inpatients on pharmacy protocol
PLT	<10,000	>900,000	
PT		> 6 INR	
PTT		> 85 seconds	Patients on heparin

TEST	LOW VALUE	HIGH VALUE	COMMENTS
		>100 seconds	Inpatients on pharmacy protocol
FIBRINOGEN	<50 mG/dL		
D-DIMER		>1.5 mg/ L	
CSF FLUID CELL COUNTS			ER or myelogram patients in Radiology – unnecessary to call. ALL OTHER LOCATIONS – call any abnormal cell counts, cells, findings to M.D

F. Immunology

TEST/ EVENT	RESULT	ACTION	COMMENTS
RPR	Preliminary Reactive	• Call all preliminary reactive results to ordering MD • Document actions taken	MCPH: Fax: 831-775-8076 (preferred) Phone: 831-755-4521
		• Send-out for confirmation (RPRQ)	If RPR screen is (+) Titer and FTA Confirmatory testing is performed

G. Microbiology

RESULT	ACTION
Positive blood culture gram stain	First positive per bacterial morphotype or yeast
Blood culture Verigene result	All – (exception below): "No Target Detected" values not called to Pulmonologists 1700-0600
ESBL on blood	First positive
Inappropriate antibiotic therapy for CSF or positive blood culture	First positive
Positive blood or stool parasite	First positive
Eye culture growing <i>Ps. aeruginosa</i> or potential pathogen from corneal or vitreous eye fluid sources	First positive
Identified <i>Coccidioides immitis</i>	No previous history
Identified <i>Cryptococcus neoformans</i>	First positive
Mold resembling <i>Coccidioides immitis</i>	First positive

RESULT	ACTION
Mycobacterium species identification	First positive
Positive AFB smears and culture	First positive per source
Positive Bordetella pertussis	First positive
Positive Botulism result	First positive
Positive CSF smear and/or culture	First positive
Positive culture for E.coli O157	First positive
Positive Shiga Toxin	First positive
Positive <i>Legionella</i> or <i>Strep. pneumoniae</i> urine antigen	First positive
Potential agents of bioterrorism detected	All

H. Histology

RESULT	ACTION
Unexpected malignancies	Pathologist to Report to Clinician
Unsuspected infectious disease	Pathologist to Report to Clinician
Herpes smear-Positive or negative	Pathologist to Report to Clinician
Products of Conception – no POC identified	Pathologist to Report to Clinician
Products of Conception – unexpected findings	Pathologist to Report to Clinician
Significant discrepancy between frozen section diagnosis and final diagnosis	Pathologist to Report to Clinician
All new diagnoses of Lymphoma(except SLL), Leukemia(except CLL), Small Cell Carcinoma of Lung, High Grade Neuroendocrine Carcinoma	Pathologist to call Oncologist if associated with patient, otherwise call to Clinician

I. Special Instructions By Section

J. Chemistry

- Although most critical results are only called initially, clinical judgment must be used when serially monitored test results vacillate between normal and critical.
- Assure the test was repeated and results were still critical.
- Check previous results for the same test on the patient
- Visually inspect the specimen for interferants such as hemolysis, icterus, lipemia or odd coloration. Assure that testing was performed on appropriate specimen type (e.g. plasma/serum as required and not on an unspun specimen).
- Check to see if specimen was drawn from a line or port.
- Check instrument, method, and reagent by looking at other patients' results within the run, to assure they are not abnormal or critical also. This may indicate an instrument testing problem.

- Check with phlebotomist to assure collection was appropriate/correct (not above I.V., specimen was not placed in incorrect anticoagulant first and then transferred to correct tube, etc.).
- Document notification as a specimen comment using critical call canned text.
 - Answer all prompts that are appropriate.
- If result is questionable, call the patient's RN to determine if result corresponds with:
 - The patient condition
 - Administration of a recent medication
 - A recent procedure that could have created the result.

K. Hematology/Coagulation

- Documentation will occur via an automatically reflexed test in the computer. Complete all applicable prompts.
- Results on oncology patients may be called to the ordering provider's assistant or nurse.
- Check with phlebotomist to assure collection was appropriate (i.e., not above IV).

L. Microbiology

- Critical results for the Microbiology department will be documented with the test result using canned text "MCALL" and the applicable prompts completed.
- Critical results on patients discharged from the Emergency Department can be called to the Emergency Department Charge Nurse.

VI. EDUCATION/TRAINING

- A. Education and/or training is provided as needed.

VII. REFERENCES

- A. Changes to critical call ranges referenced from historical ranges found in Meditech Laboratory Information System for bilirubin and potassium.

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/Accreditation Coordinator	Pending

MEC	Katherine DeSalvo: Director Medical Staff Services	10/2025
Laboratory Medical Director	Johnny Hu: PHYSICIAN	09/2025
Policy Committee	Rebecca Alaga: Regulatory/ Accreditation Coordinator	09/2025
Policy Owner	Lori Orosco: Director Laboratory Services	08/2025

Standards

No standards are associated with this document



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 Last N/A
 Approved
 Next Review 1 year after approval

Owner **Melissa Deen:**
 Manager
 Infection
 Prevention
 Area **Plans and
 Program**

Respiratory Virus (Influenza) Pandemic Plan

I. SCOPE

- A. To prevent the spread of influenza (and/or other aerosolizing infectious diseases) by: vaccination, early detection and treatment with antiviral medications and the use of infection control measures to prevent transmission during patient care.
- B. To limit transmission in healthcare settings by use of appropriate infection control measures.
- C. To minimize close contact of known or suspect patients with influenza. Transmission requires close exposure to large droplets (droplet transmission), direct contact (contact transmission), or near-range exposure to aerosols (airborne transmission)
- D. To establish guidance based on our current knowledge of routes of influenza transmission (S4-II.A), the pathogenesis of influenza (S4-II.B), and the effects of influenza control measures used during past pandemics.
- E. Given some uncertainty about the characteristics of any new pandemic strain, all aspects of preparedness planning for pandemic influenza must allow for flexibility and real-time decision-making that take new information into account as the situation unfolds.

II. OBJECTIVES/GOALS

- A. Prevention and control of influenza or any other unknown communicable respiratory condition will be through a set of well-established strategies that include:
 1. vaccination of patients and healthcare personnel;
 2. early detection of respiratory viral cases in a facility;
 3. use of antiviral medications to treat ill persons and, if recommended, as prophylaxis;
 4. isolation of infectious patients in private rooms or cohort units;
 5. Barrier precautions during patient care, as recommended for identified respiratory viruses, as Standard, Droplet, Contact, or Airborne Precautions.

6. Administrative measures include restricting visitors, educating patients and staff, and cohorting healthcare workers assigned to an outbreak unit.
- B. Salinas Valley Health Medical Center (SVHMC) (will follow the guidelines established by the Center for Disease Control and Prevention (CDC), the California Department of Public Health (CDPH), and Cal OSHA for detection, treatment to minimize the transmission and treatment of influenza any other unknown communicable respiratory condition.
- C. SVHMC will follow the recommendation of the Monterey Public Health Department in the event of an untoward influx of patients identified as having a communicable disease.
- D. SVHMC will initiate surge capacity and activate additional components of the Emergency Management Plan as needed.

III. DEFINITIONS

- A. **Modes of transmission of influenza** - Epidemiologic pattern observed for seasonal influenza is generally consistent with spread through close contact (i.e., exposure to large respiratory droplets, direct contact, or near-range exposure to aerosols through small particle aerosols).
- B. **Droplet transmission** - Droplet transmission involves contact with the conjunctivae or the mucous membranes of the nose or mouth of a susceptible person with large-particle droplets containing microorganisms generated from a person who has a clinical disease or is a carrier of the microorganism.
 1. Droplets are generated from the source person primarily during coughing, sneezing, talking, and during specific procedures, such as suctioning.
 2. Transmission via large-particle droplets requires close contact between source and recipient persons because droplets do not remain suspended in the air and generally travel only short distances (about 3 – 6 feet) through the air. Because droplets do not remain suspended in the air, special air handling and ventilation are not required to prevent droplet transmission.
- C. **Contact transmission** - Contact (direct) transmission involves skin-to-skin contact and physical transfer of microorganisms to a susceptible host from an infected or colonized person, such as occurs when personnel turn patients, bathe patients, or perform other patient-care activities that require physical contact.
 1. Direct-contact transmission can also occur between two patients (e.g., by hand contact), with one serving as the source of infectious microorganisms and the other as a susceptible host.
 2. Indirect-contact transmission involves contact of a susceptible host with a contaminated intermediate object, usually inanimate, in the patient's environment.
 3. Contact transmission of influenza may occur through direct skin-to-skin contact or indirect contact with virus in the environment.
 4. Transmission via contaminated hands and fomite has been suggested as a contributing factor in some studies.
- D. **Airborne transmission** - Airborne transmission occurs by dissemination of either airborne droplet nuclei or small particles in the respirable size range containing the infectious agent.

Microorganisms carried in this manner—such as *M. tuberculosis*— may be dispersed over long distances by air currents and inhaled by susceptible individuals who have not had face-to-face contact with (or been in the same room with) the infectious individual.

1. Organisms transmitted in this manner must be capable of sustaining infectivity, despite desiccation and environmental variation that generally limit survival in the airborne state.
2. Preventing the spread of agents that are transmitted by the airborne route requires the use of special air handling and ventilation systems (e.g., negative pressure rooms).
3. The relative contribution of airborne transmission to influenza outbreaks is uncertain. Evidence is limited and is principally derived from laboratory studies in animals and some observational studies of influenza outbreaks in humans, particularly on cruise ships and airplanes, where other mechanisms of transmission were also present. Additional information suggesting airborne transmission was reported in a Veterans Administration Hospital study that found lower rates of influenza in wards exposed to ultraviolet radiation (which inactivates influenza viruses) than in wards without UV radiation.
4. Another study indicated that humidity can play a role in the infectivity of aerosolized influenza, although the influence of humidity on the formation of droplet nuclei was not evaluated.
5. Aerosol-generating procedures (e.g., endotracheal intubation, suctioning, nebulizer treatment, and bronchoscopy) could increase the potential for dissemination of droplet nuclei in the immediate vicinity of the patient. (Although transmission of SARS-CoV was reported in a Canadian hospital during an aerosol-generating procedure [intubation], it occurred in a situation involving environmental contamination with respiratory secretions.) Although this mode of transmission has not been evaluated for influenza, additional precautions for healthcare personnel who perform aerosol-generating procedures on influenza or other respiratory viruses may be warranted. When these aerosol-generating procedures are performed on patients known or suspected of having an aerosol-transmissible disease, healthcare workers will use a PAPR (powered air purifying respirator.)

- E. ***Pathogenesis of influenza and implications for infection control*** - The cellular pathogenesis of human influenza or any other unknown communicable respiratory condition indicates that infection principally occurs within the respiratory tract. Following respiratory transmission, the virus attaches to and penetrates respiratory epithelial cells in the trachea and bronchi. Pathogenic mechanisms of viral disease include (1) implantation of virus at the portal of entry, (2) local replication, (3) spread to target organs (disease sites), and (4) spread to sites of shedding of virus into the environment. This information suggests that preventing direct and indirect inoculation of the respiratory tract is paramount for preventing person-to-person transmission when caring for infectious patients.

IV. PLAN MANAGEMENT

A. Plan Elements

1. **Control of transmission in healthcare facilities** - These are the primary infection control measures recommended in this plan. They will be updated, as necessary, based on the observed characteristics of the pandemic influenza / emerging communicable disease such as new or Novel virus, SARS etc).
2. **Recommendations for Infection Control in Healthcare Settings** - The recommendations for infection control described below are generally applicable throughout the different pandemic phases. In some cases, as indicated, recommendations may be modified as the situation progresses from limited cases to widespread community illness.
 - a. Basic infection control principles for preventing the spread of pandemic influenza or any other unknown communicable respiratory condition in healthcare settings. The following infection control principles apply in any setting where persons with pandemic influenza or viral respiratory illness might seek and receive healthcare services (e.g. hospitals, emergency departments, out-patient facilities, residential care facilities, homes).
 - b. Limit contact between infected and non-infected persons
 - i. Isolate infected persons (i.e., confine patients to a defined area appropriate for the healthcare setting).
 - ii. Limit contact between nonessential personnel and other persons (e.g., social visitors) and patients who are ill with pandemic influenza or any other unknown communicable respiratory condition.
 - iii. Promote spatial separation in common areas (i.e., sit or stand as far away as possible, at least 6 feet from potentially infectious persons) to limit contact between symptomatic and non-symptomatic persons.
 - c. Protect persons caring for influenza patients or other respiratory viral illnesses in healthcare settings from contact with the virus. Persons who must be in contact should:
 - i. Wear a surgical or procedure mask for close contact with infectious patients. Wear gloves (gown if necessary) for contact with respiratory secretions. Other unknown communicable respiratory conditions may require Airborne precautions with the use of an N95 respirator or PAPR, possibly with Contact (gown & gloves) and eye protection based on current guidelines from CDC, CDPH, or Cal OSHA.
 - ii. Perform hand hygiene before and after contact with infectious patients
 - a. Contain infectious respiratory secretions:
 - i. Instruct persons who have "flu-like" symptoms (see below) to use respiratory hygiene/cough etiquette (See Box 2).
 - ii. Promote the use of masks by symptomatic

persons (including visitors) or when transported (e.g., transfers between departments).

3. **Symptoms of influenza and other respiratory viral illnesses** include fever, headache, myalgia, prostration, coryza, sore throat, and cough. Otitis media, nausea, diarrhea, and vomiting are also commonly reported among children and adults over 65. Typical influenza or viral symptoms, such as fever, may not always be present in elderly patients, young children, patients in long-term care facilities, or persons with underlying chronic illnesses (see Supplement 5, Box 2).

B. Plan Management

1. **Management of infectious patients**

- a. **Respiratory hygiene/cough etiquette** - Respiratory hygiene/cough etiquette has been promoted as a strategy to contain respiratory viruses at the source and to limit their spread in areas where infectious patients might be awaiting medical care (e.g., waiting rooms, physician offices, emergency departments) (see S4-IV.B.2).
- b. The impact of covering sneezes and coughs and/or placing a mask on a coughing patient on the containment of respiratory secretions or on the transmission of respiratory infections. Masks block aerosols produced during coughs and exhalations ("source control"). Masks also slow and deflect cough and exhalation airflows, which changes the dispersion of aerosols. Factors such as the directions in which people are facing (orientation) and separation distance also affect aerosol dispersion. In theory, any measure that limits the dispersal of respiratory droplets should reduce the opportunity for transmission. **Masking should be encouraged with patients and visitors who are actively coughing** but may be difficult in some settings, e.g., pediatrics, where the emphasis will be on cough hygiene.
- c. The elements of respiratory hygiene/cough etiquette include:
 - i. Healthcare facility staff, patients, and visitors should be educated on the importance of containing respiratory secretions to help prevent the transmission of influenza and other respiratory viruses with masking.
 - ii. Posted signs in languages appropriate to the populations served with instructions to patients and accompanying family members or friends to report symptoms of a respiratory infection as directed immediately
 - iii. Source control measures (e.g., using masks on the coughing person when they can be tolerated and are appropriate)
 - iv. Hand hygiene before and after contact with respiratory secretions and
 - v. When possible, persons with respiratory infections should be separated spatially, ideally by more than 6 feet, in common

waiting areas.

2. ***Droplet precautions and patient placement***

- a. Patients with known or suspected pandemic influenza or other respiratory viral illnesses should be placed on appropriate precautions (Droplet or Airborne) based on SVHMC's current policy and/or current guidelines from CDC, CDPH, and Cal OSHA. Immunocompromised patients may shed the viruses for extended periods, and they may be placed on precautions for the duration of their illness. Healthcare personnel should wear appropriate PPE (see S4-IV.C). The placement of patients will vary depending on the healthcare setting (see setting-specific guidance). If the pandemic virus is associated with diarrhea, contact precautions (i.e., gowns and gloves for all patient contact) should be added. CDC, CDPH, and Cal OSHA will update these recommendations if changes occur in the anticipated pattern of transmission.
- b. Patients suspected of H1N1 influenza will be placed on Droplet Precautions for at least 7 days. They should remain in Droplet precautions until clearance to discontinue Precautions has been obtained from an infectious disease physician, a pulmonologist, or consultation with Infection Prevention.

3. ***Infection control practices for healthcare personnel***

- a. Infection control practices for pandemic influenza or other respiratory viral illnesses primarily involve the application of standard and droplet precautions (Box 1) during patient care in healthcare settings (e.g., hospitals, nursing homes, outpatient offices, emergency transport vehicles). Some respiratory viruses, such as Novel Influenzas or other types of SARS, will require *airborne isolation* with contact precautions and possible eye protection based on current guidance from the CDC, CDPH, or Cal OSHA. This guidance also applies to healthcare personnel entering patients' homes.
- b. Infection control practices for H1N1 influenza require *Droplet Precautions* and the use of a regular "ear loop" face mask.
- c. During a pandemic, conditions that could affect infection prevention may include shortages of antiviral drugs, decreased efficacy of the vaccine, increased virulence of the influenza strain, shortages of single-patient rooms, and shortages of personal protective equipment. These issues may necessitate changes in the standard recommended infection control practices for influenza and other respiratory viral illnesses. CDC, CDPH, and/or Cal OSHA will provide updated infection control guidance as circumstances dictate. Additional guidance is provided for family members providing home care (S4-IV.G) and for use in public settings (e.g., schools, workplaces) where people with pandemic influenza or other respiratory viral illnesses may be encountered (S4-V and S4-VI).
 - i. **Personal Protective Equipment** - PPE is used to prevent direct contact with the pandemic influenza virus or other respiratory

viruses. PPE that may be used to provide care includes surgical or procedure masks, as recommended for droplet precautions, and gloves and gowns, as recommended for standard precautions (Box 1). Additional precautions may be indicated during the performance of aerosol-generating procedures or per guidelines from CDC, CDPH, or Cal OSHA (see below).

ii. Masks ("Ear-loop")/ Respirators (N95 or PAPR)

- a. Wear a mask "ear loop" when entering a patient's room. A mask should be worn once and then discarded. If pandemic influenza patients are cohorted in a common area or in several rooms on a nursing unit, and multiple patients must be visited over a short time, it may be practical to wear one mask for the duration of the activity; however, other PPE (e.g., gloves, gown) must be removed between patients and hand hygiene performed.
- b. Respirators (N95 or PAPRs) may be required in place of "ear-loop" masks if required by CDC, CDPH, and/or Cal OSHA if the respiratory virus is identified as "Novel" or "SARS," etc.
- c. Change masks "ear loop"/respirators "N95s" when they become moist.
- d. Do not leave masks dangling around the neck.
- e. Upon touching or discarding a used mask, perform hand hygiene.

iii. Gloves

- a. A single pair of patient care gloves should be worn for contact with blood and body fluids, including during hand contact with respiratory secretions (e.g., providing oral care and handling soiled tissues). Gloves made of latex, vinyl, nitrile, or other synthetic materials are appropriate for this purpose; if possible, latex-free gloves should be available for healthcare workers with latex allergies.
- b. Gloves should fit comfortably on the wearer's hands.
- c. Remove and dispose of gloves after use on a patient; do not wash gloves for subsequent reuse.
- d. Perform hand hygiene after glove removal.
- e. If gloves are in short supply (i.e., the demand during a pandemic could exceed the supply), priorities for glove use might need to be established. In this circumstance, reserve gloves for situations where there is a likelihood of extensive patient or

environmental contact with blood or body fluids, including during suctioning.

iv. Gowns

- a. Wear an isolation gown if soiling personal clothes or uniform with a patient's blood or body fluids, including respiratory secretions, is anticipated. Most patient interactions do not necessitate the use of gowns. However, procedures such as intubation and activities that involve holding the patient close (e.g., in pediatric settings) are examples of when a gown may be needed when caring for pandemic influenza patients. Additionally, gowns may be required during a pandemic or for other respiratory viral illnesses.
- b. A disposable gown made of synthetic fiber or a washable cloth gown may be used.
- c. Ensure that gowns are of the appropriate size to fully cover the area to be protected.
- d. Gowns should be worn only once and then placed in a waste or laundry receptacle, as appropriate, and hand hygiene performed.
- e. If gowns are in short supply (i.e., the demand during a pandemic could exceed the supply), priorities for their use may need to be established. In this circumstance, reinforcing the situations in which they are required can reduce the volume used. Alternatively, other coverings (e.g., patient gowns) could be used.

v. Goggles or face shield

- a. In general, wearing goggles or a face shield for routine contact with patients with H1N1 influenza is not necessary. Respiratory viral illnesses like "Novel" influenza or "SARS" may require eye protection; follow current SVHMC policy for isolation, including CDC/CDPH or Cal OSHA guidance.
- b. However, if sprays or splatters of infectious material are likely, goggles or a face shield should be worn as recommended for standard precautions.

vi. References:

- a. [Aerosol Transmitted Diseases Exposure Control Plan](#)
- b. [Isolation - Standard and Transmission Based Precautions](#)

Box 2. Respiratory Hygiene/Cough Etiquette	
To contain respiratory secretions, all persons with signs and symptoms of a respiratory infection, regardless of presumed cause, should be instructed to:	A. Cover the nose/mouth when coughing or sneezing. Encourage the use of masks for any persons with an active cough. B. Use masks, such as "ear loop" masks, to contain respiratory secretions. C. Dispose of tissues in the nearest waste receptacle after use. D. Perform hand hygiene after contact with respiratory secretions and contaminated objects/materials.
Healthcare facilities should ensure the availability of materials for adhering to respiratory hygiene/cough etiquette in waiting areas for patients and visitors:	A. Provide ear loop masks, tissues, and no-touch receptacles for used mask/tissue disposal. B. Provide conveniently-located dispensers of alcohol-based hand rub. C. Provide soap and disposable towels for handwashing where sinks are available.
Masking and separation of persons with symptoms of respiratory infection:	A. During periods of increased respiratory infection in the community, persons who are coughing should be offered either a procedure mask (i.e., with ear loops) or a surgical mask (i.e., with ties) to contain respiratory secretions. Coughing persons should be encouraged to sit as far away as possible (at least 6 feet) from others in common waiting areas. Some facilities may wish to institute this recommendation year-round.

C. Plan Responsibility

1. *PPE for special circumstances*

a. **PPE for aerosol-generating procedures**

During procedures that may generate increased small-particle aerosols of respiratory secretions (e.g., endotracheal intubation, nebulizer treatment, bronchoscopy, suctioning), healthcare personnel should wear gloves, gown, face/eye protection, and a Powered Air Purifier (PAPr) or other appropriate particulate respirators. Respirators should be used within a respiratory protection program that includes fit testing, medical clearance, and training. If possible and when practical, the use of an airborne isolation room may be considered when conducting aerosol-generating procedures.

b. PPE for managing pandemic influenza or other respiratory viral illness with increased transmissibility

The addition of airborne precautions, including respiratory protection (an N95 respirator or other appropriate particulate respirator), may be considered for strains of influenza or respiratory viruses exhibiting increased transmissibility during the initial stages of an outbreak of an emerging or novel strain of influenza, and as determined by other factors such as vaccination/immune status of personnel and availability of antivirals. As the epidemiologic characteristics of the pandemic virus are more clearly defined, CDC/CDPH/CalOSHA will provide updated infection control guidance, as needed.

c. Precautions for early stages of a pandemic

Early in a pandemic, it may not be clear that a patient with severe respiratory illness has pandemic influenza or other viral illness. Therefore precautions consistent with all possible etiologies, including a newly emerging infectious agent, should be implemented. This may involve the combined use of airborne and contact precautions, in addition to standard precautions, until a diagnosis is established.

2. *Caring for patients with pandemic viral illness* - Healthcare personnel should be particularly vigilant to avoid:

- a. Touching their eyes, nose or mouth with contaminated hands (gloved or ungloved). Careful placement of PPE before patient contact will help avoid the need to make PPE adjustments and the risk of self-contamination during use. Careful removal of PPE is also important, with good hand hygiene after removal.
- b. Contaminating environmental surfaces that are not directly related to patient care (e.g., door knobs, light switches)

3. *Hand hygiene* - Hand hygiene has frequently been cited as the single most important practice to reduce the transmission of infectious agents in healthcare settings and is an essential element of standard precautions. The term "hand hygiene" includes both hand washing with either plain or antimicrobial soap and water and the use of alcohol-based products (gels, rinses, foams) containing an emollient that does not require the use of water.

- a. If hands are visibly soiled or contaminated with respiratory secretions, wash hands with soap and water.

- b. In the absence of visible soiling of hands, approved alcohol-based products for hand disinfection are preferred over soap and water because of their superior micro-biocidal activity, reduced drying of the skin, and convenience.
 - c. Always perform hand hygiene between patient contacts and after removing PPE.
 - d. Ensure that resources to facilitate hand washing (e.g., sinks with warm and cold running water, soap, disposable paper towels) and hand disinfection (e.g., alcohol-based products) are readily accessible in areas where patient care is provided.
 - e. For additional guidance on hand hygiene, see: [Clinical Safety: Hand Hygiene for Healthcare Workers](#)
- 4. **Disposal of solid waste** - Standard precautions are recommended for disposal of solid waste (medical and non-medical) that might be contaminated with a pandemic influenza virus:
 - a. Contain and dispose of contaminated medical waste in accordance with facility-specific procedures and/or local or state regulations for handling and disposal of medical waste, including used needles and other sharps, and non-medical waste.
 - b. Discard as routine waste used patient-care supplies that are not likely to be contaminated (e.g., paper wrappers).
 - c. Wear disposable gloves when handling waste. Perform hand hygiene after removal of gloves.
- 5. **Linen and laundry** - Standard precautions are recommended for linen and laundry that might be contaminated with respiratory secretions from patients with pandemic influenza:
 - a. Place soiled linen into a laundry bag in the patient's room. Contain linen in a manner that prevents the linen bag from opening or bursting during transport and while in the soiled linen holding area.
 - b. Wear gloves and gown when handling soiled linen and laundry (e.g., bedding, towels, personal clothing) as per standard precautions. Do not shake or otherwise handle soiled linen and laundry in a manner that might create an opportunity for disease transmission or contamination of the environment.
 - c. Wear gloves to transport bagged linen and laundry.
 - d. Perform hand hygiene after removing gloves that have been in contact with soiled linen and laundry.
 - e. Wash and dry linen according to routine standards and procedures.
- 6. **Dishes and eating utensils** - Standard precautions are recommended for handling dishes and eating utensils used by a patient with known or possible pandemic:
 - a. Wash reusable dishes and utensils in a dishwasher at the recommended

water temperature.

- b. Disposable dishes and utensils (e.g., those used in an alternative care site set up for large numbers of patients) should be discarded with other general waste.
- c. Wear gloves when handling patient trays, dishes, and utensils.

7. **Patient-care equipment** - Follow standard practices for handling and reprocessing used patient-care equipment, including medical devices:

- a. Wear gloves when handling and transporting used patient-care equipment.
- b. Wipe heavily soiled equipment with a hospital-approved disinfectant before removing it from the patient's room. Follow current recommendations for cleaning and disinfecting or sterilizing reusable patient-care equipment.
- c. Upon removal from the patient's room, wipe the external surfaces of portable equipment used for X-rays and other procedures with a hospital-approved disinfectant.

8. **Environmental cleaning and disinfection** - Cleaning and disinfection of environmental surfaces are important components of routine infection control in healthcare facilities. Environmental cleaning and disinfection for pandemic influenza follow the same general principles in healthcare settings.

9. **Cleaning and disinfection of patient-occupied rooms:**

- a. Wear gloves in accordance with facility policies for environmental cleaning and wear a surgical or procedure mask in accordance with droplet precautions. Gowns are not necessary for routine cleaning of an influenza patient's room.
- b. Keep areas around the patient free of unnecessary supplies and equipment to facilitate daily cleaning.
- c. Use any hospital-approved detergent-disinfectant. Follow the manufacturer's recommendations for use-dilution (i.e., concentration), contact time, and care in handling.
- d. Follow facility procedures for regular cleaning of patient-occupied rooms. Give special attention to frequently touched surfaces (e.g., bed-rails, bedside and over-bed tables, TV controls, call buttons, telephones, lavatory surfaces including safety/pull-up bars, doorknobs, commodes, ventilator surfaces) in addition to floors and other horizontal surfaces.
- e. Clean and disinfect spills of blood and body fluids in accordance with current recommendations for Isolation Precautions. Cleaning and disinfection after patient discharge or transfer
- f. Follow standard facility procedures for post-discharge cleaning of an isolation room.
 - i. Clean and disinfect all surfaces that were in contact with the patient or might have become contaminated during patient care.

No special treatment is necessary for window curtains, ceilings, and walls unless there is evidence of visible soiling.

- ii. Do not spray (i.e., fog) occupied or unoccupied rooms with disinfectant. This is a potentially dangerous practice that has no proven disease control benefit.
- iii. Utilization of UV light disinfection will be incorporated into the discharge cleaning process during a pandemic and/or when guidelines from CDC, CDPH, or Cal OSHA are recommended.

10. **Postmortem care**

- a. Follow standard facility practices for care of the deceased. Practices should include standard precautions for contact with blood and body fluids. For H1N1 patients, use gown, gloves, regular face mask, and eye protection at a minimum. Other respiratory viruses may require specific handling and PPE, following current SVHMC policy or current guidance from CDC, CDPH, and Cal OSHA.

11. **Laboratory specimens and practices** - Follow standard facility and laboratory practices for the collection, handling, and processing of laboratory specimens.

- a. [Aerosol Transmissible Pathogens - Pathology](#)

12. **Occupational health issues** - Healthcare personnel are at risk for pandemic influenza through community and healthcare-related exposures. Once pandemic influenza has reached a community, healthcare facilities must implement systems to monitor for illness in the facility workforce and manage those who are symptomatic or ill.

- a. Implement a system to educate personnel about occupational health issues related to pandemic influenza.
- b. Screen all personnel for symptoms before they come on duty. Symptomatic personnel should be sent home until they are physically ready to return to duty. Also, the current SVHMC processes for staff screening and return-to-work policies related to respiratory viral illness or pandemic should be followed. CDC, CDPH, and/or Cal OSHA may require additional screening and return-to-work guidance based on the viral disease or pandemic.
- c. Personnel who are at high risk for complications of pandemic viral illness (e.g., pregnant women, immunocompromised persons) should be informed about their medical risk and offered an alternate work assignment, away from pandemic patient care if possible or considered for administrative leave until the pandemic has abated in the community. During an identified pandemic, follow SVMHC's current Human Resources policies related to assignments, etc.
- d. Reducing the exposure of persons at high risk for complications during a pandemic - Persons who are well but at high risk for respiratory viral illness or its complications (e.g., persons with underlying diseases) should be instructed to avoid unnecessary contact with healthcare facilities caring

for pandemic patients (i.e., do not visit patients, postpone nonessential medical care).

13. **Hospitals** - Detection of persons entering the facility who may have pandemic influenza or other respiratory viral illness - Post visual alerts (in appropriate languages) at the entrance to hospital outpatient facilities (e.g., emergency departments, outpatient clinics) instructing persons with respiratory symptoms (e.g., patients, persons who accompany them) to:
 - a. Inform reception and healthcare personnel when they first register for care and
 - b. Practice respiratory hygiene/cough etiquette and encourage "ear-loop" masks for all patients and visitors
 - c. Triage patients calling for medical appointments for symptoms
 - d. Discourage unnecessary visits to medical facilities.
 - e. Instruct symptomatic patients on infection control measures to limit transmission in the home and when traveling to necessary medical appointments.
 - f. As the scope of the pandemic escalates locally, consider setting up a separate triage area for persons presenting with symptoms of respiratory infection. Because not every patient presenting with symptoms will have the pandemic virus, infection control measures will be important in preventing further spread.
 - g. During the peak of the pandemic, emergency departments and outpatient offices may be overwhelmed with patients seeking care. A "triage officer" may be useful for managing patient flow.
 - h. Designate separate waiting areas for patients with influenza-like symptoms. If this is not feasible, the waiting area should be set up so that patients with respiratory symptoms can sit as far away as possible (at least 6 feet) from other patients.
14. "Source control" measures to limit dissemination of respiratory virus from respiratory secretions - Post signs that promote respiratory hygiene/cough etiquette in common areas (e.g., elevators, waiting areas, cafeterias, lavatories) where they can serve as reminders to all persons in the healthcare facility. Signs should instruct persons to:
 - a. Cover the nose/mouth when coughing or sneezing.
 - b. Use ear-loop masks to contain respiratory secretions.
 - c. Dispose of mask/tissues in the nearest waste receptacle after use.
 - d. Perform hand hygiene after contact with respiratory secretions.
 - e. Facilitate adherence to respiratory hygiene/cough etiquette by ensuring the availability of materials in waiting areas for patients and visitors.
 - f. Provide masks/tissues and no-touch receptacles (e.g., waste containers with pedal-operated lids or uncovered waste containers) for used tissue disposal.

- g. Provide conveniently-located dispensers of alcohol-based hand rub.
- h. Provide soap and disposable towels for handwashing where sinks are available.
- i. Promote the use of masks and spatial separation by persons with symptoms of respiratory viral illness.
- j. Offer and encourage the use of either procedure masks (i.e., with ear loops) or surgical masks (i.e., with ties or elastic) by symptomatic persons to limit the dispersal of respiratory droplets.
- k. Encourage coughing persons to sit as far away as possible (at least 6 feet) from other persons in common waiting areas.

15. ***Hospitalization of pandemic patients***

a. Patient Placement

- i. Limit admission of pandemic patients to those with severe complications who cannot be cared for outside the hospital setting.
 - a. Admit patients to either a single-patient room or an area designated for cohorts of patients with the same identified viral illness.

b. Cohorting

- i. Designated units or areas of a facility should be used for cohorting patients with pandemic illness. During a pandemic, other respiratory viruses (e.g., non-pandemic influenza, respiratory syncytial virus, parainfluenza virus) may be circulating concurrently in a community. Therefore, to prevent cross-transmission of respiratory viruses, assign only patients with the same confirmed virus to the same room whenever possible. At the height of a pandemic, laboratory testing to confirm viral pandemic is likely to be limited, in which case cohorting should be based on having symptoms consistent with identified viral pandemic.
- ii. Personnel (clinical and non-clinical) assigned to cohorted patient care units for viral pandemic patients should not "float" or otherwise be assigned to other patient care areas. The number of personnel entering the cohorted area should be limited to those necessary for patient care and support.
- iii. Personnel assigned to cohorted patient care units should be aware that patients with viral pandemic may be concurrently infected or colonized with other pathogenic organisms (e.g., *Staphylococcus aureus*, *Clostridium difficile*) and should adhere to infection control practices (e.g., hand hygiene, changing gloves between patient contact) used routinely, and as part of standard precautions, to prevent nosocomial transmission.

- iv. Because of the high patient volume anticipated during a pandemic, cohorting should be implemented early in the course of a local outbreak.

c. Patient transport

- i. Limit patient movement and transport outside the isolation area to medically necessary purposes.
- ii. Consider having portable x-ray equipment available in areas designated for cohorting pandemic patients.
- iii. If transport or movement is necessary, ensure the patient wears an "ear-loop" mask. If a mask cannot be tolerated (e.g., due to the patient's age or deteriorating respiratory status), apply the most practical measures to contain respiratory secretions. Patients should perform hand hygiene before leaving the room.
- iv. During a pandemic, additional transfer guidelines will be implemented based on guidelines from the CDC, CDPH, and CalOSHA. Check for current SVHMC policies for the transfer of a pandemic patient and or current SVHMC isolation policy.

d. Visitors

- i. Screen visitors for signs and symptoms of viral illness before entry into the facility and exclude persons who are symptomatic.
- ii. Family members accompanying patients with viral symptoms to the hospital are assumed to have been exposed to the virus and should wear "ear-loop" masks.
- iii. Limit visitors to persons necessary for the patient's emotional well-being and care.
- iv. Instruct visitors to wear "ear-loop" masks while in the patient's room.
- v. Instruct visitors on hand hygiene practices.

16. ***Control of healthcare-acquired (nosocomial) pandemic transmission*** - Once patients with pandemic virus are admitted to the hospital, nosocomial surveillance should be heightened for evidence of transmission to other patients and healthcare personnel. (Once the pandemic virus is firmly established in a community, this may not be feasible or necessary.) If limited nosocomial transmission is detected (e.g., has occurred on one or two patient care units), appropriate control measures should be implemented. These may include:

- a. Cohorting of patients and staff on affected units
- b. Restriction of new admissions (except for other pandemic patients) to the affected unit(s)
- c. Restriction of visitors to the affected unit(s) to those who are essential for patient care and support
- d. If widespread nosocomial transmission occurs, controls may need to be

implemented hospital-wide and might include:

- i. Restricting all nonessential persons
- ii. Stopping admissions not related to the pandemic virus and stopping elective surgeries

17. **Care of pandemic viral patients at alternative sites** - If a viral pandemic results in severe illness that overwhelms the capacity of existing healthcare resources, it may become necessary to provide care at alternative sites (e.g., schools, auditoriums, conference centers, hotels). Existing "all-hazard" plans have likely identified designated sites for this purpose. The same principles of infection control apply in these settings as in other healthcare settings. Careful planning is necessary to ensure that resources are available and procedures are in place to adhere to the fundamental principles of infection control. These sites would be managed in collaboration with local county, state, and federal authorities under Emergency Management.

D. Performance Measurement

1. The performance measurement process is one part of evaluating the effectiveness of the Influenza (Respiratory Virus) Pandemic Plan. Performance measures have been established to measure at least one important aspect of the plan.
2. The Pharmacy, Therapeutics, and Infection Prevention Committee evaluates the plan's scope, objectives, performance, and effectiveness on an annual basis to manage risks to the staff, visitors, and patients at SVHMC.

E. Orientation and Education

1. Orientation, education, and/or training are provided on an as-needed basis.

V. REFERENCES

- A. Reed C, Biggerstaff M, Finelli L, et al. Novel Framework for Assessing Epidemiologic Effects of Influenza Epidemics and Pandemics. *Emerging Infectious Diseases*. 2013; 19(1):85-91. doi:10.3201/eid1901.120124.
- B. CDC: [Pandemic Influenza](#)
- C. CDC: [National Pandemic Strategy | Pandemic Flu | CDC](#)
- D. CDC: [Community Mitigation Guidelines to Prevent Pandemic Influenza – United States, 2017](#)
- E. CDC: [Preventing Transmission of Viral Respiratory Pathogens in Healthcare Settings](#)
- F. CDC: [Conserving Supplies of Personal Protective Equipment in Healthcare Facilities during Shortages](#)
- G. CDC: [CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings](#)
- H. CDC: [Environmental Infection Control Guidelines](#)
- I. SVHMC Plans and Policies:
 1. [Aerosol Transmitted Diseases Exposure Control Plan](#)

- 2. [Aerosol Transmissible Pathogens - Pathology](#)
- 3. [Isolation - Standard and Transmission Based Precautions](#)
- 4. [Patient Room Cleaning - Discharge/Transfer](#)
- 5. [Medical Equipment Care, Cleaning and Maintenance](#)
- 6. [Outbreak Investigation](#)
- 7. [Emergency Management Program Plan](#)
- 8. [Infection Prevention Pandemic Plan Emerging Infectious Diseases](#)
- 9. [Employees Exposures & Prevention Plans: Specific Disease Exposures and Work Restrictions](#)

Approval Signatures

Step Description	Approver	Date
Board	Kathryn Haines: Administrative Assistant - PD	Pending
Board	Rebecca Alaga: Regulatory/ Accreditation Coordinator	Pending
MEC	Katherine DeSalvo: Director Medical Staff Services	10/2025
P&T/IP Committee	Genevieve delos Santos: Director Pharmacy	09/2025
P&T/IP Committee	Kiri Golleher: Pharmacy Clinical Coordinator	09/2025
Emergency Management	James Hively: Manager Environmental Health & Safety	07/2025
Policy Committees	Rebecca Alaga: Regulatory/ Accreditation Coordinator	07/2025
Policy Owner	Melissa Deen: Manager Infection Prevention	07/2025

Standards

No standards are associated with this document

BOARD EDUCATION

(VERBAL)

GARY RAY, CLO

ADJOURNMENT