

May 20, 2021

### **TO:** Members of the Board of Directors

Victor Rey, Jr. – President Regina M. Gage – Vice President Juan Cabrera – Secretary Richard Turner – Treasurer Joel Hernandez Laguna – Assistant Treasurer

Legal Counsel Ottone Leach & Ray LLP

News Media Salinas Californian Monterey County Herald El Sol Monterey County Weekly KION-TV KSBW-TV/ABC Central Coast KSMS/Entravision-TV

The Regular Meeting of the Board of Directors of the Salinas Valley Memorial Healthcare System will be held <u>THURSDAY, MAY 27, 2021, AT 4:00 P.M., IN THE DOWNING</u> <u>RESOURCE CENTER, ROOMS A, B & C AT SALINAS VALLEY MEMORIAL</u> <u>HOSPITAL, 450 E. ROMIE LANE, SALINAS, CALIFORNIA, OR BY PHONE OR</u> <u>VIDEO (Visit symh.com/virtualboardmeeting for Access Information)</u>.

<u>Please note:</u> Pursuant to Executive Order N-25-20 issued by the Governor of the State of California in response to concerns regarding COVID-19, Board Members of Salinas Valley Memorial Healthcare System, a local health care district, are permitted to participate in this duly noticed public meeting via teleconference and certain requirements of The Brown Act are suspended.

Pete Delgado President/Chief Executive Officer

# **REGULAR MEETING OF THE BOARD OF DIRECTORS SALINAS VALLEY MEMORIAL HEALTHCARE SYSTEM**

### THURSDAY, MAY 27, 2021 4:00 P.M. – DOWNING RESOURCE CENTER, ROOMS A, B & C SALINAS VALLEY MEMORIAL HOSPITAL 450 E. ROMIE LANE, SALINAS, CALIFORNIA OR BY PHONE OR VIDEO

(Visit symh.com/virtualboardmeeting for Access Information)

<u>Please note:</u> Pursuant to Executive Order N-25-20 issued by the Governor of the State of California in response to concerns regarding COVID-19, Board Members of Salinas Valley Memorial Healthcare System, a local health care district, are permitted to participate in this duly noticed public meeting via teleconference and certain requirements of The Brown Act are suspended.

		AGENDA	Presented By
I.	<u>Call</u>	to Order/Roll Call	Victor Rey, Jr.
II.	<u>Clos</u>	ed Session (See Attached Closed Session Sheet Information)	Victor Rey, Jr.
III.	Reco	onvene Open Session/Closed Session Report (Estimated time 5:00 pm)	Victor Rey, Jr.
IV.	<u>Rep</u>	ort from the President/Chief Executive Officer	Pete Delgado
V.	<u>Publ</u>	<u>lic Input</u>	Victor Rey, Jr.
	not to	pportunity is provided for members of the public to make a brief statement, exceed three (3) minutes, on issues or concerns within the jurisdiction of this ct Board which are not otherwise covered under an item on this agenda.	
VI.	<u>Boar</u>	rd Member Comments	Board Members
VII.		sent Agenda—General Business and Member may pull an item from the Consent Agenda for discussion.)	Victor Rey, Jr.
	A.	Minutes of the Regular Meeting of the Board of Directors, April 29, 2021	
	B.	Financial Report	
	C.	Statistical Report	
	D.	Policies Requiring Board Approval	
		1. Emergency Codes for SVMH	
		2. Medical Device Alarm Safety and Management	
		3. ATP (Adenosine Triphosphate Bioluminescence) Monitoring System for Manual Cleaning of Flexible Endoscopes	
		4. Surgical Smoke	

- 5. Intra-Aortic Balloon Pump (IABP) Management
- 6. IV to PO Protocol
- 7. Administration of Investigational Medications in Clinical Research
- Board President Report
- Board Questions to Board President/Staff
- ➢ Motion/Second
- Public Comment
- Board Discussion/Deliberation
- Action by Board/Roll Call Vote

# VIII. Reports on Standing and Special Committees

A.	<b>Quality and Efficient Practices Committee</b> - Minutes from the May 24, 2021 Quality and Efficient Practices Committee meeting have been provided to the Board. Additional Report from Committee Chair, if any.	Juan Cabrera
B.	<b>Finance Committee</b> - Minutes from the May 24, 2021 Finance Committee meeting have been provided to the Board. Two proposed recommendations have been made to the Board.	Richard Turner
	<ol> <li>Recommend Board Approval of Project Funding for the SVMHS Retail Pharmacy Project         <ul> <li>Committee Chair Report</li> <li>Board Questions to Committee Chair/Staff</li> <li>Motion/Second</li> <li>Public Comment</li> <li>Board Discussion/Deliberation</li> <li>Action by Board/Roll Call Vote</li> </ul> </li> <li>Recommend Board Approval of Fiscal Year 2022 Operating and Capital Budget         <ul> <li>Committee Chair Report</li> <li>Board Questions to Committee Chair/Staff</li> </ul> </li> </ol>	
	<ul> <li>Public Comment</li> <li>Board Discussion/Deliberation</li> <li>Action by Board/Roll Call Vote</li> </ul>	
C.	<b>Community Advocacy Committee</b> – Minutes from the May 25, 2021 Community Advocacy Committee have been provided to the Board. Additional Report from Committee Chair, if any.	Regina M. Gage
Me	port on Behalf of the Medical Executive Committee (MEC) eting of May 13, 2021, and Recommendations for Board proval of the following:	Rachel McCarthy Beck, M.D.

A. From the Credentials Committee:

IX.

1. Credentials Committee Report

- 1. Interdisciplinary Practice Committee Report
- C. Rules and Regulations
  - 1. Ongoing Professional Practice Evaluation (OPPE) Policy Amendment
  - 2. Telemedicine Credentialing Policy Amendment
- Chief of Staff Report
- Board Questions to Chief of Staff
- ➢ Motion/Second
- Public Comment
- Board Discussion/Deliberation
- Action by Board/Roll Call Vote

### X. <u>Extended Closed Session (if necessary)</u> (See Attached Closed Session Sheet Information)

Victor Rey, Jr.

XI. <u>Adjournment</u> – The next Regular Meeting of the Board of Directors is scheduled for Thursday, June 24, 2021, at 4:00 p.m.

The complete Board packet including subsequently distributed materials and presentations is available at the Board Meeting and in the Human Resources Department of the District. All items appearing on the agenda are subject to action by the Board. Staff and Committee recommendations are subject to change by the Board.

<u>Notes</u>: Requests for a disability related modification or accommodation, including auxiliary aids or services, in order to attend or participate in a meeting should be made to the Executive Assistant during regular business hours at 831-755-0741. Notification received 48 hours before the meeting will enable the District to make reasonable accommodations.

### SALINAS VALLEY MEMORIAL HEALTHCARE SYSTEM BOARD OF DIRECTORS 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**

### LICENSE/PERMIT DETERMINATION [] (Government Code §54956.7)

Applicant(s): (Specify number of applicants)

### **CONFERENCE WITH REAL PROPERTY NEGOTIATORS** [] (Government Code §54956.8)

**Property:** (Specify street address, or if no street address, the parcel number or other unique reference, of the real property under negotiation):

Agency negotiator: (Specify names of negotiators attending the closed session):

**Negotiating parties**: (Specify name of party (not agent):\_\_\_\_\_ **Under negotiation:** (Specify whether instruction to negotiator will concern price, terms of payment, or both):\_\_\_

### **CONFERENCE WITH LEGAL COUNSEL-EXISTING LITIGATION** []

(Government Code §54956.9(d)(1))

**Name of case:** (Specify by reference to claimant's name, names of parties, case or claim numbers):

Case name unspecified: (Specify whether disclosure would jeopardize service of process or existing settlement negotiations):

### **CONFERENCE WITH LEGAL COUNSEL-ANTICIPATED LITIGATION** [] (Government Code §54956.9)

Significant exposure to litigation pursuant to Section 54956.9(d)(2) or (3) (Number of potential cases):

Additional information required pursuant to Section 54956.9(e):

Initiation of litigation pursuant to Section 54956.9(d)(4) (Number of potential cases):

### [] LIABILITY CLAIMS

(Government Code §54956.95)

Claimant: (Specify name unless unspecified pursuant to Section 54961):

# Agency claimed against: (Specify name):

### [] <u>THREAT TO PUBLIC SERVICES OR FACILITIES</u> (Government Code §54957)

Consultation with: (Specify name of law enforcement agency and title of officer):

### [] <u>PUBLIC EMPLOYEE APPOINTMENT</u>

(Government Code §54957)

Title: (Specify description of position to be filled):

### [] <u>PUBLIC EMPLOYMENT</u>

(Government Code §54957)

Title: (Specify description of position to be filled):

### [] <u>PUBLIC EMPLOYEE PERFORMANCE EVALUATION</u> (Government Code §54957)

Title: (Specify position title of employee being reviewed):

### [] <u>PUBLIC EMPLOYEE DISCIPLINE/DISMISSAL/RELEASE</u> (Government Code \$5/4957)

(Government Code §54957)

(No additional information is required in connection with a closed session to consider discipline, dismissal, or release of a public employee. Discipline includes potential reduction of compensation.)

# [] <u>CONFERENCE WITH LABOR NEGOTIATOR</u>

(Government Code §54957.6)

Agency designated representative: (Specify name of designated representatives attending the closed session):\_

**Employee organization**: (Specify name of organization representing employee or employees in question):

\_\_\_\_\_, or

**Unrepresented employee**: (Specify position title of unrepresented employee who is the subject of the negotiations):

### []] <u>CASE REVIEW/PLANNING</u> (Government Code §54957.8)

(No additional information is required to consider case review or planning.)

### [X] <u>REPORT INVOLVING TRADE SECRET</u>

(Government Code §37606 & Health and Safety Code § 32106)

**Discussion will concern**: (Specify whether discussion will concern proposed new service, program, or facility): Strategic planning/proposed new programs and services

Estimated date of public disclosure: (Specify month and year): <u>unknown</u>

### [X] <u>HEARINGS/REPORTS</u>

(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. Report of the Medical Staff Quality and Safety Committee
- 2. Report of the Medical Staff Credentials Committee
- 3. Report of the Interdisciplinary Practice Committee

### [] <u>CHARGE OR COMPLAINT INVOLVING INFORMATION PROTECTED</u> <u>BY FEDERAL LAW</u> (Government Code §54956.86)

(No additional information is required to discuss a charge or complaint pursuant to Section 54956.86.)

### ADJOURN TO OPEN SESSION

# CALL TO ORDER/ROLL CALL (VICTOR REY, JR.)

# CLOSED SESSION

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

(VICTOR REY, JR.)

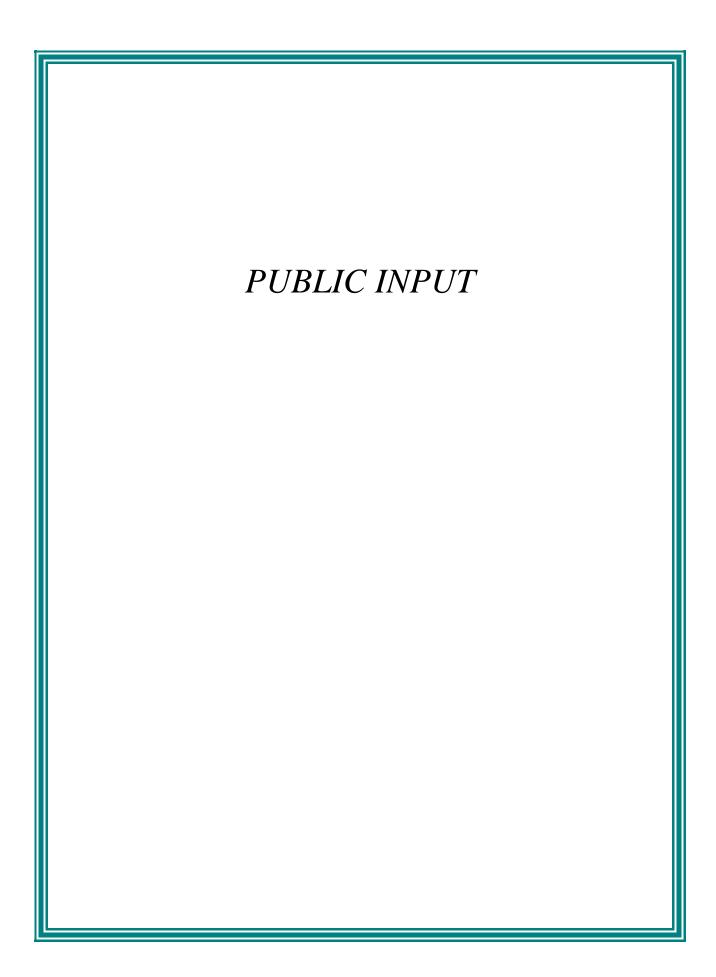
# RECONVENE OPEN SESSION/ CLOSED SESSION REPORT (ESTIMATED TIME: 5:00 P.M.)

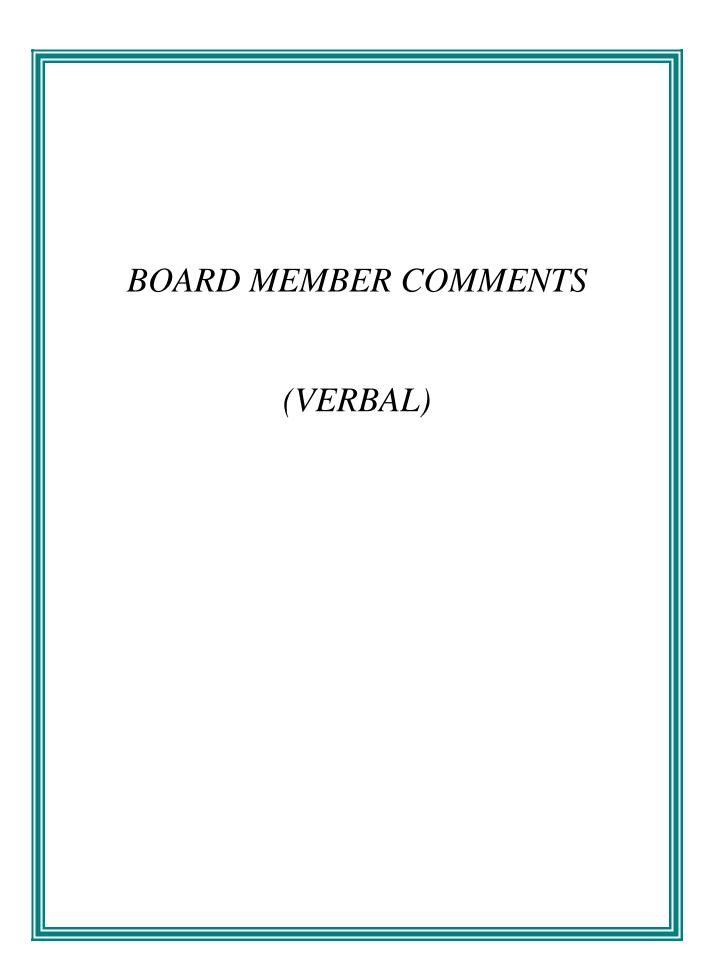
(VICTOR REY, JR.)

# REPORT FROM THE PRESIDENT/ CHIEF EXECUTIVE OFFICER

(VERBAL)

(PETE DELGADO)





### **REGULAR MEETING OF THE BOARD OF DIRECTORS SALINAS VALLEY MEMORIAL HEALTHCARE SYSTEM**

### THURSDAY, APRIL 29, 2021 – 4:00 P.M. DOWNING RESOURCE CENTER, ROOMS A, B & C SALINAS VALLEY MEMORIAL HOSPITAL 450 E. ROMIE LANE, SALINAS, CALIFORNIA AND BY PHONE OR VIDEO (VISIT symh.com/virtualboardmeeting FOR ACCESS INFORMATION)

Pursuant to Executive Order N-25-20 issued by the Governor of the State of California in response to concerns regarding COVID-19, Board Members of Salinas Valley Memorial Healthcare System, a local health care district, are permitted to participate in this duly noticed public meeting via teleconference and certain requirements of The Brown Act are suspended.

<u>Present</u>: President Victor Rey, Jr., Directors Regina M. Gage, Juan Cabrera, Richard Turner and Joel Hernandez Laguna in person.

<u>Also Present</u>: Pete Delgado, President/Chief Executive Officer; Rachel McCarthy Beck, M.D., Chief of Staff, and Matthew Ottone, Esq., District Legal Counsel in person.

A quorum was present and the meeting was called to order by President Victor Rey, Jr, at 4:04 p.m.

### **Closed Session**

President Victor Rey, Jr., announced that the closed session items to be discussed in Closed Session as listed on the posted Agenda are: (1) Liability Claims – one claim; (2) Report Involving Trade Secret – strategic planning/proposed new programs and services; and (3) Hearings/Reports – Report of the Medical Staff Quality and Safety Committee, Report of the Medical Staff Credentials Committee, and Report of the Interdisciplinary Practice Committee.

The meeting was recessed into Closed Session under the Closed Session Protocol at 4:06 p.m. The Board completed its business of the Closed Session at 5:00 p.m.

### **Reconvene Open Session/Report on Closed Session**

The Board reconvened Open Session at 5:05 p.m. President Rey announced that in Closed Session the Board discussed: (1) Liability Claims – one claim; (2) Report Involving Trade Secret - strategic planning/proposed new programs and services; and (3) Hearings/Reports – Report of the Medical Staff Quality and Safety Committee, Report of the Medical Staff Credentials Committee, and Report of the Interdisciplinary Practice Committee. In Closed Session, the Board received and accepted the Medical Staff Quality and Safety Committee Report. The Board also reviewed the claim of Adriel De Jesus Cruz, and granted leave to file a late claim and rejected the claim. No other action was taken by the Board.

Mr. Rey stated that Closed Session has not been completed and will reconvene after completion of the open session portion of the meeting to discuss the remaining item.

### **Report from the President/Chief Executive Officer (CEO)**

The President/CEO's Report by Pete Delgado, President/CEO, members of Hospital Leadership and others, began with a Mission Moment featuring SVMHS Chaplain Chriss Peterson. A summary of key highlights, centered around the pillars that are the foundation of the Hospital's vision for the organization, is as follows:

- ➢ Quality
  - SVMHS received a 4 Star Rating from the Centers for Medicare and Medicaid Services, and an "A" rating from The Leapfrog Group, a national organization.
  - The Joint Commission conducted a survey of the Hospital on April 20-23, 2021.
  - Pediatrics Unit Practice Council (PUPC) Members Pam Yates, Co-Chair; and Necole Olivio presented the following areas of focus:
    - ✓ Health-Protect-Empower-Teach (common medications for pediatric patients)
    - ✓ Changes to Admission History vaping query; and safe/co-sleeping
- ➢ Growth
  - A two-day Star Excellence Institute was held in April with Hospital Leadership focused on strategic planning and continued growth of the organization.
- ➢ Finance
  - Industry News
    - 9 hospitals laying off workers
    - o 6 hospital mergers called off in past year
    - Google developing new consumer-facing health records tool: 7 things to know
    - 5 latest hospital credit rating downgrades
    - Rennova reports late payroll, cash deficiencies
  - Legislative activities at the state and federal levels were reviewed.
- ➢ Service
  - Salinas Valley Medical Clinic has administered more than 37,987 vaccines to the community.
  - SVMHS is opening visitation.
- ➢ People
  - The Employee Engagement Survey is underway.
  - Volunteers were celebrated during National Volunteer Week for their critical role to the success of SVMHS.
- ➢ Community
  - SVMHS is a long-time sponsor of the American Cancer Society's Celebration of Life. This year's celebration honored Shirley Lavorato and was emceed by Karina Rusk, SVMHS Director of Public Relations.
  - Ask the Experts Facebook Live events:
    - Nicolas Kissell, MD and Mirella Lopez, RD, CDE; Topic: Preventing and Living with Diabetes – March 31, 2021
    - Chef Arturo Salazar; Spanish-language Cooking Demonstration April 21, 2021
  - Earned Media included COVID vaccinations, Doctor's Day, and National Volunteer Week.
  - Coming Up:
    - Hospital Week: May 10

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- SVMHS Farmers' Market, Friday, MRI Parking Lot, 12:30–5:30 pm: Starting May 14
- Tribute to Norm Nelson, MD, 5–6:30 pm: June 2
- SVMHS Picnic, 11am–5 pm: June 19

There was brief discussion among the Board and staff regarding the areas of focus of the Pediatrics Unit Practice Council and outstanding work.

### <u>Public Input</u>

An opportunity was provided for persons in the audience to make a brief statement, not to exceed three (3) minutes, on issues or concerns not covered by the agenda.

None.

### **Board Member Comments**

Director Richard Turner commended Executive Leadership for their continued excellent work.

Director Juan Cabrera commented on the excellent training and information he received at the Governance Institute Leadership Conference, and how SVMHS is on the forefront of healthcare strategies and initiatives

Director Joel Hernandez Laguna commended the team for the efforts to launch the Facebook Live Ask the Experts events of which he has received many excellent comments, including the Spanish-language Cooking Demonstration in April. He congratulated the organization for the 4 Star Rating received from the Centers for Medicare and Medicaid Services, and thanked the Emergency Department for the quality patient care services provided to a family member. Director Hernandez Laguna also commented on the desire to learn more about the fee-for-service and value-based payment models.

Director Regina Gage thanked everyone for the continued excellence, and commented on the outstanding speakers at The Governance Institute Conference in April.

### <u>Consent Agenda – General Business</u>

- A. Minutes of the Regular Meeting of the Board of Directors, March 25, 2021
- B. Financial Report
- C. Statistical Report
- D. Policies Requiring Board Approval
  - 1. Standards of Ethical Business Practices
  - 2. Community Funding
  - 3. Emergency Management for Mass Casualty Incidents
  - 4. Endoscope Handling, Reprocessing and Storing
  - 5. Scope of Service: Respiratory, Neurodiagnostics and Sleep Medicine

- 6. Scope of Service: Outpatient Infusion
- 7. RC POCT Laboratory Safety/Chemical Hygiene Plan
- 8. Healthcare Worker Respiratory Protection Program
- 9. Influenza Pandemic Plan
- 10. Requesting a Bioethics Case Conference Procedure
- 11. Laboratory Education, Staff Development and Feedback
- 12. Admission and Shift Assessment of the Pediatric Patient

Mr. Rey presented the consent agenda items before the Board for action. This information was included in the Board packet.

No Public Comment.

<u>MOTION</u>: The Board of Directors approves Consent Agenda – General Business, Items (A) through (D), as presented. Moved/Seconded/Roll Call Vote: Ayes: Rey, Gage, Cabrera, Turner, Hernandez Laguna; Noes: None; Abstentions: None; Absent: None; Motion Carried.

### **Reports on Standing and Special Committees**

### **<u>Quality and Efficient Practices Committee</u>**

Juan Cabrera, Committee Chair, reported the minutes from the Quality and Efficient Practices Committee Meeting of April 26, 2021, were provided to the Board. The Committee received a Patient Care Services Update and Financial and Statistical Review. No action was taken by the Committee.

### Finance Committee

Richard Turner, Committee Chair, reported the minutes from the Finance Committee Meeting of April 26, 2021, were provided to the Board. Background information supporting the proposed recommendations made by the Committee was included in the Board packet and summarized by Director Turner.

1. <u>Recommend to Board of Directors to Adopt the Initial Study and the Mitigated Negative</u> Declaration and Approve the Mitigation Monitoring and Reporting Program for the Downing Resource Center Parking Garage Annex and Ancillary Improvements

Mr. Turner noted that this recommendation will be considered under Board Agenda Item IX. – Public Hearing to Consider the Adoption of the Initial Study and Mitigated Negative Declaration and Approval of the Mitigation Monitoring and Reporting Program for the Downing Resource Center Parking Garage Annex and Ancillary Improvements.

2. <u>Recommend Board Approval of the Three-Year Licensing and Support Agreement</u> <u>Renewal of DrFirst as Sole Source Justification and Contract Award</u>

No Public Comment.

<u>MOTION</u>: The Board of Directors approves the three-year licensing and support agreement renewal of DrFirst as sole source justification and contract award in the amount of \$484,335 over the three-year term, as presented. Moved/Seconded/Roll Call Vote: Ayes: Rey, Gage, Cabrera, Turner, Hernandez Laguna; Noes: None; Abstentions: None; Absent: None; Motion Carried.

### 3. <u>Recommend Board Approval of Lease with the Lugo Family Living Trust for 650 Work</u> <u>Street Suite B Salinas, CA</u>

No Public Comment.

<u>MOTION</u>: The Board of Directors approves the Lease with the Lugo Family Living Trust for 650 Work Street, Suite B, Salinas, California, as presented. Moved/Seconded/ Roll Call Vote: Ayes: Rey, Gage, Cabrera, Turner, Hernandez Laguna; Noes: None; Abstentions: None; Absent: None; Motion Carried.

### Personnel, Pension and Investment Committee

Regina M. Gage, Committee Chair, reported the minutes from the Personnel, Pension and Investment Committee Meeting of April 27, 2021, were provided to the Board. The Committee received a review of the investment performance of SVMHS's General & Board Designated Funds from Graystone Consulting. No action was taken by the Committee.

Director Joel Hernandez Laguna noted his attendance at the Personnel, Pension and Investment Committee Meeting and good report provided by Graystone consulting.

### Transformation, Strategic Planning and Governance Committee

Joel Hernandez Laguna, Committee Chair, reported the minutes from the Transformation, Strategic Planning and Governance Committee Meeting of April 28, 2021, were provided to the Board.

### <u>Public Hearing to Consider the Adoption of the Initial Study and Mitigated Negative</u> <u>Declaration and Approval of the Mitigation Monitoring and Reporting Program for the</u> <u>Downing Resource Center Parking Garage Annex and Ancillary Improvements</u>

Richard Turner, Finance Committee Chair, recommended the Board of Directors make the necessary findings and adopt the Initial Study and Mitigated Negative Declaration and approve the Mitigation Monitoring and Reporting Program for the Downing Resource Center Parking Garage Annex and Ancillary Improvements. This information was presented in the Board packet.

No Public Comment.

Director Joel Hernandez Laguna inquired if this is the application submitted to the City of Salinas for approval. District Legal Counsel responded that as the lead agency for the Downing Resource Center Parking Garage Annex and Ancillary Improvements ("DRC Annex") construction project, the SVMHS Board of Directors is responsible for compliance with the California Environmental Quality Act (CEQA). The SVMHS Board of Directors must adopt the Initial Study and Mitigated Negative Declaration (IS/MND) which is the environmental study, and approve the Mitigation Monitoring and Reporting Program. Following action by the SVMHS Board, the City of Salinas Planning Commission must also consider the adopted IS/MND. This project would then be considered by the SVMHS Board of Directors.

<u>MOTION</u>: The Board of Directors makes the following findings: (i) the proposal is a logical component of the SVMHS campus, consistent with the objectives of the SVMHS Master Plan, and consistent with existing land uses of the immediate project area; (ii) identified adverse impacts are proposed to be mitigated by construction best practices, pre-construction surveys and other standard conditions as identified in the Initial Study; (iii) the proposed project is consistent with the adopted goals, policies and land uses of the City of Salinas General Plan and Municipal Code; and (iv) with the application of mitigation measures, the proposed project will not have any significant impacts on the environment; and further, adopts the Initial Study and Mitigated Negative Declaration and approves the Mitigation Monitoring and Reporting Program for the Downing Resource Center Parking Garage Annex and Ancillary Improvements, as presented. Moved/Seconded/Roll Call Vote: Ayes: Rey, Gage, Cabrera, Turner, Hernandez Laguna; Noes: None; Abstentions: None; Absent: None; Motion Carried.

### Consider Resolution No. 2021-02 Setting General Prevailing Wage Rates

Matthew Ottone, Esq., District Legal Counsel, reported that <u>Resolution No. 2021-02 Setting</u> <u>General Prevailing Wage Rates</u>, for the Board's consideration, was included in the Board packet. California law requires the System to make available to contractors prevailing wage rates issued by the Department of Industrial Relations for public works projects. Resolution No. 2021-02 adopts the most recent prevailing wage rates which are available for review in the office of the President/Chief Executive Officer of the District and project job sites.

No Public Comment.

<u>MOTION</u>: The Board of Directors adopts <u>Resolution No. 2021-02 Setting General</u> <u>Prevailing Wage Rates</u>, as presented. Moved/Seconded/Roll Call Vote: Ayes: Rey, Gage, Cabrera, Turner, Hernandez Laguna; Noes: None; Abstentions: None; Absent: None; Motion Carried.

### <u>Report on Behalf of the Medical Executive Committee (MEC) Meeting of April 8, 2021,</u> and Recommendations for Board Approval of the following:

The following recommendations from the Medical Executive Committee (MEC) Meeting of April 8, 2021, were reviewed by Rachel McCarthy Beck, M.D., Chief of Staff, and recommended for Board approval.

### Recommend Board Approval of the Following:

- A. From the Credentials Committee:
  - 1. Credentials Committee Report
- B. From the Interdisciplinary Practice Committee:
- 1. Interdisciplinary Practice Committee Report
- C. Policies
  - 1. Antimicrobial Stewardship Plan

No Public Comment.

Dr. Beck noted that the Medical Staff was proud of the performance of the hospital staff and medical staff during the recent survey by The Joint Commission and was proud to be part of the process. Dr. Beck also commented on the importance of the COVID-vaccine.

There was brief discussion among the Board, Executive Leadership, and Dr. Beck regarding the COVID-vaccine.

<u>MOTION</u>: The Board of Directors approves Recommendations (A) through (C) of the April 8, 2021, Medical Executive Committee Meeting, as presented. Moved/Seconded/ Roll Call Vote: Ayes: Rey, Gage, Cabrera, Turner, Hernandez Laguna; Noes: None; Abstentions: None; Abstenti. None; Motion Carried.

### Extended Closed Session

Mr. Rey noted that the item to be discussed in the Extended Closed Session is Report Involving Trade Secret - strategic planning/proposed new programs and services. The meeting was recessed into the Extended Closed Session at 6:13 p.m.

The Board reconvened Open Session at 6:51 p.m. Mr. Rey announced that the item discussed in Closed Session was Report Involving Trade Secret - strategic planning/proposed new programs and services. There was no action taken in the Closed Session.

<u>Adjournment</u> – The next Regular Meeting of the Board of Directors is scheduled for <u>Thursday</u>, <u>May 27, 2021, at 4:00 p.m.</u> There being no further business, the meeting was adjourned at 6:52 p.m.

Juan Cabrera Secretary, Board of Directors

/ks

### SALINAS VALLEY MEMORIAL HOSPITAL SUMMARY INCOME STATEMENT April 30, 2021

		Month of Ap	ril,	Ten months ended	April 30,
	-	current year	prior year	current year	prior year
Operating revenue: Net patient revenue Other operating revenue	\$	38,023,958 \$ 984,136	46,094,423 11,383,400	\$  473,326,514 \$ 11,839,162	476,095,738 22,735,888
Total operating revenue	•	39,008,094	57,477,823	485,165,676	498,831,626
Total operating expenses		37,767,175	37,194,223	409,492,349	388,062,977
Total non-operating income	-	169,535	327,862	(26,282,400)	(13,179,796)
Operating and non-operating income	\$	1,410,454_\$	20,611,462	\$\$\$	97,588,854

### SALINAS VALLEY MEMORIAL HOSPITAL BALANCE SHEETS April 30, 2021

	_	Current year	 Prior year
ASSETS:			
Current assets Assets whose use is limited or restricted by board Capital assets Other assets Deferred pension outflows	\$	410,604,300 141,155,312 251,757,480 192,703,438 83,379,890	\$ 372,593,795 127,184,754 256,153,130 186,341,739 62,468,517
	\$_	1,079,600,420	\$ 1,004,741,935
LIABILITIES AND EQUITY:			
Current liabilities Long term liabilities Net assets	-	143,281,283 14,780,976 126,340,336 795,197,825 1,079,600,420	 147,609,915 16,189,004 108,929,468 732,013,548 1,004,741,935

### SALINAS VALLEY MEMORIAL HOSPITAL SCHEDULES OF NET PATIENT REVENUE April 30, 2021

		Month of April,		Ten months ended Ap		April 30,	
	-	current year		prior year	current year		prior year
Patient days:							
By payer:							
Medicare		1,720		1,381	17,092		18,478
Medi-Cal		1,003		1,064	10,513		10,756
Commercial insurance		463		761	7,581		8,068
Other patient		82		32	1,221		1,095
Total patient days	-	3,268		3,238	36,407		38,397
Gross revenue:							
Medicare	\$	02 604 196	¢	65 5 40 95 A (	007 660 007	¢	925 060 169
Medicale	Φ	92,604,186 55,220,953	φ	65,540,854 \$ 45,046,155	837,662,927 533,244,531	φ	835,069,168 523,649,976
Commercial insurance		40,095,134		40,893,525	478,737,208		473,308,666
Other patient		9,040,889		3,651,680	83,415,984		79,643,774
	-	9,040,009		3,031,000	03,413,904		79,043,774
Gross revenue	-	196,961,162		155,132,214	1,933,060,650		1,911,671,584
Deductions from revenue:							
Administrative adjustment		350,266		219,510	3,303,702		3,600,193
Charity care		1,454,212		555,119	10,201,070		9,171,026
Contractual adjustments:							
Medicare outpatient		28,465,111		18,325,300	246,421,490		249,854,164
Medicare inpatient		37,283,623		29,284,065	372,816,155		388,015,512
Medi-Cal traditional outpatient		2,661,545		1,941,269	21,076,259		28,270,667
Medi-Cal traditional inpatient		4,349,427		8,676,794	70,669,624		63,588,096
Medi-Cal managed care outpatient		21,625,200		11,546,157	183,390,354		195,690,124
Medi-Cal managed care inpatient		21,225,579		9,474,633	186,646,017		166,541,819
Commercial insurance outpatient		19,151,873		12,334,998	158,712,331		143,678,154
Commercial insurance inpatient		17,739,136		14,777,633	161,890,141		144,090,333
Uncollectible accounts expense		3,889,018		2,617,483	35,670,540		33,761,892
Other payors	-	742,214		(715,171)	8,936,453		9,313,864
Deductions from revenue	-	158,937,204		109,037,791	1,459,734,136		1,435,575,846
Net patient revenue	\$	38,023,958	\$	46,094,423 \$	473,326,514	\$	476,095,738
	=						
Gross billed charges by patient type:							
Inpatient	\$	99,760,333	\$		1,065,771,045	\$	1,025,350,565
Outpatient		74,245,737		49,946,401	656,073,575		635,907,559
Emergency room	-	22,955,090		14,514,150	211,216,030		250,413,460
Total	\$	196,961,160	_\$_	155,132,214 \$	1,933,060,650	\$	1,911,671,584

### SALINAS VALLEY MEMORIAL HOSPITAL STATEMENTS OF REVENUE AND EXPENSES April 30, 2021

		Month of Ap	oril,	Ten months ended A	pril 30,
		current year	prior year	current year	prior year
Operating revenue:	\$	20 022 0E0 ¢	46 004 433 ¢	472 226 E14 ¢	476 005 729
Net patient revenue Other operating revenue	Ф	38,023,958 \$ 984,136	46,094,423 \$ 11,383,400	473,326,514 \$ 11,839,162	476,095,738 22,735,888
Total operating revenue		39,008,094	57,477,823	485,165,676	498,831,626
Total operating revenue		39,000,094	57,477,025	400,100,070	490,031,020
Operating expenses:					
Salaries and wages		14,728,428	14,035,384	157,699,250	145,894,157
Compensated absences		2,933,549	3,046,476	26,509,506	26,412,643
Employee benefits		7,428,676	5,374,048	72,783,553	71,728,580
Supplies, food, and linen		6,226,309	5,740,656	62,019,123	57,109,778
Purchased department functions		3,953,150	3,196,180	32,513,734	30,764,232
Medical fees		(2,326,614)	1,933,235	13,263,607	17,341,404
Other fees		1,572,439	1,007,829	14,692,076	10,463,954
Depreciation		1,825,421	1,739,797	17,926,148	16,962,312
All other expense		1,425,817	1,120,618	12,085,352	11,385,917
Total operating expenses		37,767,175	37,194,223	409,492,349	388,062,977
Income from operations		1,240,919	20,283,600	75,673,327	110,768,649
Non-operating income:					
Donations		166,667	166,667	2,166,667	1,670,867
Property taxes		333,333	333,333	3,333,333	3,333,333
Investment income		2,793,943	1,153,096	2,934,168	4,851,281
Taxes and licenses		0	(29,074)	0	(29,074)
Income from subsidiaries		(3,124,408)	(1,296,160)	(34,716,568)	(23,006,203)
Total non-operating income		169,535	327,862	(26,282,400)	(13,179,796)
Operating and non-operating income		1,410,454	20,611,462	49,390,927	97,588,854
Net assets to begin		793,787,372	711,402,085	745,806,898	634,424,694
Net assets to end	\$	795,197,825 \$	732,013,548 \$	795,197,825 \$	732,013,548
Net income excluding non-recurring items Non-recurring income (expense) from cost	\$	1,410,454 \$	14,010,030 \$	41,609,783 \$	90,757,048
report settlements and re-openings and other non-recurring items		0	6,601,432	7,781,144	6,831,806

### SALINAS VALLEY MEMORIAL HOSPITAL SCHEDULES OF INVESTMENT INCOME April 30, 2021

		Month of Ann		Ten months ended April 30,			
		Month of Apr current year	prior year	current year	pril 30, prior year		
	_		1 7 7 1		1 7 7 7		
Detail of other operating income:							
Dietary revenue	\$	129,968 \$	55,166 \$	1,326,455 \$	1,571,560		
Discounts and scrap sale		15,559	952	770,777	1,375,915		
Sale of products and services		141,281	7,686	320,371	134,433		
Clinical trial fees		7,282	0	109,426	0		
Stimulus Funds		0	10,941,377	0	10,941,377		
Rental income		152,065	137,694	1,595,685	1,427,967		
Other	_	537,981	240,525	7,716,448	7,284,636		
Total	\$_	984,136_\$	11,383,400 \$	11,839,162 \$	22,735,888		
Detail of investment income:							
Bank and payor interest	\$	90,102 \$	235,719 \$	1,160,273 \$	2,436,129		
Income from investments	Ψ	(474,094)	917,377	(1,442,533)	2,408,496		
Gain or loss on property and equipment	_	3,177,935	0	3,216,429	2,400,450 6,657		
Total	\$	2,793,943 \$	1,153,096 \$	2,934,168 \$	4,851,281		
	.=	<u>,</u> , .	, , , .		,,		
Detail of income from subsidiaries:							
Salinas Valley Medical Center:	•						
Pulmonary Medicine Center	\$	(111,611) \$	1,946,784 \$	, .	286,597		
Neurological Clinic		(179,365)	(66,322)	(795,041)	(712,399)		
Palliative Care Clinic		(97,409)	(40,195)	(783,339)	(547,249)		
Surgery Clinic		(202,085)	(14,731)	(1,702,499)	(1,055,021)		
Infectious Disease Clinic		(10,602)	(37,824)	(270,088)	(262,885)		
Endocrinology Clinic		(154,951)	(174,512)	(1,758,812)	(1,433,008)		
Early Discharge Clinic		0	0	0	0		
Cardiology Clinic		(530,408)	(501,921)	(4,816,947)	(4,430,997)		
OB/GYN Clinic		(470,386)	(124,613)	(3,577,435)	(1,825,984)		
PrimeCare Medical Group		(983,978)	(928,558)	(8,651,433)	(6,295,099)		
Oncology Clinic		(201,742)	(319,115)	(2,667,006)	(2,273,349)		
Cardiac Surgery		(172,771)	(130,944)	(1,638,223)	(1,102,196)		
Sleep Center		(62,888)	(69,676)	(579,583)	(730,538)		
Rheumatology		(82,760)	(101,556)	(537,205)	(303,260)		
Precision Ortho MDs		458,487	(418,237)	(2,827,312)	(2,866,702)		
Precision Ortho-MRI		78	(9,084)	(1,492)	(19,762)		
Precision Ortho-PT		(51,248)	(49,471)	(490,589)	(98,965)		
Dermatology		(27,014)	(9,042)	(304,373)	(163)		
Hospitalists		0	0	0	0		
Behavioral Health		(78,949)	(54,474)	(753,354)	(505,840)		
Pediatric Diabetes		(29,766)	(41,359)	(335,569)	(325,676)		
Neurosurgery		4,443	(25,047)	(255,618)	(197,926)		
Multi-Specialty-RR		11,300	(8,060)	45,611	107,166		
Radiology		(238,292)	0	(1,994,263)	0		
Salinas Family Practice		(16,529)	0	(30,511)	0		
Total SVMC		(3,228,446)	(1,177,956)	(36,516,521)	(24,593,256)		
Doctors on Duty		69,000	(389,532)	196,825	(56,808)		
Assisted Living		(4,685)	(9,614)	(66,031)	(57,836)		
Salinas Valley Imaging		0	15,674	(19,974)	35,578		
Vantage Surgery Center		33,310	(29,478)	210,071	133,937		
LPCH NICU JV		0	0	0	0		
Central Coast Health Connect		0	0	0	0		
Monterey Peninsula Surgery Center		256,805	(84,476)	1,049,476	1,130,491		
Aspire/CHI/Coastal		(308,966)	292,487	(369,545)	(117,756)		
Apex		(583)	(63,314)	69,948	46,564		
21st Century Oncology		6,713	148,273	(49,803)	308,131		
Monterey Bay Endoscopy Center		52,443	1,777	778,986	164,752		
Total	\$_	(3,124,408) \$	(1,296,160) \$	(34,716,568) \$	(23,006,203)		

### SALINAS VALLEY MEMORIAL HOSPITAL BALANCE SHEETS April 30, 2021

		Current year	Prior year
ASSETS	_		
Current assets:			
Cash and cash equivalents	\$	319,601,383 \$	5 293,279,167
Patient accounts receivable, net of estimated			
uncollectibles of \$19,179,565		73,262,199	63,426,231
Supplies inventory at cost Other current assets		8,354,961 9,385,757	7,402,360 8,486,038
	-	5,505,757	0,400,000
Total current assets	_	410,604,300	372,593,795
Assets whose use is limited or restricted by board	_	141,155,312	127,184,754
Capital assets:			
Land and construction in process		41,211,080	65,007,168
Other capital assets, net of depreciation	_	210,546,400	191,145,963
Total capital assets	_	251,757,480	256,153,130
Other assets:			
Investment in Securities		148,333,295	145,674,324
Investment in SVMC		10,907,131	11,570,317
Investment in Aspire/CHI/Coastal		4,264,404	4,766,439
Investment in other affiliates		24,897,312	21,285,626
Net pension asset	_	4,301,296	3,045,033
Total other assets	_	192,703,438	186,341,739
Deferred pension outflows	_	83,379,890	62,468,517
	\$	1,079,600,420 \$	5 1,004,741,935
LIABILITIES AND NETASSETS	=		
Current liabilities:	۴	50 440 000 @	54 0 47 000
Accounts payable and accrued expenses	\$	52,118,232 \$	
Due to third party payers Current portion of self-insurance liability		73,745,527 17,417,524	75,840,874 16,922,002
Current portion of sen-insurance hability	-	17,417,524	10,922,002
Total current liabilities		143,281,283	147,609,915
Long term portion of workers comp liability	_	14,780,976	16,189,004
Total liabilities	_	158,062,259	163,798,919
Pension liability	_	126,340,336	108,929,468
Net assets:			
Invested in capital assets, net of related debt		251,757,480	256,153,130
Unrestricted		543,440,345	475,860,418
Total net assets	-	795,197,825	732,013,548
	-	100,101,020	102,010,040
	\$_	1,079,600,420 \$	1,004,741,935

### SALINAS VALLEY MEMORIAL HOSPITAL STATEMENTS OF REVENUE AND EXPENSES - BUDGET VS. ACTUAL April 30, 2021

		Mont	h of April,		Ten months ended April 30,				
	Actual	Budget	Variance	% Var	Actual	Budget	Variance	% Var	
Operating revenue:									
	\$ 196,961,162	\$ 187 590 865	9,370,297	5.00% \$	1,933,060,650 \$	5 1,714,004,566	219,056,084	12.78%	
Dedutions from revenue	158,937,204	143,177,208	15,759,996	11.01%	1,459,734,136	1,302,285,851	157,448,285	12.09%	
Net patient revenue	38,023,958	44,413,658	(6,389,700)	-14.39%	473,326,514	411,718,715	61,607,799	14.96%	
Other operating revenue	984,136	919,590	64,546	7.02%	11,839,162	9,195,896	2,643,266	28.74%	
Total operating revenue	39,008,094	45,333,247	(6,325,153)	-13.95%	485,165,676	420,914,610	64,251,066	15.26%	
Operating expenses: Salaries and wages Compensated absences Employee benefits Supplies, food, and linen Purchased department functions Medical fees Other fees Depreciation All other expense	14,728,428 2,933,549 7,428,676 6,226,309 3,953,150 (2,326,614) 1,572,439 1,825,421 1,425,817	15,094,242 2,332,342 7,899,753 5,321,989 3,115,228 1,678,265 824,350 1,789,255 1,387,859	(365,814) 601,207 (471,077) 904,320 837,922 (4,004,879) 748,089 36,166 37,958	-2.42% 25.78% -5.96% 16.99% 26.90% -238.63% 90.75% 2.02% 2.73%	157,699,250 26,509,506 72,783,553 62,019,123 32,513,734 13,263,607 14,692,076 17,926,148 12,085,352	142,249,359 26,579,646 73,915,348 51,074,339 31,093,676 16,950,129 8,442,123 17,892,553 14,021,852	15,449,891 (70,140) (1,131,795) 10,944,784 1,420,058 (3,686,522) 6,249,953 33,595 (1,936,500)	10.86% -0.26% -1.53% 21.43% 4.57% -21.75% 74.03% 0.19% -13.81%	
Total operating expenses	37,767,175	39,443,284	(1,676,109)	-4.25%	409,492,349	382,219,026	27,273,323	7.14%	
Income from operations	1,240,919	5,889,964	(4,649,045)	-78.93%	75,673,327	38,695,585	36,977,742	95.56%	
Non-operating income:									
Donations	166,667	166,667	0	0.00%	2,166,667	1,666,666	500,001	30.00%	
Property taxes	333,333	333,333	(0)	0.00%	3,333,333	3,333,333	(0)	0.00%	
Investment income	2,793,943	160,094	2,633,850	1645.19%	2,934,168	1,600,935	1,333,233	83.28%	
Income from subsidiaries	(3,124,408)	(3,999,365)	874,957	-21.88%	(34,716,568)	(38,544,634)	3,828,066	-9.93%	
Total non-operating income	169,535	(3,339,272)	3,508,807	-105.08%	(26,282,400)	(31,943,699)	5,661,300	-17.72%	
Operating and non-operating income	\$	\$	(1,140,238)	-44.70% \$	49,390,927 \$	6,751,885	42,639,042	631.51%	

	Month of Apr		Ten montl		
	2020	2021	2019-20	2020-21	Variance
NEWBORN STATISTICS					
Medi-Cal Admissions	55	36	455	428	(27)
Other Admissions	112	94	1,091	945	(146)
Total Admissions	167	130	1,546	1,373	(173)
Medi-Cal Patient Days	77	63	728	653	(75)
Other Patient Days	173	142	1,844	1,532	(312)
Total Patient Days of Care	250	205	2,572	2,185	(387)
Average Daily Census	8.3	6.8	8.5	7.2	(1.3)
Medi-Cal Average Days	1.6	1.8	1.7	1.6	(0.1)
Other Average Days	0.7	1.6	1.7	1.6	(0.1)
Total Average Days Stay	1.6	1.6	1.7	1.6	(0.1)
ADULTS & PEDIATRICS					
Medicare Admissions	260	313	3,779	3,180	(599)
Medi-Cal Admissions	264	214	2,510	2,340	(170)
Other Admissions	401	280	3,196	2,778	(418)
Total Admissions	925	807	9,485	8,298	(1,187)
Medicare Patient Days	1,176	1,359	16,544	1,344	(15,200)
Medi-Cal Patient Days	1,005	1,012	10,837	1,048	(9,789)
Other Patient Days	863	894	9,767	33,992	24,225
Total Patient Days of Care	3,044	3,265	37,148	36,384	(764)
Average Daily Census	101.5	108.8	122.2	119.7	(2.5)
Medicare Average Length of Stay	4.4	4.0	4.4	0.4	(3.9)
Medi-Cal AverageLength of Stay	4.0	4.0	3.7	0.4	(3.3)
Other Average Length of Stay	2.2	2.4	2.3	9.2	6.9
Total Average Length of Stay	3.4	3.4	3.4	3.7	0.4
Deaths	22	34	258	382	124
Total Patient Days	3,294	3,470	39,720	38,569	(1,151)
Medi-Cal Administrative Days	1	0	67	165	98
Medicare SNF Days	0	0	0	0	0
Over-Utilization Days	0	0	0	0	0
Total Non-Acute Days	1	0	67	165	98
Percent Non-Acute	0.03%	0.00%	0.17%	0.43%	0.26%

	Month of Apr		Ten month		
	2020	2021	2019-20	2020-21	Variance
PATIENT DAYS BY LOCATION					
Level I	228	247	2,848	2,656	(192)
Heart Center	348	342	3,525	3,404	(121)
Monitored Beds	688	473	8,762	8,095	(667)
Single Room Maternity/Obstetrics	380	317	4,066	3,441	(625)
Med/Surg - Cardiovascular	466	679	7,302	7,368	66
Med/Surg - Oncology	270	245	2,546	1,716	(830)
Med/Surg - Rehab	335	374	4,041	4,299	258
Pediatrics	68	69	1,043	957	(86)
Nursery	250	205	2.572	2,185	(387)
Neonatal Intensive Care	195	161	1,236	1,315	79
			.,_00	.,	
PERCENTAGE OF OCCUPANCY					
Level I	58.46%	63.33%	71.83%	66.99%	
Heart Center	77.33%	76.00%	77.05%	74.40%	
Monitored Beds	84.94%	58.40%	106.40%	98.30%	
Single Room Maternity/Obstetrics	34.23%	28.56%	36.03%	30.49%	
Med/Surg - Cardiovascular	34.52%	50.30%	53.20%	53.68%	
Med/Surg - Oncology	69.23%	62.82%	64.21%	43.28%	
Med/Surg - Rehab	42.95%	47.95%	50.96%	54.21%	
Med/Surg - Observation Care Unit	0.00%	70.20%	0.00%	60.42%	
Pediatrics	12.59%	12.78%	19.00%	17.43%	
Nursery	50.51%	41.41%	25.55%	21.71%	
Neonatal Intensive Care	59.09%	48.79%	36.84%	39.20%	

	Month of Apr		Ten montl	Ten months to date			
	2020	2021	2019-20	2020-21	Variance		
DELIVERY ROOM		407		4 0.57	(100)		
Total deliveries	155	127	1,519	1,357	(162)		
C-Section deliveries	52	50	481	431	(50)		
Percent of C-section deliveries	33.55%	39.37%	31.67%	31.76%	0.10%		
OPERATING ROOM							
In-Patient Operating Minutes	16,964	20,061	217,518	199,610	(17,908)		
Out-Patient Operating Minutes	14,824	27,494	254,974	226,910	(28,064)		
Total	31,788	47,555	472,492	426,520	(45,972)		
Open Heart Surgeries	11	12	116	115	(1)		
In-Patient Cases	124	150	1,634	1,422	(212)		
Out-Patient Cases	158	275	2,678	2,422	(256)		
EMERGENCY ROOM							
Immediate Life Saving	21	25	299	323	24		
High Risk	441	418	6,090	4,981	(1,109)		
More Than One Resource	1,466	2,350	25,781	21,322	(4,459)		
One Resource	1,035	1,078	15,213	12,052	(3,161)		
No Resources	31	34	476	361	(115)		
Total	2,994	3,905	47,859	39,039	(8,820)		

	Month of Apr		Ten months to date		
	2020	2021	2019-20	2020-21	Variance
CENTRAL SUPPLY In-patient requisitions	12,261	14,775	148,284	148,817	533
Out-patient requisitions	7,289	14,775	140,204	96,828	-5,273
Emergency room requisitions	1,158	1,460	28,328	90,828 15,389	-12,939
Interdepartmental requisitions	5,848	5,934	20,320 69,986	68,237	-1,749
Total requisitions	26,556	32,439	348,699	329,271	-19,428
	20,000	02,400	040,000	525,271	10,420
LABORATORY					
In-patient procedures	27,889	32,828	342,626	355,343	12,717
Out-patient procedures	7,463	12,074	100,639	110,406	9,767
Emergency room procedures	5,272	9,222	97,008	87,254	-9,754
Total patient procedures	40,624	54,124	540,273	553,003	12,730
BLOOD BANK	055		0.000	0.050	
Units processed	255	266	2,838	2,858	20
ELECTROCARDIOLOGY					
In-patient procedures	775	909	10,264	9,302	-962
Out-patient procedures	259	399	4,510	3,971	-539
Emergency room procedures	576	901	9,154	8,768	-386
Total procedures	1,610	2,209	23,928	22,041	-1,887
	· · · · · ·			,	
CATH LAB					
In-patient procedures	71	83	836	765	-71
Out-patient procedures	61	83	838	846	8
Emergency room procedures	0	0	0	1	1
Total procedures	132	166	1,674	1,612	-62
ECHO-CARDIOLOGY					
In-patient studies	239	310	2,996	2,962	-34
Out-patient studies	85	206	1,877	1,836	-41
Emergency room studies	2	0	14	18	4
Total studies	326	516	4,887	4,816	-71
		4.40	4 700	4 550	4 - 7 4
In-patient procedures	171	148	1,732	1,558	-174
Out-patient procedures	17	24	215	240	25
Emergency room procedures Total procedures	<u> </u>	0 172	<u> </u>	0 1,798	-1 -150
rotal procedures	100	172	1,948	1,798	-150

	Month of Apr		Ten months to date		
	2020	2021	2019-20	2020-21	Variance
SLEEP CENTER					
In-patient procedures	0	0	0	1	1
Out-patient procedures	47	187	1,887	1,892	5
Emergency room procedures	0	0	0	0	0
Total procedures	47	187	1,887	1,893	6
RADIOLOGY					
In-patient procedures	1,178	1,128	13,261	13,360	99
Out-patient procedures	400	474	4,328	5,657	1,329
Emergency room procedures	716	1,050	13,833	10,867	-2,966
Total patient procedures	2,294	2,652	31,422	29,884	-1,538
MAGNETIC RESONANCE IMAGING					
In-patient procedures	103	122	1,323	1,249	-74
Out-patient procedures	57	132	815	1,380	565
Emergency room procedures	6	5	101	103	2
Total procedures	166	259	2,239	2,732	493
MAMMOGRAPHY CENTER					
In-patient procedures	693	3,168	33,068	30,354	-2,714
Out-patient procedures	690	3,145	32,950	30,168	-2,782
Emergency room procedures	0	0	7	3	-4
Total procedures	1,383	6,313	66,025	60,525	-5,500
NUCLEAR MEDICINE					
In-patient procedures	11	16	179	130	-49
Out-patient procedures	55	97	820	738	-82
Emergency room procedures	2	0	6	7	1
Total procedures	68	113	1,005	875	-130
PHARMACY					
In-patient prescriptions	70,658	77,825	880,653	878,283	-2,370
Out-patient prescriptions	11,556	16,267	159,582	144,694	-14,888
Emergency room prescriptions	3,427	5,606	73,809	52,846	-20,963
Total prescriptions	85,641	99,698	1,114,044	1,075,823	-38,221
RESPIRATORY THERAPY					
In-patient treatments	14,180	11,890	158,834	201,490	42,656
Out-patient treatments	224	439	5,215	4,621	-594
Emergency room treatments	82	150	3,936	1,689	-2,247
Total patient treatments	14,486	12,479	167,985	207,800	39,815
PHYSICAL THERAPY	0.470	0.407	04.050	00.040	4.040
In-patient treatments	2,172	2,407	24,253	23,213	-1,040
Out-patient treatments	130	256	2,560	2,591	31
Emergency room treatments	0	0	26.912	25.804	0
Total treatments	2,302	2,663	26,813	25,804	-1,009

	Month of Apr		Ten months to date		
	2020	2021	2019-20	2020-21	Variance
OCCUPATIONAL THERAPY					
In-patient procedures	1,345	1,653	14,538	14,281	-257
Out-patient procedures	90	142	1,239	1,273	34
Emergency room procedures	0	0	0	0	0
Total procedures	1,435	1,795	15,777	15,554	-223
SPEECH THERAPY	270	400	2 720	2.052	214
In-patient treatments	376 26	460 27	3,739 241	3,953 279	214
Out-patient treatments Emergency room treatments	28	27	241	279	38 -2
Total treatments	402	487	3,982	4,232	250
	-102	-01	0,002	4,202	
CARDIAC REHABILITATION					
In-patient treatments	0	0	1	0	-1
Out-patient treatments	373	526	4,591	4,241	-350
Emergency room treatments	0	0	0	1	1
Total treatments	373	526	4,592	4,242	-350
CRITICAL DECISION UNIT	050	050	0.000	0.040	000
Observation hours	259	356	3,020	2,818	-202
ENDOSCOPY					
In-patient procedures	80	106	899	948	49
Out-patient procedures	62	33	365	242	-123
Emergency room procedures	0	0	0	0	0
Total procedures	142	139	1,264	1,190	-74
C.T. SCAN In-patient procedures	480	600	6,235	5,537	-698
Out-patient procedures	314	389	2,690	4,860	2,170
Emergency room procedures	306	524	5,733	4,646	-1,087
Total procedures	1,100	1,513	14,658	15,043	385
DIETARY					
Routine patient diets	14,440	16,469	192,709	164,129	-28,580
Meals to personnel	18,703	19,525	243,870	202,351	-41,519
Total diets and meals	33,143	35,994	436,579	366,480	-70,099
LAUNDRY AND LINEN					
Total pounds laundered	81,215	93,920	1,233,184	994,239	-238,945
		,	.,,		



# Memorandum

To: Board of Directors

From: Allen Radner, M.D. CMO

Date: May 27, 2021

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 your approval.

	Policy Title	Summary of Changes	Responsible VP
1.	Emergency Codes for SVMH	Updated Policy Statement. Under Definitions updated "Code Green" description. Updated Procedure section and References.	Clement Miller
2.	Medical Device Alarm Safety and Management	Updated Policy Statement. Updated General Information section. Updated Education statement to standard verbiage. Updated Attachment B, Critical Alarm Defaults.	Clement Miller
3.	ATP (Adenosine Triphosphate Bioluminescence) Monitoring System for Manual Cleaning of Flexible Endoscopes	Updated References section.	Clement Miller
4.	Surgical Smoke	New policy.	Clement Miller
5.	Intra-Aortic Balloon Pump (IABP) Management	Updated Purpose statement. Updated Procedure section. Updated Education statement to standard verbiage. Updated References section.	Clement Miller



6.	IV to PO Protocol	Updated Policy Statement. Updated References. Updated Education statement to standard verbiage. Updated Attachment A Conversion Criteria	Clement Miller
7.	Administration of Investigational Medications in Clinical Research	Updates made in collaboration with John Choi Director of Pharmacy. Policy Statement updated. Education Statement updated to standard verbiage.	Clement Miller



# EMERGENCY CODES FOR SVMH

Reference Number	6304
Effective Date	Not Approved Yet
Applies To	All Departments and Services
Attachments/Forms	

### I. **POLICY STATEMENT:**

A. In the event of an emergency situation, a standardized emergency notification code system will be used to alert staff <u>at the hospital</u> via the overhead paging system and prompt an appropriate, predetermined response. <u>Staff who work at Salinas Valley</u> <u>Memorial Hospital's off site locations will report the emergency as outlined below.</u>

### II. **PURPOSE:**

A. To provide appropriate staff <u>and emergency responder</u> notification of emergency situations.

### III. **DEFINITIONS:**

A. The following is a listing of SVMH Emergency Notification Codes for the hospital.

CODE NAME	DESCRIPTION	CORRESPONDING POLICY IF ONE EXISTS
CODE Red	An actual or suspected fire	# 618 FIRE RESPONSE PLAN (CODE RED)
CODE Blue	A suspected or actual cardiopulmonary arrest ages 14 yrs. and over	# 66 CODE BLUE, CODE WHITE, CODE WHITE NEONATAL
CODE White	A suspected or actual cardiopulmonary arrest ages 31 days to 13 yrs.	# 66 CODE BLUE, CODE WHITE, CODE WHITE NEONATAL
CODE White Neonatal	A suspected or actual cardiopulmonary arrest. Ages 0 to 30 days.	# 66 CODE BLUE, CODE WHITE, CODE WHITE NEONATAL



# EMERGENCY CODES FOR SVMH

CODE Orange	Haz Mat Spill	# 988 HAZARDOUS MATERIALS SPILL RESPONSE PROCEDURE
CODE Green	A <u>patient who is missing</u> <u>from the</u> <u>facility/elopement.</u> <u>missing</u> <u>patient who is determined</u> to be a danger to themselves or has been identified as a safety risk	NA <u>#5842</u> PATIENT ELOPEMENT/MISSING PATIENT
CODE Pink	A suspected or actual infant abduction	# 696 CODE PINK RESPONSE PROCEDURE
CODE YELLOW	A bomb threat or the discovery of a suspicious device	#6362 CODE YELLOW
CODE Gray	A combative or potentially combative person	#546 CODE GRAY
CODE SILVER	A person with a deadly weapon	
CODE Silver - Active Shooter	A person who is brandishing a weapon or actively shooting with in the facility or SVMH property	# 6287 CODE SILVER ACTIVE SHOOTER
CODE Purple	ED is at max capacity	# 90 CODE PURPLE
CODE Triage Internal	An internal disaster affecting one or more departments	# 2654 EMERGENCY OPERATIONS PLAN
CODE Triage External	An external disaster	#2654 EMERGENCY OPERATIONS PLAN

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# EMERGENCY CODES FOR SVMH

CODE Triage External MCI	A mass casual incident where the ED is expecting several trauma victims	#2654 EMERGENCY OPERATIONS PLAN	
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#### IV. **PROCEDURE:**

- A. Response and All Clear
  - Initiating an emergency notification code:
    - 1. Hospital
      - a. When an emergency occurs, call the operator at extension # 2222 and provide the nature <u>and location</u> of the emergency and the location of the incident. <u>Please do not dial "0" to</u> report any emergency as this may delay your ability to reach the operator.
      - b. The operator will page overhead the appropriate emergency notification code.
    - 2. Other <u>Off-Site SVMH locations:</u>
      - a. For those medical emergencies that occur in offsite locations, an assessment of the emergency will be completed by the appropriate licensed individuals to determine what emergency care is required. Follow directions of the physician; if no medical staff are present, <u>DialDial 9-911</u> and provide the nature <u>and address</u> of the emergency.
      - b. For <u>all non-medical other emergenciesy situations</u>, dial <u>9-911</u> <u>and provide the nature and location of the emergency.</u>
      - 3. <u>Dial extension 2222 to Nn</u>otify <u>the hospital operator who will</u> <u>in turn notify the appropriate hospital staff including the</u> <u>Administration/Administrative Supervisor\_Administrator on</u> <u>Call and the Hospital Administrative Supervisor. of the</u> <u>emergency as soon as is reasonable appropriate.</u>
      - a.c. Emergency Codes requiring a notification of All Clear
    - 4.3. Hospital and Off Site Facilities
      - a. When the emergency is over, <u>call extension 2222 to</u> notify the operator. <u>In the hospital, the operator will</u> to page an

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# EMERGENCY CODES FOR SVMH

"All Clear". For off-site locations, the operator will notify the appropriate hospital personnel. 5.\_\_\_\_

## V. EDUCATION/TRAINING:

A. Education and / or training is provided as necessary

#### VI. **REFERENCES:**

- A. <u>Healthcare Emergency Codes: A Guide for Code Standardization, Second Edition,</u> March 2009, accessible via the Internet at www.HASC.org.
- B.A. The Hospital Incident Command System (HICS) Guidebook, accessible via the Internet at <u>www.emsa.ca.gov/HICS</u>.

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Reference Number	5873
Effective Date	Not Approved Yet
Applies To	All Clinical Departments
Attachments/Forms	Attachment A: List of Devices & Critical Alarms
	Attachment B: Critical Alarm Defaults - Corometric Monitors
	Attachment C: Adult and NICU Ventilator Alarm Settings

# I. **POLICY STATEMENT:** This policy applies to all care settings and services for which medical devices utilized in the provision of patient care contain alarms.

A. Non-critical alarm parameters shall be set either to the default settings established by <u>SVMH or SVMH or</u> as clinically warranted based on the patients' condition. Based on SVMH's equipment risk assessment and clinical/medical staff input, non-critical alarm parameters may be set and/or adjusted by the patient's physician or by staff trained and qualified to operate the equipment and understand the clinical implications of such action. In general, non-critical alarms should not be turned off, but the volume may be set so that it is not disruptive to the therapeutic milicu or contribute to alarm fatigue.

## II. PURPOSE:

A. To guide the staff in a standardized process for the use and management of medical device alarms for patient safety.

## III. **DEFINITIONS:**

- A. MEDICAL EQUIPMENT/DEVICE: a piece of equipment designated by the Food & Drug Administration as a medical device
- B. CRITICAL ALARMS: high priority alarms on medical equipment/device designed to alert staff to the presence of a life threatening or potentially life threatening condition
- C. NON-CRITICAL ALARMS: medium or low priority alarms on medical equipment/device designed to alert staff to the presence of a non-life threatening condition
- D. QUALIFIED STAFF: healthcare providers that have been trained in the use of medical equipment/devices. This includes but is not limited to; licensed independent practitioners, registered nurses; respiratory care practitioners
- E. FIXED SETTING: critical alarm setting that can be changed only with physician's order
- F. ADJUSTABLE SETTING: non-critical alarm setting that can be adjusted according to approved parameters as clinically warranted based on the patient's condition.

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- G. SUSPEND: device will temporarily not make audible alarm, but may continue to produce visual alarm
- H. MONITOR STANDBY: device is not suspended, and temporarily placed on "stand by" only
- I. COMFORT CARE MONITOR PROFILE: this setting is built into the Philips cardiac monitor, which can silence alarms that are not clinically significant during end-of-life care.

## IV. GENERAL INFORMATION:

- A. <u>This policy applies to all care settings and services for which medical devices utilized</u> in the provision of patient care contain alarms.
- B. <u>In general, non-critical alarms should not be turned off, but the volume may be set so</u> that it is not disruptive to the therapeutic milieu or contribute to alarm fatigue.
  - It is recognized that medical devices contain alarm signals designed to alert staff to a wide variety of clinical presentations. In some instances, these presentations are reflective of a patient's "normal and expected" condition. Under these circumstances, it is permissible to suspend or turn off the alarm component(s) or parameter(s) designed to alert staff of a normal and expected clinical presentation.
- C. <u>An inventory of medical equipment/devices equipped with alarms will be maintained</u> in the Bio-Medical Department.
  - 1. For each medical equipment/device, the default settings will be documented.
    - a. <u>The default settings will be categorized by FIXED settings and ADJUSTABLE</u> <u>settings</u>
    - b. <u>The default settings will be identified by location and patient population (adult, pediatric or neonatal)</u>
- D. For each medical device, the alarms will be categorized by CRITICAL and NON-CRITICAL alarms.
- E. <u>Alarms will be suspended only by staff trained and qualified to operate the medical equipment/device.</u>

#### F. CRITICAL ALARM SETTINGS

- 1. Critical alarms on medical equipment/devices will be maintained in the ON position and will be sufficiently audible to staff.
  - a. Alarms will be maintained in the ON position as long as the medical equipment/device is being used on a patient.
  - b. Certain alarms may be temporarily suspended while the patient is off of the medical equipment/device or staff is working directly with the patient, but

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must be returned to the ON position when placed back on the patient or when care is completed. Note: NICU monitors are not suspended but placed on "monitor standby" when patient goes to procedure (e.g. MRI), receives bath, or is discharged home.

- c. Staff are required to verify that critical alarms are in the ON position at the beginning of their patient assignment or when a patient is admitted and placed on a medical equipment/device.
- d. Alarm volumes will be set at a level so that staff can hear them.
  - i. If there is competing noise in the area, or the patient is located at some distance to the staff, then the volume of alarms will be set high enough to be distinguishable.
  - ii. If a central medical equipment/device will allow individual patient alarms to be heard at a central location then the alarm volume can be lowered at the location of the patient (bedside).
- e. Authority to set alarm parameters:
  - i. Unless otherwise specified in Attachment A of this policy, parameters for critical alarms will be consistent with default settings established by SVMH. Changes to the manufacturer default settings may only be made upon order of the patient's physician, or qualified designee, who is familiar with the patient's clinical condition.
- f. Authority to change alarm parameters:
  - i. Unless otherwise specified in Attachment A of this policy, critical alarm parameters may only be changed upon order of the patient's physician, or qualified designee, who is familiar with the patient's clinical condition.
  - ii. Conditions under which alarm settings may be adjusted are specified in Attachments B and C of this policy.
  - iii. If physician or qualified designee makes an order to maintain a parameter outside of the default setting, then this constitutes an order for alarm limit adjustment.
- g. Monitoring & responding to alarm signals:
  - i. Staff shall monitor and respond to the activation of a critical alarm in a timely manner. Monitoring may be either direct or indirect depending on the patient's clinical condition, care setting, medical devices in use and other pertinent factors.

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h. Alarm parameters may be individualized for patients' clinical presentation and care needs by the patient's physician or staff according to physician's order. Changes must be communicated at handoff.

## F.G. COMFORT CARE MONITOR PROFILE

- 1. <u>Comfort care monitor profile may be ordered by the patient's physician. This</u> setting can silence alarms that are not clinically significant during end-of-life care.
- G.H. Routine preventative maintenance and testing of clinical alarms and alarm systems associated with medical equipment will be performed by the Bio-Medical Department.

## H.I. IDENTIFICATION OF ALARM SIGNALS

- 1. <u>The organization shall identify alarms on medical equipment based on the following:</u>
  - a. Input from the medical staff and clinical departments
  - b. <u>Risk to patients if the alarm signal is not attended to or if it malfunctions</u>
  - c. <u>Whether specific alarm signals are needed or unnecessarily contribute to alarm</u> <u>noise and alarm fatigue</u>
  - d. <u>Potential for patient harm based on internal incident history</u>
  - e. <u>Published best practices and guidelines</u>
- 2. <u>Based on the above analysis, a list of medical devices and attendance critical alarm</u> signals is appended to this policy as Attachment A, and is incorporated by reference herein.

#### LJ. IMPROVING ON MEDICAL DEVICE ALARM SAFETY

- <u>A cross-disciplinary team that includes representation from clinicians, clinical</u> engineering, information technology, and risk management shall meet on as needed <u>basis to:</u>
  - a. <u>Improve and optimize critical alarm system configurations and practices</u>
  - b. <u>Review trends and patterns in alarm-related events including the potential</u> <u>issue of alarm fatigue – to identify opportunities for improving alarm use</u>
  - <u>J.b.</u>

#### V. **PROCEDURE:**

- A. Qualified staff will assess that medical equipment/devices are set at appropriate settings consistent with the patient's clinical presentation, care needs or specific physician orders. This will occur for:
  - 1. New admissions and transfers

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- 2. Shift report/handoff
- B. Qualified staff are responsible to recognize critical and non-critical alarms on medical equipment/devices, and to respond timely to critical and non-critical alarms.
- C. Immediately report any medical equipment/device malfunctions or concerns to the Engineering/Bio-Medical Department. Remove the medical equipment/device from operation. <u>MEDICAL EQUIPMENT CARE, CLEANING AND MAINTENANCE</u>
- D. Quality metrics <u>maywill be</u> be established to monitor patient safety related to alarm management.
- E. Documentation: Documentation of physician notification for changes to the default settings will be made in the electronic health record (EHR)

## VI. EDUCATION/TRAINING:

- A. Education is provided during general or department specific orientation and periodically as practice or policy changes. Education and/or training is provided as needed.
- B. Physicians and other practitioners shall be educated about the purpose and proper operation of alarm systems for which they are responsible. Evidence that these individuals have been granted clinical privileges which require using a medical device shall be considered inclusive of training on attendant alarm systems.

#### VII. **REFERENCES:**

A. The Joint Commission National Patient Safety Goals 06.01.01, 2014



Device	Critical Alarm Signal	Fixed Setting	Adjustable Setting
Cardiac Monitors- Adult	Apnea	Х	<u> </u>
	Asystole	X	
	Blood Pressure	X	
	(systolic, diastolic)		
	Heart Rate	Х	
	O2 Saturation (%)	Х	
	Respiratory Rate	X	
Cardiac Monitors- NICU	Apnea	X	
	Blood Pressure	X	
	(systolic, diastolic)		
	Heart Rate	X	
	O2 Saturation (%)	Х	
	Respiratory Rate	Х	
Ventilators – both ICU and	End Tidal C02	Х	
non-invasive	Low CPAP		Х
	Low PEEP		Х
	Minute Volume		Х
	Pressure		Х
	Respiratory rate	X (low rate)	X (high rate)
	Tidal Volume		X
Intra-Aortic Balloon Pumps	Occlusion	Х	
*	Disconnection	Х	
	Power Failure	Х	
Anesthesia Machines	Apnea	Х	
	O2 Saturation (%)	Х	
	EKG	Х	
	Gas Analyzer (End Tidal C02)	X	
	Ventilator alarm	Х	
	Heart Rate	Х	
	Blood Pressure	Х	
Corometric Monitors: Fetal parameters	Heart Rate Baseline	Х	
Corometric Monitors: Maternal Parameters	Blood Pressure (systolic, diastolic)	X	
	BP MAP	X	
	Heart Rate	X	X
	O2 Saturation (%)	X	

#### ATTACHMENT A LIST OF DEVICES & CRITICAL ALARMS

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## ATTACHMENT B

#### **Critical Alarm Defaults – Corometric Monitors**

Maternal Parameters	High	Low
BP Systolic	150	80
BP Diastolic	100	50
BP MAP	120	50
Heart Rate	120*	50
SpO2	100%	94%
Fetal Parameters	High	Low
Fetal Heart Rate Baseline	170	100

#### **\*Value may be changed according to the following algorithm:**

If maternal HR is intermittently above 120 during the active pushing phase of the second stage of labor, the RN may adjust alarms up to 140 provided no other cardiac or respiratory concerns are present.

#### **Critical Alarm Defaults- Phillips Monitors**

Parameter	Low	High
Temp	<u>36</u>	<u>39</u>
Heart Rate	<u>50</u>	<u>120</u>
Respiratory Rate	<u>8</u>	<u>30</u>
Apnea Delay	20 Seconds	<u>n/a</u>
<u>SpO2</u>	<u>90</u>	<u>100</u>
BP Systolic	<u>90</u>	<u>160</u>
<b>BP</b> Diastolic	<u>50</u>	<u>90</u>
BP MAP	<u>70</u>	<u>100</u>
CVP	<u>0</u>	<u>16</u>
ICP	<u>0</u>	<u>20</u>



## Attachment C Adult and NICU Ventilator Alarm Settings

Certain Ventilator alarms may be adjusted according to patient achievement on current ventilator settings as ordered by the physician. See below for details:

#### I-Vent & Servo-I ventilators (invasive)

Alarm Type	Alarm Settings Guidelines. May adjust from machine's default settings to:
Pressure: high	• If pressure is < 30 cmH20: set alarm limit to 10 cmH20 above the peak inspiratory
	pressure achieved by the patient (PIP)
	<ul> <li>If pressure is <u>&gt;</u>30 cmH20: set alarm limit to 20% above PIP. Notify physician.</li> </ul>
Pressure: low	Set alarm limit to 5 cmH20 below PIP
Minute Volume: high	• Set alarm limit to 15% above the patient's average achievement value
Minute Volume: low	• Set alarm limit to 15% below patient's average volume achievement value
Respiratory Rate: high	• Set alarm limit to 10 bpm higher than the patient's total achievement (which
	includes both the ventilator's set volumes and patient's volumes)
Respiratory Rate: low	<ul> <li>May not be changed from 5bpm without a physician order</li> </ul>
Low PEEP	• Set alarm limit to 2 units below the patient's achievement value
End Tidal C02	May not be changed from default settings without a physician order
Tidal Volume: high	Set alarm limit to 15% above the patient's average achievement value
Tidal Volume: low	• Set alarm limit to 15% below the tidal volume set by the physician

#### V60 (non-invasive): for all modes

Alarm Type	Alarm Settings Guidelines:
Pressure: high	Set alarm limit to 20% above PIP
Pressure: low	Set alarm limit to 5 cmH20 below PIP
Minute Volume: high	Set alarm limit to 15% above the patient's average achievement value
Minute Volume: low	Set alarm limit to 15% below patient's average volume achievement value
Respiratory Rate: high	• Set alarm limit to 10 bpm higher than the patient's total achievement (which
	includes both the ventilator's set volumes and patient's volumes)
Respiratory Rate: low	<ul> <li>May not be changed from 8bpm without a physician order</li> </ul>
Low CPAP	• Set alarm limit to 2 units below the patient's achievement value
End Tidal C02	<ul> <li>May not be changed from default settings without a physician order</li> </ul>
Tidal Volume: high	Set alarm limit to 15% above the patient's average achievement value
Tidal Volume: low	• Set alarm limit to 15% below the tidal volume set by the physician



Alarm Type	Alarm Settings Guidelines:
Pressure: high	Set alarm limit to 5 cmH20 above PIP
Pressure: low	Set alarm limit to 3 cmH20 below PIP
Low PEEP	Set alarm limit to 2 cmH20 below set PEEP

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Reference Number	6731
Effective Date	Not Approved Yet
Applies To	ENDO, SSPD
Attachments/Forms	

#### I. **POLICY STATEMENT:**

A. N/A

#### II. **PURPOSE:**

- A. To provide a systematic, ATP-based, approach that provides quantitative and objective data to monitor cleaning efficacy.
- B. ATP Monitoring System will be used on ALL Flexible Endoscopes to test efficacy of manual cleaning before they are processed for high-level disinfection.

#### III. **DEFINITIONS:**

- A. ATP Adenosine Triphosphate Bioluminescence
- B. Endo Endoscopy
- C. IFU Instruction for Use
- D. PPE Personal Protective Equipment
- E. RLU Relative Light Units
- F. S/B Connector Suction/Biopsy Channel (Connector)
- G. SSPD Sterile Supply Processing Department

#### IV. GENERAL INFORMATION:

A. ATP is the molecule that provides energy for cellular metabolism and is present in all living cells. Consequently, it is present in any organic residue (e.g. body fluids, skin cells, and microorganisms) making ATP an excellent marker for organic contamination or contamination from a biological source. Luciferin-luciferase is an enzyme that reacts with any ATP residue. A product of this reaction is the generation of light by the enzyme solution, which can be measured and expressed in Relative Light Units (RLUs). The greater the level of ATP present, the greater the amount of light generated resulting in higher RLU level.

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## V. **PROCEDURE:**

- A. Sample the flexible endoscope after manual cleaning, but before high-level disinfection or sterilization.
- B. Test points:
  - Sample exterior surface using one surface test swab and starting at the distal end of the bending section of insertion tube, swab all sides for a length of 10 cm. Measure ATP levels (follow the IFU for proper operation of the Luminometer.

Note: For Duodenoscopes the following additional test points should be added: 1) Elevator mechanism and its recessed housing. 2) Elevator guide wire channel (in newer model duodenoscopes the elevator guide wire channel is sealed and therefore cannot be tested).

- 2. Preparation of Flexible Endoscope for Sampling of Suction/Biopsy Channel A connector is required so that a syringe may be used to sample the interior channels of the flexible endoscope. The connector fits on the suction/biopsy channel located on the light guide end of the universal cord of the flexible endoscope. Appropriate PPE should be worn while preparing and sampling the flexible endoscope.
  - a. Fill a 60 cc syringe with air and attach the syringe to the connector.
  - b. Depress the suction valve located on the control head (valve with red dot). Slowly push the air through the lumen. This process removes any cleaning agent in the lumen.
  - c. Secure the distal end of the flexible endoscope into the 50 cc conical sample collection tube. To avoid contamination of the sample, make sure that the distal end of the flexible endoscope does not go below the 40 cc mark.
  - d. Remove the 60 cc syringe from the connector and draw up 40 cc of sterile water from the water container. Pull up an additional 20 cc of air.
  - e. Attach the syringe to the S/B connector on the light guide end on the universal cord. Make sure the instrument port is capped to avoid sample leakage.
  - f. Depress the suction valve located on the control head (valve with red dot).



- g. Keeping the suction valve depressed, push the water through the scope by depressing the syringe plunger. The rinsate should flow into the collection tube.
- h. Release the suction valve and detach the syringe from the S/B connector.
- i. Draw air into the syringe up to the 60 cc mark.
- j. Re-attach the 60 cc syringe to the S/B connector.
- k. Depress the suction valve.
- 1. Keeping the suction valve depressed, use the syringe plunger to push all the air into the scope. This process will displace the 40 cc rinsate into the 50 cc conical collection tube.
- m. Securely cap the sample collection tube to maintain sample integrity.
- n. Following the IFU, measure the ATP level of the 40 cc water rinsate sample using the ATP Water Test and the Luninometer.
- C. Pass/Fail Threshold (3M Clean-Trace only)
  - 1. Pass: less than or equal to 200 RLU
  - 2. Fail: equal to or greater than 201 RLU
- D. Analyze results
  - 1. Use the 3M Clean-Trace online software to automatically capture and analyze results.
  - 2. All test points for all flexible endoscopes should show passing RLU values of less than or equal to 200 RLU.
  - 3. If any of the test points fail, redo manual cleaning and retest. If the second test results in failure, take the endoscope out-of-service and send it to the manufacturer for repair.
- E. Documentation N/A

## VI. EDUCATION/TRAINING:

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

## VII. **REFERENCES:**

A. American Society for Gastrointestinal Endoscopy (ASGE). 2001. Transmission of infection by gastrointestinal endoscopy. *Gastrointestinal Endoscopy 54(6)*. 824-828.

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- B.A. ANSI/AAMI ST91:2015 Flexible and semi-rigid endoscope processing in healthcare facilities.
- C. Olfstead, Cori L., Langlay, Alexandraa Dirlam, Wetzler, Harry P., Tosh, Pritish, Baron, Todd, Ofstead and Associates, Inc., St. Paul, MN, Division of Infectious Diseases and Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, MN. Transmission of multidrug resistant organisms via contaminated duodenoscopes. American Society for Gastrointestinal Endoscopy/Digestive Disease Week. Orlando, FLA. May 18-21, 2013.
- <u>3M Clean-Trace Flexible Endoscope Implementation Guide for Routing Cleaning</u> <u>Monitoring; issued 06/2017 (3M ID 70-2011-6875-7)</u><del>3M Clean-Trace Hygiene</del> <u>Management Guide for flexible endoscopes (3M ID 70-2010-8473-1)</u>

<u>B.</u>

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# SURGICAL SMOKE

Reference Number	6864
Effective Date	Not Approved Yet
Applies To	SURGERY
Attachments/Forms	

## I. **POLICY STATEMENT:**

A. When surgical smoke (e.g., plume, aerosols) is generated by energy-generating devices (e.g., electrosurgical units [ESUs], lasers, ultrasonic scalpels/dissectors) during operative or other invasive procedures, all surgical smoke will be captured and filtered through the use of smoke evacuators or in-line filters positioned on suction lines.

#### II. **PURPOSE:**

A. To provide guidance to perioperative personnel for creating an environment that reduces the exposure of patients and perioperative personnel to surgical smoke. The expected outcome is that the patient's respiratory status is maintained at or improved from baseline levels and the patient and perioperative team are free from signs and symptoms of chemical injury.

#### III. **DEFINITIONS:**

- A. Electrosurgical Unit [ESU] equipment used for cauterization and fulguration of tissue.
- B. Laser light amplification by stimulated emission of radiation-used as an intensely hot, precisely focused beam of light to remove or vaporize tissue and control bleeding.

#### IV. GENERAL INFORMATION:

A. Surgical smoke: The gaseous product of burning organic material created as a result of the destruction of tissue by lasers, electrosurgical units, ultrasonic devices, power instruments, and other heat-producing surgical tools. Surgical smoke can contain toxic gases and vapors such as benzene; hydrogen cyanide; formaldehyde; bio aerosols; dead and live cellular material, including blood fragments; and viruses. At high concentrations, surgical smoke causes ocular and upper-respiratory tract irritation in health care workers and creates obstructive visual problems for the surgeon. Surgical smoke has unpleasant odors and has been shown to have mutagenic potential.

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# SURGICAL SMOKE

## V. **PROCEDURE:**

- A. All surgical smoke will be removed using a smoke evacuation system during operative and other invasive procedures that generate surgical smoke.
  - 1. A smoke evacuation unit with a 0.1  $\mu$ m filter (e.g., an ultra-low particulate air [ULPA] filter) will be used.
  - 2. When a medical-surgical suction system is used to evacuate smoke, a 0.1 μm in-line ULPA filter will be used.
    - a. The filter will be placed between the suction wall/ceiling connection and the suction canister.
  - 3. Suction tubing with a suction tip attached will be used, or the suction tubing may be attached directly to the ESU pencil with smoke evacuator tubing.
  - 4. The smoke capture device (e.g., wand, tubing) will<u>be</u> positioned as close to the surgical site as necessary to effectively collect the surgical smoke.
  - 5. The smoke evacuator will be activated at all times when surgical smoke is produced during the procedure.
- B. Suction tubing with a suction tip attached will be used, or the suction tubing may be attached directly to the ESU pencil with smoke evacuator tubing.
- C. Surgical smoke will be evacuated with the smoke evacuation device throughout minimally invasive procedures.
- D. Standard precautions will be used to handle used smoke evacuator filters, tubing, and wands as potentially infectious waste and to dispose of these items as biohazardous waste.
- E. Respiratory protection (i.e., a fit-tested N95 filtering face piece respirator) may be used as secondary protection against residual surgical smoke.
- F. A fit-tested surgical N95 filtering face piece respirator will be worn during higherrisk, aerosol-generating procedures and procedures on patients with known or suspected aerosol transmissible diseases (e.g., tuberculosis, varicella, rubeola).
- G. Documentation: N/A



# SURGICAL SMOKE

## VI. EDUCATION/TRAINING:

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

#### VII. **REFERENCES:**

- A. Guideline for surgical smoke safety. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2016.
- B. Fencl, J.L. (2017), Guideline Implementation: Surgical Smoke Safety. AORN Journal, 105: 488-497. https://doi.org/10.1016/j.aorn.2017.03.006

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<b>R</b> eference Number	132
Effective Date	Not Approved Yet
Applies To	CATH LAB, ICU/CCU
Attachments/Forms	Attachment A: Theory of IABPAttachment B: Arterial Waveform Variation During IABP TherapyAttachment C: Timing ErrorsAttachment D: Balloon Pressure WaveformsAttachment E: TroubleshootingAttachment F: Complications/Side Effects

## I. POLICY STATEMENT:

N/A

## II. **PURPOSE:**

- A. To guide the staff where IABP procedures may be performed and the department's responsibilities and roles of each unit for the utilization, maintenance, supply inventory, and expertise for operating the IABP and transporting of patients while having IABP therapy
- A.B. To provide a systematic guide for the ICU/CCU RN in monitoring and care of the patient with intra-aortic balloon pump.

## III. **DEFINITIONS:**

- A. Intra-aortic Balloon Pump therapy is designed to increase coronary artery perfusion, increase systemic perfusion, decrease myocardial workload, and decrease afterload.
- B. Intra-aortic Balloon Pump (IABP) is an acute, short-term therapy for patients with reversible left ventricular failure.

## IV. GENERAL INFORMATION:

- A. Intra-Aortic Balloon Pump placement can be performed in the Operating room, Cath Lab, and ICU
- A.<u>B.</u> An ICU/CCU RN who completed and demonstrated competency in Intra-aortic Balloon Pump management, can care for patients with IABP support in the ICU.

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## V. **PROCEDURE:**

- A. In the OR:
  - Maintenance: The OR's IABP remains plugged in at all times and fully charged. If the IABP is removed from the ICU storage location, the House Supervisor should be notified. Before each heart case, the IABP Helium and CO<sub>2</sub> source is checked along with the electrical function safety checks of the unit. Specialty Care Group makes these checks on any IABP unit immediately prior to use in the OR.
    - ICU and Cath Lab staff are responsible for checking and maintaining their own IABP units.

## A.B. Equipment

- Intra-aortic Balloon Pump (CS100)
- Helium tank (gas supply)
- ECG and arterial monitoring supplies <u>See ARTERIAL CATHETER INSERTION</u> (ASSIST) CARE AND REMOVAL and
- Intra-aortic Balloon Pump Catheters
  - 1. 7.5fr and 8fr with 34ml balloon for 5'4"
  - 2. 7.5 fr and 8 fr with 40 ml balloon for 5'4'' 6'
    - 2.a. Balloon Catheters are not stocked in the O.R. Materials Management staff are responsible for maintaining a par level in the Cardiac Cath Lab and ICU.
- IABP catheter insertion kit
- Cardiac procedure cart (yellow)
- Analgesics and/or sedatives as prescribed
- Crash cart for emergency medications and resuscitation equipment
- Additional equipment to have available depending on patient status includes the following:
  - 1. Vasopressors, antibiotics, and/or Heparin infusion as prescribed.

B.C. Indications

- Cardiogenic shock or left ventricular failure decreases left ventricular function by 40%.
- Unstable angina refractory to medical therapy.
- Acute myocardial infarction (MI) complicated by ventricular failure

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- Management of recurrent ventricular dysrhythmias as a result of ischemia.
- Failure to wean successfully from cardiopulmonary bypass.
- Bridge to cardiac <u>transplantion</u>transplantation, ventricular assist devices or total artificial hearts..
- Support before, during and/or after coronary artery angioplasty or additional interventional cardiology procedure-s for high risk patients
- Mechanical complications of acute MI including aortic stenosis, mitral stenosis, mitral valvuloplasty, mitral insufficiency, ventricular septal defect and left ventricular aneurysm.

C.D. Contraindications

- Irreversible brain damage.
- Moderate to severe aortic insufficiency.
- Thoracic and abdominal aneurysms.
- Value of IABP therapy in the presence of severe aorto-iliac disease, major coagulopathies, and terminal diseases should be evaluated individually.

D.E. Set-up (Insertion/Assist)

- Prepare patient for insertion by verifying understanding of procedure and obtain consent. Most IABP insertions are done in Cath lab or in Surgery.
- Sedate patient as needed. Immobilize the affected extremity to prevent further movement during insertion of the catheter.
- Establish ECG input to IABP console and obtain optimal R wave amplitude and absence of any artifact. The R wave, QRS complex, or arterial pressure waveform may be the trigger for balloon pump inflation and deflation.
- Assist with placement of hemodynamic monitoring lines if they are not already present.
- Complete IABP console preparation to ensure adequate functioning of device.
- Make available the most appropriate size of balloon catheter. An adequate volume is necessary to achieve optimal hemodynamic effects from IABP therapy.
- Avoid fast flush and blood sampling from the central aortic lumen. When "fast flush" or manual flushing is required, ensure that IABP is on "stand-by" and not pumping. The risk of air embolus entry or dislodging a thrombus at the lumen tip is a major concern.

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- Upon insertion use **AUTO MODE.** Start at FULL AUGMENTATION and 1:1 ratio. If timing needs adjustment, it must be done on **SEMI\_AUTO or Manual Mode.**
- Zero and calibrate the pressure transducer to ensure accurate measurement, timing, maintenance, and functioning of the IABP.
- Obtain a portable chest x-ray to confirm position. Know the correct position of the IABP marker on CXR. (i.e.: between 2<sup>nd</sup> and 3<sup>rd</sup> intercostal space; 2cm below the top of the aortic knob; or 2cm above the carina). Be sure to inform MD if the position is low.
- Apply sterile dressing to catheter insertion site.

## E.F. Operation

- Auto operation mode provides simplicity and minimizing operator interventions. All aspects of IABP operation are automated. Most appropriate trigger source is automatically selected.
  - 1. Automatically selects the best available trigger source and automatically sets timing.
  - 2. In the event of a loss trigger source (e.g. a lost ECG lead) the pump will sequentially search for the next best available trigger source and then reset timing accordingly.
  - 3. Timing adjusts automatically if trigger source, heart rate, or rhythm changes.
  - 4. With sustained unpredictable rhythms, R-wave deflation is automatically selected. The message *Auto R-Wave Deflate* will be displayed. The deflation indicator will automatically be repositioned to the far right, "R-Trac" will be displayed in the IABP deflation indicator. The system will return to predictive timing once the rhythm becomes predictable.
- Semi-Auto operation mode is partially automated.
  - 1. Operator is responsible for both selection of the trigger source and for initial timing of the IABP. Thereafter, the IABP's timing algorithms will adjust timing in response to changes in heart rate or rhythm.
  - 2. When trigger source is lost the IABP will alarm and stop pumping.
  - 3. This operation mode provides the most flexibility for difficult clinical cases.
- **Manual** operation mode, the operator is responsible for selection of trigger source and setting IAB timing.
  - 1. This mode is used only in exceptional cases such as pediatrics, where a large range of timing settings must be accommodated.

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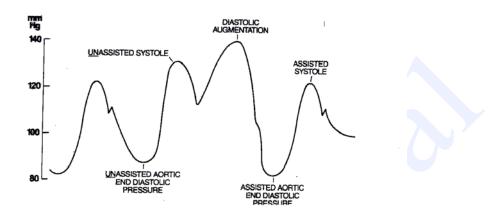


- Setting Inflation timing is not applicable in <u>Auto</u> operation mode.
- In the standby mode an inflation marker appears as a highlighted interval on the arterial pressure waveform. Appropriate movement of the inflate and deflate timing control will shift the duration and position of the marker.
- Deflation timing is an option in <u>Auto</u> mode. On the standby mode, use the IAB deflation arrows to adjust the end of the highlighted segment prior to ventricular ejection.
- In Manual mode, assess the timing every four hours or whenever heart rate changes by more than 10 beats per minutes or for any rhythm changes.

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## Figure 1:



- F. Maintenance/Care
  - Perform systematic cardiovascular, peripheral vascular and hemodynamic assessment every 15-60 minutes in a patient status requires.
    - 1. Level of consciousness. Assess for adequate cerebral perfusion. Thrombi may develop and dislodge during IABP therapy or IAB may migrate, decreasing blood flow to the carotid arteries.
    - 2. Vital signs and pulmonary pressures. Demonstrates the effectiveness of IABP therapy. Vital signs are documented every 30 minutes or every 15 minutes when patient is unstable
    - 3. Arterial line and IABP waveforms.
    - 4. Hemodynamic parameters cardiac output, cardiac index, and systematic vascular resistance.
    - 5. Circulation to extremities validates adequate peripheral perfusion. If reportable conditions are found, they may indicate catheter or embolus obstruction of perfusion to extremity. Specifically, decreased perfusion to the left arm may indicate misplacement of the IAB catheter.
      - a. Capillary refill greater than 2 seconds.
      - b. Diminished or absent pulses.
      - c. Color pale, mottled, or cyanotic.
      - d. Diminished or absent sensation.
      - e. Pain.

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- f. Diminished or absent movement.
- g. Cool or cold to the touch.
- 6. Urine output validates adequate perfusion to kidneys. Reportable conditions:
  - a. Urine output less than 0.5 than 0.5 ml/kg per hour.
- Assess heart and lung sounds every four hours and as needed. When patient condition permits, place the IABP on standby to accurately auscultate.
- Maintain the head of the bed at less than 45 degrees. Prevents kinking or migration of the catheter.
- Monitor for signs of inappropriate IAB placement. The IAB may be placed too high or too low, thus occluding at the left subclavian, celiac, inferior or superior mesenteric, or renal arteries.
  - 1. Compromised CNS to extremities.
  - 2. Dampened radial arterial pressure waveform.
  - 3. Diminished or absent bowel sounds.
  - 4. Increased abdominal girth, abdominal pain, tympanic, abdomen firm to touch.
  - 5. Decreased urine output.
  - 6. Increased urine osmolality.
  - 7. Increased BUN or creatine.
  - 8. Reduced IABP augmentation.
- Monitor for signs of balloon perforation. In the event of balloon perforation, a very small amount of helium will be released into the aorta, potentially causing an embolic event.
  - 1. Blood or brown flecks in tubing.
  - 2. Loss of IABP augmentation
  - 3. Control console alarm activation
- Maintain accurate IABP timing.
  - 1. If timing is not accurate, cardiac output may decrease rather than increase.
- Log roll patient every two hours and reposition for comfort. Instruct patient to keep extremity straight. Immobilize the extremity if necessary.
- Assess the area around the site every 2 hours and as needed for evidence of bleeding or hematoma.
- Monitor patient for systemic evidence of bleeding or coagulation disorders.

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- Change IAB site dressings every <u>48 hours</u>. Cleanse site with chlorhexadine, then apply sterile dressing. Label with date, time, and <u>nurse'snurses</u> initial.
- Monitor for signs and symptoms of aortic dissection. Aortic dissection may occur as a result of IAB placement into a false lumen in the aorta.
  - 1. Acute back, flank, testicular, or chest pain.
  - 2. Decreased pulses.
  - 3. Variation in blood pressure between left and right arm.
  - 4. Decreased cardiac output
  - 5. Increased heart rate
  - 6. Decreased hemoglobin and hematocrit
  - 7. Decreased filling pressures
- Assess and manage patient's pain.
- Identify parameters that demonstrate clinical readiness to wean from IABP therapy. The presence of these reportable conditions indicates that special consideration should be given to weaning the patient from IABP:
  - 1. No angina
  - 2. Heart rate less than 110
  - 3. Absence of lethal or unstable dysrhythmias
  - 4. MAP greater than 70 mmHg with little or no vasopressor support
  - 5. PCWP less than 18 mmHg
  - 6. Cardiac Index greater than 2.4
  - 7. Capillary refill less than 3 seconds
  - 8. Urine output greater than 0.5 ml/kg/hr
- G. Catheter Removal, (Assist)
  - Assess clinical readiness for weaning. Optimal clinical and hemodynamic parameters validate readiness for weaning.
  - Decrease assist ratio per physician orders and patient response.
  - Change assist ratio to 1:2, then 1:3. May or may not decrease augmentation by 50% maximum. Evaluate patient response after each change. The length of time required to wean from IABP therapy depends on hemodynamic response of patients.

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- Discontinue anticoagulation 4-6 hours prior to catheter removal.
- Assist with catheter removal.
  - 1. Equipment
    - a. C-clamp or FemoStop per physician's preference
    - b. Pain medication
  - 2. Turn IABP console "off."
  - 3. Assist physician with removal of percutaneous balloon.
  - 4. Ensure that pressure is held on the insertion site for 30-45 minutes after the IAB catheter is withdrawn. Ensure that hemostasis is obtained.
  - 5. Assess insertion site for signs of bleeding or hematoma formation before application of sterile pressure dressing.
  - 6. Monitor vital signs and hemodynamic parameters every 15 minutes x 4, every 30 minutes x 2, then every hour as patient condition warrants.
  - 7. Assess the quality of perfusion to the decannulated extremity immediately, during C-clamp or FemoStop application, after removal, and every 1hour x 2, then every 2 hours.
  - 8. Maintain immobility of decannulated extremity and bed rest with HOB elevated no greater than 30 degrees for 6-8 hours.

## H. Documentation:

- 1. In the OR documentation will be done on the Perfusion record
- 1. Patient and family education.
- 2. Insertion of IAB catheter (including the size of catheter used and balloon volume).
- 3. Peripheral pulses and neurovascular assessment of affected extremity. Record hourly distal pulse checks and IABP ratio. Left brachial pulses should be checked every four hours.
- 4. Hourly UOP<u>documented on the ICU flowsheet</u>.
- 5.4. Patient's response to procedure and IABP therapy.
- 6.5. Confirmation of IABP placement (e.g., chest x-ray).
- 7.<u>6.</u> Insertion site assessment.
- 8.—Hemodynamic status.

7.

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- 9.8. IABP pressures (balloon augmented pressure, assisted systolic pressure, assisted end-diastolic pressure, and mean arterial pressure) every 15 minutes.
   <u>↓ are documented with vital signs gns are documented</u> every 30minutes, or every 15minutes when patient is unstable
- 10.9. Strips are posted every 4 hours and done on 1:2 or 1:3, so as to document correct timing
- <u>11.10.</u> Occurrence of unexpected outcomes.
- <u>12.11.</u> Additional nursing interventions taken.

#### V. EDUCATION/TRAINING:

- A. Education and/or training is provided as needed. training for ICU/CCU RN is provided periodically in accordance with identified needs.
- B. ICU/CCU RN upon completion of Intra-aortic Balloon Pump competency and one-onone hands-on experience with a preceptor.

#### VI. **REFERENCES:**

- A. Khan TM, Siddiqui AH. Intra-Aortic Balloon Pump (IABP) [Updated 2019 Sep 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2019 Jan.Datascope
- A. Parissis, H., Graham, V., Lampridis, S. *et al.* IABP: history-evolutionpathophysiology-indications: what we need to know. *J Cardiothorac Surg* 11, 122 (2016) doi:10.1186/s13019-016-0513-0 (2007). Cardiac Assist Operator's Manual, P/N 0065-00-0683-01-R1 April 2007.
- B. <u>Kim, J.T., Lee, J.R., Kim, J.K., Yoon, S.Z., Jeon, Y., Bahk, J.H., et al. (2007). The</u> <u>carina as a useful radiographic landmark for positioning the intraaortic balloon pump.</u> <u>International Anesthesia Research Society, 105(3), 735-738.</u>
- C. IABP Trainer (CS100) Operation Manual, Datascope, Cardiac Assist Division, Revision B, December, 2003.

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# <u>B.</u>

- D.C. Policies and Procedures Related to IABP Therapy. Courtesy of Datascope Corp. Clinical Education Services Department
- E. Reid, M. B. and Cottrell, D. (2005), Nursing Care of Patients Receiving Intra-Aortic Balloon Counterpulsation., *Critical Care Nurse*. 30, (15).
- F.D. Castellucci, D<sub>772</sub> Intraaortic Balloon Pump Management, In Weigand, D. (editor), AACN Procedure Manual for Critical Care Nurse, (pp 443-463) 6th edition, St Louis, Missouri: 2011 Elsevier, Saunders.
- E. American Journal of Critical Care, Intra-Aortic Balloon Pump Timing: Review of Evidence Supporting Current Practice, Patricia Hanlon-Pena and Susan Quaal, volume 20 no. 4. July, 2011.
- F. Laham, R., Aroesty, J., & Pinto, D (2019). Intraaortic balloon pump counterpulsation. <u>UpToDate</u>. Retreived from https://www.uptodate.com/contents/intraaortic-balloonpump-counterpulsation#H18



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## ATTACHMENT A

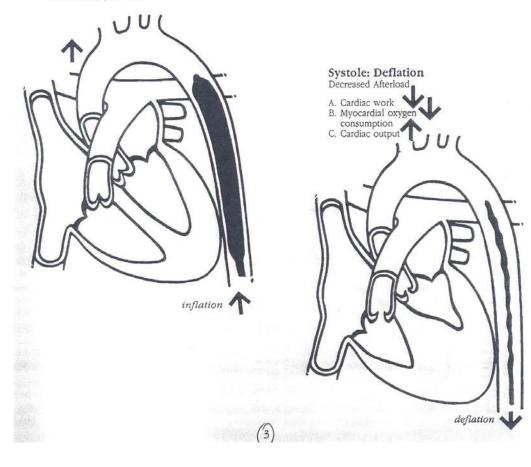
#### Theory of IABP I.

#### A. Counterpulsation

- 1. Balloon Structure and Position
- 2. Increased Coronary Perfusion
- a. Inflation
  - b. Augmentation of Diastolic Pressure
- 3. Decreased Left Ventricular Workload
  - a. Deflation
- b. Afterload Reduction
- 4. Physiological Pressure Wave Changes
  - a. Dicrotic Notch b. Diastole: Augmentation
  - c. Decreased End-Diastolic Pressure
  - d. Systole: Decreased Assisted Systolic Pressure

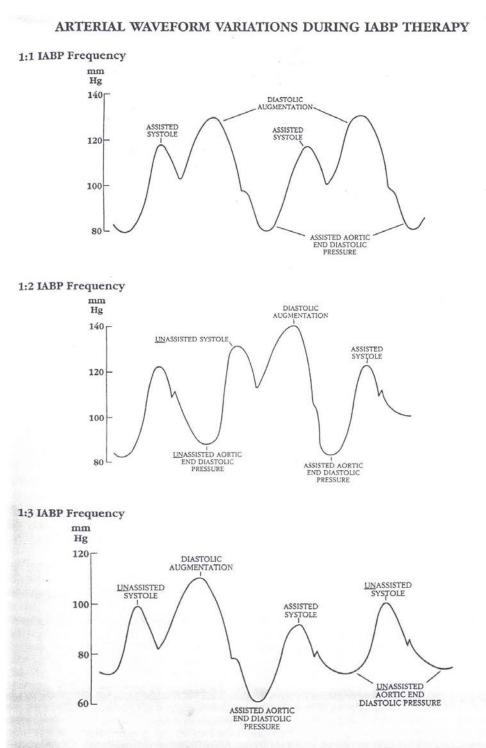
# Diastole: Inflation Augmentation of Diastolic Pressure

A. Coronary perfusion



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## ATTACHMENT B

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## ATTACHMENT C

## **TIMING ERRORS**

## I. Timing Errors

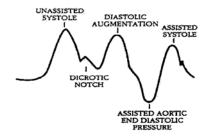
- A. Early Inflation Inflation of the IAB prior to aortic valve closure
  - Waveform Characteristics
    - 1. Inflation of IAB prior to dicrotic notch.
    - 2. Diastolic augmentation encroaches onto systole (may be unable to distinguish).
  - Physiologic Effects
    - 1. Potential premature closure of aortic valve.
    - 2. Potential increase in LVEDV and LVEDP or PCWP.
    - 3. Increased left ventricular wall stress or afterload.
    - 4. Aortic regurgitation
    - 5. Increased MVO<sub>2</sub> demand
  - Intervention
    - 1. Move inflation later.



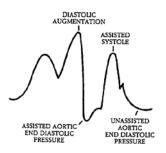
- B. Late Inflation Inflation of the IAB markedly after closure of the aortic valve.
  - Waveform Characteristics
    - 1. Inflation of the IAB after the dicrotic notch.
    - 2. Absence of the sharp V.
    - 3. Sub-optimal diastolic augmentation.
  - Physiologic Effects
    - 1. Sub-optimal coronary artery perfusion.
  - Intervention
    - 1. Adjust inflation earlier.

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- C. Early Deflation Premature deflation of the IAB during the diastolic phase.
  - Waveform Characteristics
    - 1. Deflation of IAB is seen as a sharp drop following diastolic augmentation.
    - 2. Suboptimal diastolic augmentation
    - 3. Assisted aortic end diastolic pressure may be equal to or less than the unassisted aortic end diastolic pressure.
    - 4. Assisted systolic pressure may rise.
  - Physiologic Effects
    - 1. Sub-optimal coronary perfusion.
    - 2. Potential for retrograde coronary and carotid blood flow.
    - 3. Angina may occur as a result of retrograde coronary blood flow.
    - 4. Sub-optimal afterload reduction.
    - 5. Increase MVO<sub>2</sub> demand.
  - Interventions
    - 1. Adjust deflation later.

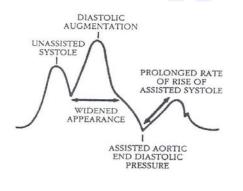


D. Late Deflation

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- Waveform Characteristics:
  - 1. Assisted aortic end-diastolic pressure may be equal to the unassisted aortic end diastolic pressure.
  - 2. Rate of rise of assisted systole is prolonged.
  - 3. Diastolic augmentation may appear widened.
- Physiologic Effects:
  - 1. Afterload reduction is essentially absent.
  - 2. Increased MVO<sub>2</sub> consumption due to the left ventricle ejecting against a greater resistance and a prolonged isovolumetric contraction phase.
  - 3. IAB may impede left ventricular ejection and increase the afterload.
- Intervention
  - 1. Adjust deflation earlier.

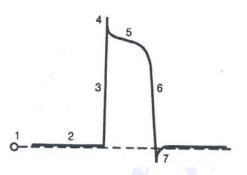




### ATTACHMENT D

### **BALLOON PRESSURE WAVEFORM**

- I. Balloon Pressure Waveform
  - A. Assess the Balloon Pressure Waveform. This represents the movement of helium in and out of the IAB catheter.
  - B. Determine if the balloon pressure waveform is normal:

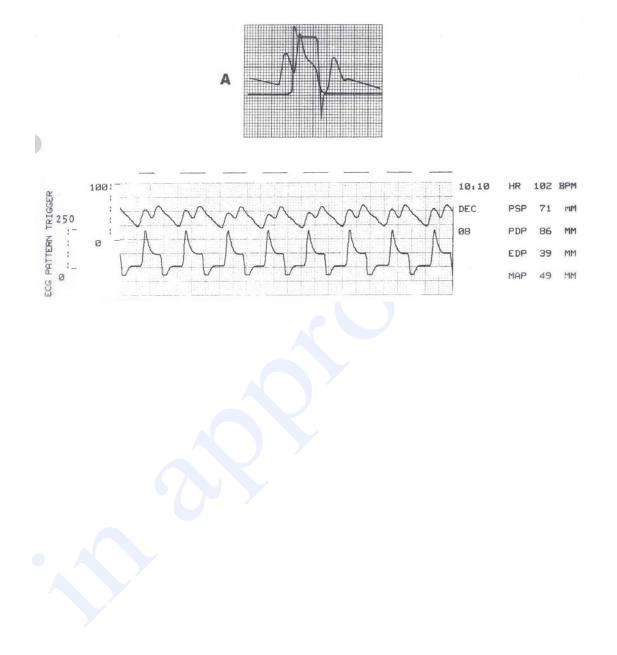


Normal balloon gas waveform. 1, zero baseline; 2, fill pressure; 3, rapid inflation; 4, peak inflation artifact; 5, plateau pressure or inflation plateau pressure; 6, rapid deflation; 7, peak deflation pressure and return to fill pressure.

- Has a fill pressure (baseline pressure) slightly above zero. Reflects pressure in the tubing between IAB and the IABP driving mechanism.
- Has a sharp upstroke. Occurs as gas inflates the IAB catheter.
- Has a peak inflation artifact. This is caused by the gas pressure in the pneumatic line.
- Has a pressure plateau. It is created as the IAB catheter remains inflated during diastole. If there is no plateau pressure, the IAB may not be fully inflated.
- Has a rapid deflation.
- Has a negative deflection below baseline, then returns to baseline. Gas returns to IABP console, then stabilizes within the system.
- C. Compare the balloon pressure waveform with the arterial pressure waveform. Note the similarity in the width of the balloon pressure waveform and the augmented arterial waveform.

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### <u>ATTACHMENT E</u> TROUBLESHOOTING

### I. Troubleshooting

- A. Atrial fibrillation: Underlying cause should be treated. IABP's will automatically deflate the balloon on the "R" wave. The real time method of timing may track dysrhythmias better than traditional or conventional IABP timing.
- B. Tachycardia: Change the IABP frequency to 1:2. Diastole is shortened during tachycardia and balloon augmentation is also shortened. Pumping every other beat may improve MAP. Underlying cause should be treated.
- C. Asystole
  - Switch trigger to arterial pressure. This trigger can be used if there is at least a 15 mmHg rise in arterial pressure.
  - Set inflation to provide diastolic augmentation, and set deflation to occur before upstroke of the next systole. Preliminary research suggests that when used during cardiopulmonary resuscitation, IAB counterpulsation increases cerebral and coronary perfusion.
  - If chest compressions do not provide an adequate trigger:
    - 1. Turn to internal trigger. This will keep the catheter moving so clot formation is minimized.
    - 2. Set the rate at 60-80 beats per minute to maintain consistent movement of catheter.
    - 3. Set the IABP frequency to 1:2. This will prevent thrombus formation.
    - 4. Turn the balloon augmentation down to 50% to maintain slight movement.
- D. Ventricular Tachycardia or Ventricular Fibrillation:
  - Ensure that personnel are cleared from the patient and equipment before cardioverting or defibrillating.
  - Cardiovert or defibrillate as necessary. The IABP is electrically isolated.
- E. Loss of vacuum or IABP failure:
  - Check and tighten connections on pneumatic tubing.
  - Check the compressor power source. Ensures that power is available to drive helium.
  - Manually inflating and deflating the IAPB catheter is necessary if the balloon remains inactive for more than 30 minutes due to potential thrombus formation.
    - 1. Obtain 60 ml syringe and one 3-way stopcock.

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- 2. Remove the catheter extender (Gas line between machine and IABP)
- 3. Attach 3-way stopcock and syringe to the gas line of pt's IABP.
- 4. ALWAYS ASPIRATE FIRST to ensure no blood present (i.e. rupture). If blood returns, do not attempt to inflate, but notify MD of balloon rupture and need for rapid removal of IABP.
- 5. If no blood returns:
  - a. Inflate IABP with 30 ml and immediately aspirate.
  - b. Repeat every five minutes while IABP is inactive.
    - \*\*\*\*Warning\*\*\*\*: NEVER inject into the arterial lumen of the IABP (central hub)
- Change IABP console.
- F. Suspected balloon perforation
  - Observe for loss of augmentation. Gas may be leaking gradually from the catheter. Always set alarm so it will sound if there is a 10 mmHg drop in diastolic augmentation.
  - Check for blood in the catheter tubing. This indicates the balloon has perforated and arterial blood is present. Due to the reaction of the helium with blood in the gas line it will appear more brown than red in color.
  - Assess for changes or lack of normal balloon pressure waveform. Balloon is unable to retain gas, or the pressure plateau may gradually decrease if the IAB is leaking gas.
- G. Balloon Perforation
  - Place the IABP on standby. This prevents further IABP pumping and continued gas
     exchange. IABP catheter has to be removed within 15-30 minutes.
  - Clamp the IAB catheter. Prevents arterial blood back-up.
  - Disconnect the IAB catheter from the console. This will prevent blood from backing into the console.
  - Notify the physician. The catheter should be removed immediately.
  - Prepare for IAB catheter removal or replacement. Catheter should not be dormant for longer than 30 minutes.
  - Discontinue anticoagulation therapy.

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### ATTACHMENT F

	Assessment	Prevention	Treatment Options
Limb Ischemia	<ul> <li>Check distal pulses, color, temp, and capillary filling q 30 min x 2 hours, then q 2 hours.</li> <li>Monitor differential toe temperature.</li> </ul>	<ul> <li>Use smallest sheath/catheter sizes indicated.</li> <li>Risk Factors: female, diabetes, peripheral vascular disease</li> <li>Select limb with best pulse.</li> </ul>	<ul> <li>Remove sheath and observe for bleeding.</li> <li>Subcutaneous Xylocaine injection for arterial spasm.</li> <li>Change insertion site to opposite limb.</li> <li>Bypass graft femoral artery.</li> </ul>
Excessive Bleeding from Insertion Site	<ul> <li>Observe anteriorly and posteriorly for blood or hematoma.</li> <li>Watch for retro- peritoneal bleed.</li> </ul>	<ul> <li>Careful insertion technique.</li> <li>Monitor anti- coagulation therapy</li> <li>Prevent catheter movement at insertion site.</li> </ul>	<ul> <li>Apply pressure. Assure distal flow.</li> <li>Surgical repair.</li> </ul>
Thrombocytopenia	• Daily platelet count	Avoid excessive heparin	• Replace platelets as needed
Immobility of balloon catheter	<ul> <li>Datascope recommends that the IABP catheter <b>not</b> be left immobile in the patient for more than 30 minutes.</li> <li>Observation of IAB status indicator movement.</li> <li>Observation of augmentation.</li> </ul>	<ul> <li>Maintain adequate trigger.</li> <li>Observe movement of IAB status indicator.</li> <li>If unable to inflate the IAB with IABP, inflate and deflate the IAB by hand, using a syringe and stopcock once</li> </ul>	<ul> <li>Notify the physician if IAB is immobile &gt; 30 minutes.</li> <li>Need to change IAB catheter.</li> </ul>

### **COMPLICATIONS/SIDE EFFECTS**

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	Assessment	Prevention	Treatment Options
Balloon Leak	<ul> <li>Observe tubing for bleed with or without the presence of blood detected, low augmentation, and/or gas loss or IAB catheter alarm.</li> </ul>	<ul> <li>every 3-5 minutes.</li> <li>Do not remove the IAB from its tray until it is ready to be inserted.</li> <li>Proper positioning of the catheter.</li> </ul>	• If blood is observed in the pneumatic tubing, <b>disconnect</b> the balloon from the IABP and notify the physician immediately.
Infection	<ul> <li>Observation of the insertion site.</li> <li>Blood cultures for symptoms of infection.</li> </ul>	• Sterile technique during insertion and dressing changes q 24 hours or PRN.	• Antibiotics
Aortic Dissection	<ul> <li>Assess for pain between shoulder blades.</li> <li>Daily hematocrit</li> <li>If suspected, aortogram may be indicated.</li> </ul>	• Insertion of IAB over guidewire with fluoroscopic control.	<ul> <li>Balloon removal.</li> <li>Surgical repair.</li> </ul>
Compartment Syndrome May Develop After IABP is Removed	<ul> <li>Observation of limb for swelling and/or hardness.</li> <li>Measure calf girth.</li> <li>Monitor interstitial pressure.</li> </ul>	<ul> <li>Use smallest catheter/sheath appropriate.</li> <li>Maintain adequate colloid osmotic pressure.</li> </ul>	• Fasciotomy is necessary.

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Reference Number	6283
Effective Date	Not Approved Yet
Applies To	PHARMACY
Attachments/Forms	Attachment A Conversion Criteria

### I. **POLICY STATEMENT:**

A. Conversion from the intravenous route of administration to the oral route of administration may be initiated by a pharmacist when patients are determined to meet specified criteria approved by the Medical Staff<sub>-</sub>.

### II. PURPOSE:

- A. To ensure a rational and evidence based approach to maintaining or improving patient outcomes while optimizing the overall costs of medication therapy.
- B. The oral route of administration may be ideal so long as the medication achieves the desired concentrations in blood and/or the targeted site(s) of action. Patients often start on parenteral therapy, but as their condition improves, they are often candidates for continuation with oral therapy. Available oral formulations have high oral bioavailability and equivalent potency.

### III. **DEFINITIONS:**

- A. IV: intravenous
- B. PO: per os; designates the oral route

### IV. GENERAL INFORMATION:

A. N/A

### V. **PROCEDURE:**

- A. Parenteral medications eligible for IV to PO conversions and approved dose interchanges are listed in <u>Attachment A</u>.
- B. If the patient is being considered for an IV to PO conversion, the clinical pharmacist can examine the route of therapy and determine if it is clinically appropriate to perform a parenteral to oral therapy switch. Inclusion/exclusion criteria are specified in section F below and in <u>Attachment A</u>.

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- C. The American Thyroid Association (ATA) published updated Guidelines for the Treatment of Hypothyroidism in 2014 (www.ismp.org/ext/278). In the update, ATA states that, <u>I</u>if there are concerns about significant malabsorption or there are other clinical reasons why a patient cannot be given enteral levothyroxine, IV levothyroxine may be administered until enteral absorption improves.-
- B.D. If the patient meets the approved criteria for transition to oral therapy, the clinical pharmacist will enter the new order using "per protocol" order source. A Pharmacy Note will be entered in the computer system detailing the conversion. An Intervention Note will also be entered on the pharmacy system for tracking purposes.
- C.E. The provider has the option to switch back to the intravenous route if parenteral therapy is preferred.
- D.<u>F.</u> Findings and feedback will be reported to the Antimicrobial Stewardship Committee and Pharmacy and Therapeutics Committee.

**E.**<u>G.</u> Criteria for patient eligibility.

	Tor partent engiointy.
Inclusion	Patients improving clinically
Criteria	Tolerating food or enteral feeding
	• Able to adequately absorb oral medications via the oral, gastric tube, or nasogastric tube route
	<ul> <li>Not displaying signs of shock, not on vasopressor blood pressure support</li> </ul>
	Taking other medications orally
	Additional requirements for antimicrobials:
	• Afebrile for at least 24 hours (temperature $\leq 100^{\circ}$ F or $\leq 37.8^{\circ}$ C)
	• Heart rate $\leq 90$ beats per minute
	• Respiratory rate $\leq 20$ breaths per minute
	• Systolic blood pressure $\geq$ 90 mm Hg (without vasopressor drugs)
	• Signs and symptoms of infection improvement according to assessment:
	- Improving WBC and differential counts
	- Improving signs and symptoms
	- Hemodynamically stable



	- Patient is not septic
Exclusion	• Persistent nausea and vomiting, diarrhea
Criteria	• Patient with the following GI conditions:
	- Ileus or suspected ileus with no active bowel sounds
	- Patient is known to have a malabsorption syndrome
	- Proximal resection of small intestines
	<ul> <li>High nasogastric (NG) tube output or requiring continuous GI suction (&gt; 500 mL/day)</li> </ul>
	- Active GI bleed
	Cystic fibrosis
	Patients with Grade III or IV mucositis
	• Significant drug-drug interactions that may affect the bioavailability of oral medications
	Additional exclusions for antimicrobials:
	• IV antimicrobials ordered by Infectious Disease physicians
	• Patient has a serious or life threatening infection:
	- Meningitis, endocarditis, intracranial abscesses, osteomyelitis, septicemia, Legionella pneumonia
	- Inadequately drained abscesses and empyema
	- Severely immunocompromised (solid organ transplant, bone marrow transplant)
	- Neutropenic patients

F.<u>H.</u> If there is any question regarding the patient's eligibility criteria, the clinical pharmacist will contact the physician for approval prior to initiating an IV to PO conversion. IV to PO conversions for antimicrobials written by an Infectious Disease physician must be approved by the ID physician.

G.I. Documentation:

1. Pharmacy will document the conversion within the electronic medical record. An Intervention Note will also be entered ion the <u>patient EMR</u>.

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### VI. EDUCATION/TRAINING:

<u>Annual Competency</u>

A. Education is provided during general or department-specific orientation and periodically as practice or policy changes.and/or training is provided as needed.

#### VII. **REFERENCES:**

- A. *Considerations for PO to IV dose conversions.* Pharmacist's Letter/Prescriber's Letter; August 2016 Resource #320842r/Prescriber's Letter 2010; 26(9):260912.
- B. Quap, C.W. "Intravenous to Oral Therapy Conversion." *Competence Assessment Tools for Health-System Pharmacies*, 5<sup>th</sup> ed. American Society of Health-System Pharmacies (2015). Pp. 351-358.
- C. Pain Management: converting Opioid doses. http://cps.learnercommunity.com/Files/Protected/ContentPageHtml/2/f/0/49343de8356 c417a9e615f990e51777d/CPS\_Pain\_Mgmt\_opioid\_conversion\_10NovFINAL.pdf
- B.D. The American Thyroid Association (ATA) Guidelines for the Treatment of Hypothyroidism in 2014 (www.ismp.org/ext/278).

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### ATTACHMENT A <u>– CONVERSION CRITERIA</u>

Medication	Additional Criteria	Intravenous Dose	Oral Equivalent
<u>Azithromycin</u>	500 mg IV Day 1 followed by 250 mg PO daily x 4 days Total 1500 mg/5 day course (alternative 500 mg IV daily x 3 days)	250 mg IV 500 mg IV	250 mg PO 500 mg PO
<u>Ciprofloxacin</u>		<u>400 mg IV q12hr</u> <u>200 mg IV q12hr</u>	500 mg PO BID 250 mg PO BID
Dexamethasone	<u>1:1 equivalency</u>	<u>4 mg IV</u> <u>10 mg IV</u>	<u>4 mg PO</u> <u>10 mg PO</u>
Doxycycline	<u>1:1 evquivalency</u> -	100 mg IV every 12 hours	100 mg PO every 12 hours
Fluconazole	<u>1:1 equivalency</u> -	100 mg IV daily 200 mg IV daily 400 mg IV daily	100 mg PO daily 200 mg PO daily 400 mg PO daily
Lacosamide	Schedule IV	<u>50 mg IV</u> <u>100 mg IV</u> <u>150 mg IV</u> <u>200 mg IV</u>	<u>50 mg PO</u> <u>100 mg PO</u> <u>150 mg PO</u> <u>200 mg PO</u>
Levetiracetam	<u>1:1 equivalency</u>	500 mg IV 750 mg IV 1500 mg IV	<u>500 mg PO</u> <u>750 mg PO</u> <u>1500mg PO</u>
Levofloxacin	-	250 mg IV daily 500 mg IV daily	250 mg PO daily 500 mg PO daily

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		750 mg IV daily	750 mg PO daily
Levothyroxine	<ul> <li>If using IV levothyroxine, the recommended equivalent IV dose is approximately 75% of the oral dose (not 50%), assuming the enteral levothyroxine dose had achieved euthyroidism.A 1:2 IV to PO conversion will be used If using IV levothyroxine, the</li> <li>recommended equivalent IV dose is approximately</li> <li>75% of the oral dose (not 50%);</li> <li>assuming the enteral levothyroxine dose had achieved euthyroidis</li> <li>m</li> <li>Exclude:         <ul> <li>Myxedema coma</li> <li>Patients with Endocrinologist consult</li> </ul> </li> </ul>	0.7505 mg IV daily	0.1 mg PO daily
Linezolid	-	600 mg IV every 12 hours	600 mg PO every 12 hours
<u>Metoclopramide</u>		<u>5 mg IV</u> <u>10 mg IV</u>	<u>5 mg PO</u> <u>10 mg PO</u>
Morphine	Equianalgesic dose is approximate; titrate to patient response	<u>10 mg IV</u>	<u>30 mg PO</u>
Metronidazole	-	500 mg IV every	500 mg PO every

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		8 hours	8 hours
Oxycodone		<u>10 mg IV</u>	<u>20 mg PO</u>
Pantoprazole	-	240 mg IV daily 40 mg IV daily	240 mg PO daily 40 mg PO daily
Rifampin	-	600 mg IV daily	600 mg PO daily

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Reference Number	1120	
Effective Date	Not Approved Yet	
Applies To	ALL NURSING UNITS, EMERGENCY DEPT, Nursing	
	Administration, PHARMACY	
Attachments/Forms	WIN Tip #43	

### I. POLICY STATEMENT:

- A. Investigational medications are not approved by the FDA for marketing in the U.S.to treat a specific disease or condition, and therefore must be prescribed and administered in accordance with 1) an IRB-approved research protocol, 2) a valid FDA Form 1572 signed by the IRB-approved Principal Investigator granting prescriptive authority, and 3) be accompanied by a the patient's signed IRB-approved research informed consent.
- B. Investigational drugs are under strict safety surveillance and the FDA mandates special Adverse Event and Serious Adverse Event reporting mechanisms for research investigators and Clinical Research Coordinators. Research participants taking investigational drugs have signed special Informed Consent Forms permitting additional levels of clinical monitoring and reporting to the study sponsors and the FDA. Non-research staff are not required to perform outside their regular scope of patient care other than a duty to inform the patient's research team of the fact of a research participant's admission to the Hospital.
- C. This policy excludes investigational drugs requiring research protocol staff to administer dosing (e.g., intravenous routes, drugs requiring admixture / compounding).
- D. This policy includes oral medications prescribed and already dispensed to the study participant for self-administration.

### II. **PURPOSE:**

- A. To outline activities and procedures for obtaining and documenting administration of investigational medications for both inpatients and outpatients who are currently participating in an IRB-approved research protocol.
  - 1. Salinas Valley Memorial **Hospital** (**SVMH**) <u>does not</u> support investigational drug research involving inpatient investigational drug administration requiring overnight observation.
  - 2. Salinas Valley Memorial **Healthcare System (SVMHS)** and its Clinical Research Program <u>do</u> support outpatient investigational drug trials at the

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Salinas Valley Medical Clinics under an active clinical trial agreement between the study sponsor and Salinas Valley Memorial Healthcare System.

- 3. From time to time, an inpatient may be admitted for care who may already be taking an investigational medication as an outpatient under a clinical trial agreement between the study sponsor and an outside institution (not SVMHS). Depending on the judgment of the SVMH treating physician, an inpatient at SVMH may keep taking oral study drug per the investigational protocol while staying in the hospital. (This circumstance was formerly known as INCIDENTAL USE of Investigational Drugs because the study drug is given incidental to the patient's hospitalization at SVMH.)
- B. Applies to SVMHS staff involved in 1) the care of inpatients at the Hospital and 2) the coordination of clinical investigations at the Clinics. SVMHS Clinical Research Coordinators may dispense oral study drug under the supervision of the Principal Investigator listed on the Form 1572.
- C. Applies to Investigational New Drug (IND) studies under FDA oversight, approved by an Institutional Review Board, for which:
  - 1. An inpatient has a signed Research Informed Consent Form with an outside research PI and location, and can bring the oral study medication to the Hospital
  - 2. An inpatient who is a current participant in an investigational drug study at SVMHS as an outpatient wishes to continue taking study drug while hospitalized.
  - 3. Per the judgment of the SVMH treating physician, applies to the inpatient who upon admission to SVMH is already prescribed an investigational oral drug by an outside physician conducting a research protocol under an outside research institution. The patient's SVMH attending physician makes the determination whether an inpatient may safely continue taking an existing investigational drug during the patient's hospital stay.

### III. **DEFINITIONS:**

- A. ICF Informed Consent Form
- B. IND Investigational New Drug
- C. PI Principal Investigator

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- D. **Incidental Use of an Investigational Drug**: Occurs when a clinical trial participant on an investigational drug happens to be admitted to our Hospital for any reason, and if appropriate, the hospital accommodates the patient's continued administration of the investigational drug under FDA oversight.
- E. **Investigational Drug:** A substance that has been tested in the laboratory and has been approved by the U.S. Food and Drug Administration (FDA) for testing in people. An investigational drug may be approved by the FDA for use in one disease or condition but still be considered investigational in other diseases or conditions. Also called investigational agent, investigational product, and investigational new drug (IND).
- F. **Investigator's Brochure (IB):** A compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration: and safety monitoring procedures.

### IV. GENERAL INFORMATION:

- A. The Statement of Investigator, Form FDA 1572, is an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic. All investigational medications or agents used in human subjects research shall be stored, handled, and dispensed in accordance with institutional policy, and state and federal laws and regulations. (Reference MEDICATION SECURITY AND STORAGE and MEDICATION USE)
- B. Investigational drugs are under strict safety surveillance and the FDA mandates special Adverse Event and Serious Adverse Event reporting mechanisms for research investigators and Clinical Research Coordinators. Research participants taking investigational drugs have signed special Informed Consent Forms permitting additional levels of clinical monitoring and reporting to the study sponsors and the FDA. Non-research staff are not required to perform outside their regular scope of patient care other than a duty to inform the patient's research team of the fact of a research participant's admission to the Hospital.
- C. This process excludes investigational drugs requiring research protocol staff to administer dosing (e.g., intravenous routes, drugs requiring admixture / compounding).

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- D. This process includes oral medications prescribed and already dispensed to the study participant for self-administration.
- A.

### V. **PROCEDURE:**

- A. Patients participating in IRB approved investigational protocols at SVMHS involving investigational medications are consented by the Clinical Research Coordinator or Principal Investigator (PI) per policy. A copy of the signed research informed consent is maintained in the patient's electronic medical record. In MEDITECH the patient's signed Research Informed Consent can be found under NOTES section.
  - 1. Inpatients participating in an outside investigational oral drug study will be provided assistance, if needed, by the Research Manager to obtain a copy of their signed Informed Consent Form from the outside research institution.
- B. Investigational medications will be used only under the supervision of the principal investigator. The patient's treating physician or Hospitalist must have access to the study Protocol and the patient's signed Informed Consent Form before writing the order to continue study drug. All Principal Investigators in the U.S. are required by the IRB to have a 24 hr. phone number listed on the research Informed Consent Form.
- C. Investigational Medications shall be stored in the pharmacy in accordance with pharmacy policies and procedures as well as sponsor guidelines.
- D. All investigational medications used at SVMHS must meet the following requirements:
  - 1. Original manufacturer's packaging for identification.
  - 2. FDA- approved labeling including the words "Investigational" clearly indicated on the label.
  - 3. A sufficient supply of study medications for the anticipated duration of the patient's hospital stay.
- E. The patient's treating physician must write an order for administration of the investigational medication.
- F. Administration of investigational medications shall be done in accordance with the SVMHS medication use policy including verification of order for

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investigational medication and any randomization numbers as appropriate. See MEDICATION USE Policy.

- G. Administration of investigational medication to inpatients requires:
  - 1. Registered Nurse or Pharmacist to verify with Pharmacy medication name, lot number and dosage of initial medication and document on study drug accountability log in the pharmacy per sponsor guidelines.
  - 2. Registered Nurse and Pharmacy to verify that a copy of the fully executed Research Informed Consent is present in patient medical record.
  - 3. Subsequent doses of investigational medication shall be obtained by the Registered Nurse from the pharmacy and signed out on study drug accountability log.
- H. For patients being admitted to the hospital who are already on an investigational medications:
  - 1. Clinical Research Department is to be notified at time of patient admission. By completing the field in Meditech admit form, the Admitting RN creates a MEDITECH Routine Clinical Trial Notification that goes to the Research Department Printer.
  - 2. Order to administer investigational medication must be written by authorized investigator, including an order for patient to bring in patient's supply of investigational drug from home.
  - 3. For investigational medications normally obtained by patient from an outside pharmacy, Pharmacy is to notify physician's office to coordinate obtaining medication as ordered.
- I. Documentation for inpatients:
  - 1. Clinical research staff will document per the standard identified in this policy in the Notes section of the patient's electronic medical record.
  - 2. Clinical Nursing staff will document medication administration per MEDICATION USE policy.
  - 3. Pharmacy will document receipt of investigational product, dispensing, storage conditions, and disposal of medication per INVESTIGATIONAL DRUG SERVICE policy.

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### VI. EDUCATION/TRAINING:

A. Education and/or training is provided by the Research Manager as needed.

### VII. **REFERENCES:**

- A. FDA Procedural: "Frequently Asked Questions Statement of Investigator (Form FDA 1572)," May 2010. Accessed July 24, 2020 at: https://www.fda.gov/media/78830/download
- B. FDA Guidance: Use of Investigational Products When Subjects Enter a Second Institution, January 1998. Accessed March 6, 2020 at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/useinvestigational-products-when-subjects-enter-second-institution
- C. The Joint Commission Standard RC.02.01.01
- D. The Joint Commission Standard RI.01.03.05
- E. The Joint Commission Standard MM.03.01.05
- F. Center for Medicare and Medicaid Services (CMS) CoP §482.25(b) Food and Drug Administration (FDA)

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### QUALITY AND EFFICIENT PRACTICES COMMITTEE

Minutes from the May 24, 2021 meeting of the Quality and Efficient Practices Committee will be distributed at the Board Meeting

(JUAN CABRERA)

### FINANCE COMMITTEE

Minutes from the May 24, 2021 meeting 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

### (RICHARD TURNER)

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

### Board Paper: Finance Committee

Agenda Item:	Consider Recommendation for Board Approval of Project Funding for the SVMHS Retail Pharmacy Project
Executive Sponsor:	Clement Miller, Chief Operating Officer / Interim CNO John S. Choi, Director of Pharmacy Dave Sullivan, Construction Management
Date:	March 9, 2021

#### **Executive Summary**

SVMHS is pursuing tenant improvements to the first level portion of the parking structure located at 450 E Romie, Salinas, CA. The planned renovations include architectural finish replacements (flooring, paint, drywall finishes), low voltage cabling, office furniture, technology equipment, office equipment, and furnishings necessary to facilitate the retail pharmacy use of the space. Facilities Management is approaching the Board to request approval of capital funding to complete renovations and procure furnishings, furniture, and equipment. The total estimated cost for the project planning, design, permitting, construction, and equipment is \$450,000.

#### Background/Situation/Rationale

The primary objectives of the retail pharmacy are to support (i) employees & covered lives prescription program, (ii) fulfill discharge prescriptions & medications to hospital beds, (iii) 340B contract pharmacy to SVMH and qualifying clinics and (iv) support SVMH Infusion Center & specialty medications.

#### **Timeline/Review Process to Date:**

March 2021:	Secure City of Salinas Building Department approvals and commence construction
August 2021:	Anticipated completion of renovations
November 2021:	Board of Pharmacy approvals to operate pharmacy

#### Meeting our Mission, Vision, Goals

#### **Strategic Plan Alignment:**

Medication management and prescription plans continue to change and evolve in the US healthcare system. SVMHS' strategic plan to provide continuity of care and services to our community and employees and covered lives beyond acute care setting includes management of ambulatory prescription distribution and participation in specialty pharmacy program that is in a rapid growth. Our retail pharmacy plan meets the immediate needs of patient's discharge prescriptions, convenience of employee prescription plans. The plan will also provide a long-term business growth in support of the infusion center pharmacy and their needs for specialty pharmacy procurement.

#### **Pillar/Goal Alignment:**

Service	People	🛛 Quality	□ Finance	🛛 Growth	□ Community
		a quanty			

#### **Financial Summary**

Proforma to be reviewed at the Finance Committee meeting.

#### Recommendation

Consider recommendation for Board Approval of project funding for the SVMHS Retail Pharmacy Project in the total project estimate amount of \$450,000.

#### Attachments

- 1. Project Cost Model prepared March 3, 2021
- 2. Retail Pharmacy Overview Presentation

### Salinas Valley Memorial Healthcare System (10348)

Project Cost Summary: DRC Retail Pharmacy Renovations Architect/Engineering: WRD Architects Budget Generated at Procurement Phase Budget Date: 3/3/2021

<b>BUDGET SU</b>	MMA	ARY		
			A	
Line Iter	n	Description	Original Budget	Notes
	1	Construction		
0100		Construction Contract	\$160,000	Multi-Prime Contract Delivery Method
0102		Owner Construction Contingency	\$7,500	Owner Held Contingency
	2	Design		
0200		Professional Fees - Fixed	\$75,000	Architectural & Consulting Engineers
	3	Inspections and Consultation		
0301		Special Inspections	\$5,000	Agency Required Inspection
	4	AHJ Fees		
0401		City Fees (Entitlement and Permitting)	\$9,000	Agency Fees
	5	Soft Costs		
0502		Construction Management - PM/CM	\$78,500	Program Management
	7	FF&E		
0703		Technology Infrastructure	\$95,000	Pioneer Rx Point of Sale Software and IT Infrastructure
	99	Contingency		
9900		Contingency	\$20,000	~5% of Project
Totals			\$450,000	



# Retail Pharmacy – Overview and Business case

John Choi, Director of Pharmacy Rolf J. Norman, Director of Financial Planning & Decision Support Retail Pharmacy – Overview

Provide:

- Discharge prescriptions at Bedside (Meds to Bed)
- Indigent Prescription Program 340B
- Employee Prescriptions convenience
- Specialty Pharmacy Program

### Retail Pharmacy – Key Assumptions

- Base retail volumes, COGS and staffing (FTE) is included as projected by CPS (Pharmacy Consultant in 2020) across the 5 year period. The volumes include discharge prescriptions for Inpatient and ED, as well as retail sales to staff.
- Staff salaries have been updated to reflect current SVMH rates for Pharmacist and Pharmacy Tech, as well as higher SVMH benefit rates.
- Oncology Oral drug volume is included as projected by SVMH Pharmacy Management based on usage data from the SVMC Oncology Clinic for specific drugs.
- Oncology drug revenue and COGS is based on Retail Cost (revenue), and SVMH 340b pricing (COGS) to project a conservative picture. In addition, the Retail Pharmacy profitability is reduced by an estimate from SVMC of current profits from the Oncology Drugs. The increased margin arises from SVMH's ability to purchase the drugs at a lower cost than what is available to SVMC.
- The up-front investment consists of the \$450k estimate for the buildout of the location, and other non-capital startup costs estimated by the CPS Consultants.
- The proforma is calculated excluding revenue/expense inflation on the SVMH base revenue/ expense

### Retail Pharmacy – Financial Forecast

	Initial investment	Year 1		Year 2		Year 3		Year 4		Year 5	5	year Total
CPS Baseline Prescription		17,749		41,412		52,586		56,603		60,406		228,75
Oral Oncology Prescriptions		203		203		203		203		203		1,01
Total Prescriptions		\$ 17,952	\$	41,615	\$	52,789	\$	56,806	\$	60,609		229,77
Capital Investment Retail Pharmacy	\$ 450,000											
Other Startup Expense	the second process of the second proces of the second proces of th											
CPS Baseline Retail Pharmacy Revenue		\$ 599,626	¢	1,633,073	¢	2,270,304	¢	2,553,032	¢	2,828,508	¢	9,884,54
Oncology Oral Drug Revenue		\$ 1,327,086		1,327,086		1,327,086				1,327,086		6,635,43
Total Revenue		\$ 1,926,712	1.0	2,960,159		3,597,390		3,880,118		4,155,594	_	16,519,97
CPS Baseline Retail Pharmacy COGS		\$ 404,747	\$	1,183,765	\$	1,677,025	\$	1,892,760	\$	2,104,536	\$	7,262,83
Oncology Oral Drug COGS		\$ 658,666		658,666		658,666		658,666		658,666		3,293,33
Salaries and Benefits Total		\$ 416,044	\$	464,199	\$	607,625	\$	694,822	\$	797,822	\$	2,980,51
Other Operating Expense (CPS Estimate)		\$ 119,822	\$	136,744	\$	147,791	\$	153,017	\$	158,114	\$	715,48
Lost Contribution Margin From SVMC		\$ 305,993	\$	305,993	\$	305,993	\$	305,993	\$	305,993	\$	1,529,96
Total Expense	\$ 512,500	\$ 1,905,272	\$	2,749,367	\$	3,397,100	\$	3,705,258	\$	4,025,132	\$	15,782,13
Operating Income	\$ (512,500)	\$ 21,440	\$	210,792	\$	200,290	\$	174,860	\$	130,462	\$	737,84
Target Rate - ROI	15.0%											
NPV	(\$32,987)											
IRR	12.2%											
Payback in Years	3.5											

# **QUESTIONS?**

# **Salinas Valley Memorial Healthcare System**

"An Integrated Healthcare Delivery System"

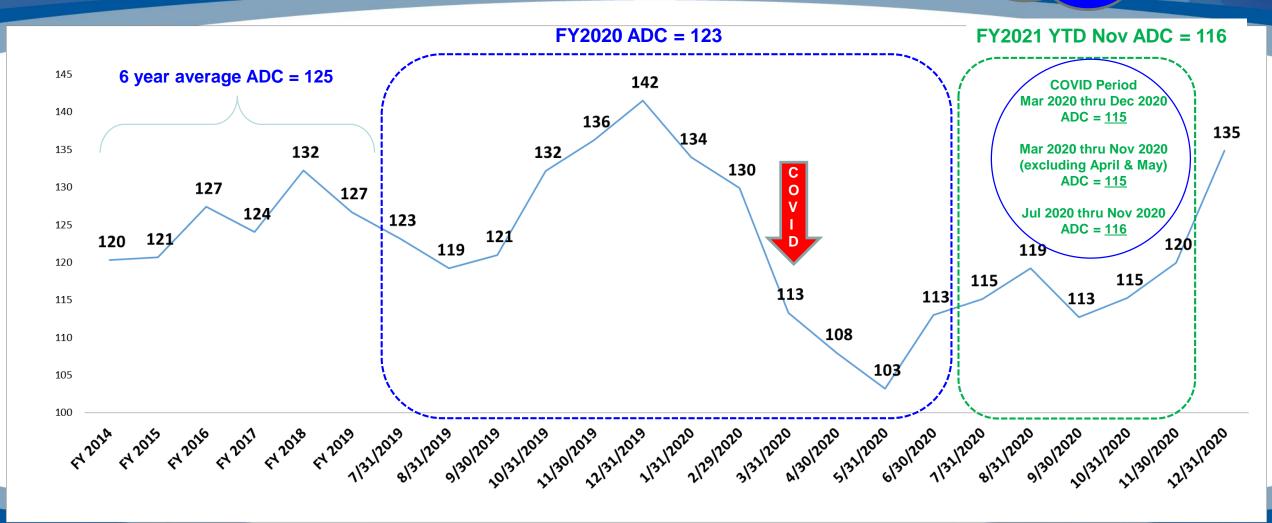
# Operating & Capital Budget Fiscal Year 2022

Augustine Lopez Chief Financial Officer



### Salinas Valley Memorial Hospital **Average Daily Census (ADC) Trend** FY 2014 thru FY 2021 YTD December

Proposed ADC Budget for FY 2022 is 115.



# Consolidated FY 2022 Budget Compared to FY 2021 Projection

	FY 2021 Projection			
PL SUMMARY	CONSOLIDATED	CONSOLIDATED	CONSOLIDATED	%
	TOTAL	TOTAL	Variance	Change
GROSS PATIENT REVENUE	2,500,660,155	2,514,408,597	(13,748,442)	-0.5%
NET PATIENT REVENUE	615,908,549	647,184,125	(31,275,576)	-4.8%
Yield	24.6%	25.7%	-1.1%	-4.3%
OTHER REVENUE	17,844,758	20,129,664	(2,284,907)	-11.4%
				<b>E</b> 00/
TOTAL REVENUE	633,753,307	667,313,790	(33,560,482)	-5.0%
TOTAL OPERATING EXPENSES	619,778,972	600 255 000	2,576,916	0.4%
TOTAL OPERATING EXPENSES	019,770,972	622,355,888	2,576,916	0.4%
OPERATING MARGIN	13,974,335	44,957,901	(30,983,566)	-68.9%
OPERATING MARGIN %	2.2%	6.7%	-4.5%	-67.3%
	2.270	0.170	4.07	-01.070
EBITDA	41,881,039	71,872,586	(29,991,547)	-41.7%
EBITDA %	6.6%	10.8%	-4.2%	-38.6%
OTHER NON OPERATING INCOME	13,036,993	13,190,580	(153,587)	-1.2%
TOTAL MARGIN	27,011,329	58,148,482	(31,137,153)	-53.5%
TOTAL MARGIN %	4.3%	8.7%	-4.5%	-51.1%

Salinas Valley Memorial Healthcare System Executive Summary - Key Budget Assumptions FY 2022 Budget

- FY 2022 Operating Margin: 2.2% or \$14.0M
   (Projected FY 2021: <u>6.7% or \$45.0M</u>)
- FY 2022 Total Margin: 4.3% or \$27.0M
   (Projected FY 2021: 8.7% or \$58.1M)
- FY 2022 Total Operating Revenues: \$634M (<5.0%> or <\$33.6M> Decrease over Projected FY 2021)
- FY 2022 Total Operating Expenses: \$620M (0.4% or \$2.6M Decrease over Projected FY 2021)

# Statement of Cash Flow - Consolidated FY14 Actuals – FY22 Budget

Dollar amounts in 000's	Audited <u>2014</u>	Audited <u>2015</u>	Audited <u>2016</u>	Audited <u>2017</u>	Audited <u>2018</u>	Audited <u>2019</u>	Audited <u>2020</u>	Projected <u>2021*</u>	Budget <u>2022*</u>	
Sources of cash:										
Net income (loss) from operations	15,190	29,150	31,502	43,317	70,065	69,173	89,435	44,958	13,974	> <b>♦</b> \$31.0M
Add back depreciation	21,131	20,107	20,225	20,267	20,729	21,970	22,385	26,915	27,907	
Add back non-cash pension expense	11,311	10,799	12,900	17,860	16,800	24,300	24,069	22,200	23,700	
Proceeds from Bonds										
Sale of assets (SVAL)	0	0	0	0	0	0	0	8,000	0	
Non-operating income (loss)	13,986	9,170	9,822	6,568	15,396	9,187	24,679	13,191	13,037	
Change in net current assets	1,658	5,337	2,124	(541)	(18,445)	27,945	4,677	(20,358)	5,250	
Total Sources of Cash	63,276	74,563	76,573	87,471	104,545	152,575	165,245	94,906	83,868	> <b>♦</b> \$11.0M
Uses of cash: Capital and strategic investments	7,855	7,268	28,142	19,854	13,324	34,067	45,225	30,446	57,500	<b>&gt;                                    </b>
Pension plan deposits	11,311	10,799	12,900	22,860	20,723	27,300	26,809	26,000	25,397	ψ27.11
Payments on long-term debt	115	776	776	41	43	46	48	48	48	
Total uses of cash	19,281	18,843	41,818	42,755	34,090	61,413	72,082	56,494	82,945	<b>&gt; ♦</b> \$25.5M
Net cash flow	43,995	55,720	34,755	44,716	70,455	91,162	93,163	38,412	923	> <b>♦</b> \$36.5M
Beginning cash and investments	95,543	139,538	195,258	230,013	274,729	345,184	436,346	529,509	567,921	
Ending cash and investments	139,538	195,258	230,013	274,729	345,184	436,346	529,509	567,921	568,844	> <b>▲</b> \$0.9M
Days cash on hand	162	219	216	233	268	307	352	348	351	<b>♦</b> 3 days

\*Projection & Budget are normalized

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# Salinas Valley Memorial Healthcare System Key Financial Indicators

Statistic	S&P A+ Rated Hospitals	2013	2014	2015	AUDITE 2016	D 2017	2018	2019	2020	2021 Projected Normalized	2022 Budget Normalized
Operating Margin	4.0%	6.8%	4.3%	7.8%	7.1%	8.8%	12.5%	10.8%	13.5%		2.2%*
Total Margin	6.6%	7.7%	7.5%	10.2%	9.3%	10.1%	14.8%	12.0%	17.2%		4.3%*
EBITDA	13.6%	14.2%	13.5%	15.5%	13.9%	14.2%	18.5%	19.6%	20.6%	12.7%	8.7%*
Days of Cash and Investments	291	116	162	219	216	233	268	269	352	348	351
Debt Service Coverage Ratio	3.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Debt to Capitalization	42.4%	0.1%	0.7%	0.5%	0.3%	0.3%	0.0%	0.0%	0.0%	0.0%	0.0%
Days of Accounts Receivable	49.0	49.4	49.2	44.1	52.7	54.5	46.0	51.0	47.0	52.0	50.0
Supply Expense as % NPR	n/a	11.7%	11.7%	11.4%	13.0%	13.2%	12.1%	11.8%	11.9%	12.9%	13.2%
SWB Expense as % NPR	53.7%	57.6%	60.1%	57.8%	54.0%	52.4%	49.2%	49.5%	49.8%	52.7%	56.0%

# SVMHS Capital Budget Fiscal Year 2022

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### Salinas Valley Memorial Healthcare System Capital Budget Summary FY 2022

FY2022 Capital Budget Summary		
Total Routine Capital	\$	18.7m
Total Strategic Capital (Including SVMC)	\$	30.7m
Master Facility Planning & Design (Garage \$36m Total, Done FY24)	\$	5.5m
Master Plan for Campus Expansion, Modernization, and Seismic Upgrade	\$	1.0m
Epic Connect Ambulatory Expansion (\$4.1m Total, Done FY23)	\$	1.6m
Total Proposed Capital Budget For FY2022	ć	57.5m

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# Salinas Valley Memorial Hospital <u>Routine</u> Capital Budget Summary - DRAFT FY 2022

Sources of Capital - Total Capital	
General Operating funds	\$ 56.0m
Estimated Foundation Contribution	\$ 1.5m
Total Sources of Capital	\$ 57.5m

**Proposed Uses Of Routine Capital** 

Subtotal Carryover Projects

Carryover Projects Started in FY2021	
1 Nurse Call Upgrade First Floor (\$1.5m Total)	\$ 1.3m
2 Second Obstetrical Operating Room (\$1m Total)	\$ 0.8m
3 Chemistry Analyzers & Lab Automation (\$2.2m Total)	\$ 0.6m
4 Heart Center Air Handler Unit Replacement- 1st flr (\$1.6m Total)	\$ 0.4m
5 Starbucks 10 year remodel (per contract)	\$ 0.3m
6 DRC Retail Pharmacy (\$0.5m Total)	\$ 0.2m
7 Tower Roof Replacement (\$0.6m)	\$ 0.2m

8

3.7m

\$

# Salinas Valley Memorial Hospital FY 2022 <u>Routine</u> Capital Budget Summary

New Capital Under Consideration		
Facilities/Construction		
1 High Speed elevator modernization	\$	2.4m
<sup>2</sup> SVMHS Rebranding/Facility Signage and Wayfinding. (Main Hospital, SVMH Clinics (13), SVMC Locations (17), DOD Offices (9), Other Locations (13)	, <b>\$</b>	<b>1.9</b> m
3 Other Projects < \$200k	\$	0.1m
Total New - Facilities/Construction	\$	4.4m

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# Salinas Valley Memorial Hospital FY 2022 <u>Routine</u> Capital Budget Summary

**New Capital Under Consideration (Continued)** 

Equipment	
1 Pharmacy automated medication storage and dispensing system replacement project	\$ 3.3m
2 Cardiac Ultrasound Replacement	\$ 0.7m
3 Nuclear Camera upgrade Ryan Ranch	\$ 0.5m
4 CT Scanner and Nuclear Medicine Camera (\$6m total over FY22-23)	\$ 0.5m
5 Patient Beds (25). House wide life-cycle replacement, with FY22 focus on 5-Main	\$ 0.3m
6 IV Pump Replacement (\$0.6m over 2 years)	\$ 0.3m
7 Blood Culture Biomerieux Virtuo System	\$ 0.2m
8 Perfusion System - Cardiac Surgery	\$ 0.2m
9 Oven and refrigeration equipment update/ replacement	\$ 0.2m
10 Specialty Beds in Labor and Delivery	\$ 0.2m
11 Other Equipment < \$200k	\$ 0.5m
Total New - Equipment	\$ 7.1m

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# Salinas Valley Memorial Hospital FY 2022 <u>Routine</u> Capital Budget Summary

New Capital Under Consideration (Continued)	
Information Technology	
1 Patient Room Interactive Education & AV System	\$ 0.6m
2 Replacement Archive (350TB) – replacement storage for current storage that's end of life	\$ 0.4m
3 Desktop Computers/Lifecycle Replacement	\$ 0.3m
4 Replacement of Windows 7 & High Risk Devices	\$ 0.3m
5 Increased Server Capacity (Capacity Needs)	\$ 0.2m
6 Video Conference Modernization (Remaining Rooms CMO/HR/Education, Finance)	\$ 0.2m
7 Mobile devices – Laptops, iPads, WebEx Patient Devices and accessories	\$ 0.2m
8 Other Information Technology < \$200k	\$ 1.3m
Total New - Information Technology	\$ 3.5m
Total Fiscal Year 2022 Routine Capital	\$ 18.7m

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# **QUESTIONS /COMMENTS**

# COMMUNITY ADVOCACY COMMITTEE

Minutes from the May 25, 2021 meeting of the Community Advocacy Committee will be distributed at the Board Meeting

(REGINA M. GAGE)



### Medical Executive Committee Summary May 13, 2021

The following items from the meeting of the Medical Executive Committee (MEC) are presented to the Board of Directors and recommended for approval or as informational as indicated:

# **Items for Board Approval:**

### **Credentials Committee**

### **Initial Appointments:**

APPLICANT	SPECIALTY	DEPT	PRIVILEGES
Garcia, Luis F, MD	Maternal Fetal Medicine	Ob/Gyn	Maternal Fetal Medicine
Goodwein, Shelley, MD	Ob/Gyn	Ob/Gyn	Obstetrical and Gyn privileges

# **Reappointments:**

APPLICANT	SPECIALTY	DEPT	PRIVILEGES
Bradley, Cedrick, MD	Internal Medicine	Medicine	Adult Hospitalist
Conly, Bethany, MD	Ob/Gyn	Ob/Gyn	Obstetrics
			Gynecology
Darmawan, Steve, MD	Pediatrics	Pediatrics	Pediatrics
Greene, Michael, MD	Emergency Medicine	Emergency	Emergency Medicine
	<u> </u>	Medicine	
Grogin, Harlan, MD	Cardiac	Medicine	Cardiology
	Electrophysiology		Cardiac Electrophysiology
			Cardiac Diagnostic Outpatient
			Center (CDOC
			Center for Advanced Diagnostic
			Imaging (CADI)
Karwowski, Eliza, DO	Psychiatry	Medicine	Tele-Psychiatry
King, Phillip, DO	Internal Medicine	Medicine	Active Community-Medicine
Oh, Christopher, MD	Cardiology	Medicine	Cardiology
			Cardiac Diagnostic Outpatient
			Center (CDOC)
			Center for Advanced
			Diagnostic Imaging (CADI)
Richardson, Zachary, MD	Ophthalmology	Surgery	Ophthalmology
Solomon, Tabitha, MD	Neonatology	Pediatrics	Neonatology
Wulff, Kristen, MD	Diagnostic	Diagnostic	Mammography
	Radiology	Imaging	
Bradley, Cedrick, MD	Internal Medicine	Medicine	Adult Hospitalist
Conly, Bethany, MD	Ob/Gyn	Ob/Gyn	Obstetrics
			Gynecology
Greene, Michael, MD	Emergency Medicine	Emergency	Emergency Medicine
		Medicine	
Grogin, Harlan, MD	Cardiac	Medicine	Cardiology
	Electrophysiology		Cardiac Electrophysiology
			Cardiac Diagnostic Outpatient
			Center (CDOC)
			Center for Advanced Diagnostic

			Imaging (CADI)
Karwowski, Eliza, DO	Psychiatry	Medicine	Tele-Psychiatry: Core
King, Phillip, DO	Internal Medicine	Medicine	Active Community-Medicine
Oh, Christopher, MD	Cardiology	Medicine	Cardiology
			Cardiac Diagnostic Outpatient
			Center (CDOC)
			Center for Advanced Diagnostic
			Imaging (CADI)
Richardson, Zachary, MD	Ophthalmology	Surgery	Ophthalmology
Solomon, Tabitha, MD	Neonatology	Pediatrics	Neonatology
Wulff, Kristen, MD	Diagnostic	Diagnostic	Mammography
	Radiology	Imaging	

Modification and/or Ad	dition of Privileges:	
NAME	SPECIALTY	RECOMMENDATION
Martinez, Alberto, MD	Family Medicine	Taylor Farms Family Health & Wellness Clinic.
		Temporary privileges effective 05/03/21.

Staff Status Modification	s:	
NAME	SPECIALTY	RECOMMENDATION
Hanlon, Stacey, MD	Anesthesiology	Resignation effective 05/22/21
Lee, David, MD	Radiology (Remote)	Resignation effective 03/28/21

Temporary/Locum Tenens Privileges:			
NAME	SPECIALTY	RECOMMENDATION	
Martinez, Alberto, MD	Family Medicine	4/28/2021 - 5/3/5021	
	Taylor Farms Family		
	Health & Wellness		
	Center		

# **Other Items:**

ould items.	
ITEM	RECOMMENDATION
Telemedicine Credentialing	The Committee reviewed and recommended approval of the proposed revision
Policy	that does not substantively modify the policy, but allow for agreements with
	Medicare participating entities versus Joint Commission only accredited entities.
	This change brings the policy into compliance with recent TJC accreditation
	standard changes.

# **Interdisciplinary Practice Committee**

# **Reappointments:**

APPLICANT	SPECIALTY	DEPT	PRIVILEGES
Fiess, Matthew, PA-C	Physician Assistant	Family	APP – Taylor Farms Family
		Medicine	Health & Wellness Center

# **Staff Status Modifications:**

NAME	SPECIALTY	RECOMMENDATION
Hurd, Sarah, PA-C	Physician Assistant	Leave of Absence effective 04/28/21

# **Other Items:** (*Attached*)

ITEM	RECOMMENDATION
Physician Assistant Clinical	Recommend approval of modification to the Emergency Medicine privilege
Privileges/Practice Agreement	criteria as follows:
	Current BLS, ACLS and PALS Certification

# Policies: None

### Rules and Regulations: (Attached)

The following amendments were approved by the MEC and are presented for review by the Board of Directors. In accordance with the Medical Staff Bylaws, these amendments will submitted for approval via Medical Staff ballot followed by submission to the Board of Directors for formal ratification.

### 1. Ongoing Professional Practice Evaluation (OPPE) Policy Amendment:

Amendment allows for 6-9 month window for completion of OPPE evaluations by the Department Chair versus the restrictive language of 6 months only.

# 2. Telemedicine Credentialing Policy Amendment:

Amendment sallow for agreement with Medicare participating entities versus Joint Commission only accredited entities. This change brings the policy into compliance with recent TJC accreditation standard changes.

# **Informational Items:**

The following items were approved/accepted as appropriate:

## I. Nominating Committee for Medical Staff Officers 10/01/2021 – 09/30/2023:

- a. Rachel McCarthy Beck, MD
- b. Ted Kaczmar, MD
- c. David E. Ramos, MD
- d. Orlando Rodriguez, MD
- e. Christina Hinz, MD

# II. Committee Reports:

- a. Quality and Safety Committee
  - i. TJC Survey 04/20/21 04/23/21 Safer Matrix
  - ii. Quality Reports:
    - 1. Throughput
      - 2. Critical Care Services
      - 3. Med Surge Cluster/Inpatient Wound Care
    - 4. Outpatient Infusion/Wound Care
    - 5. Food Services
    - 6. Community/Volunteer/Chaplain Services
    - 7. Human Resources
    - 8. Laboratory
    - 9. Transitional Care
    - 10. Taylor Farms Family Health and Wellness Center
    - 11. Sleep Medicine
    - 12. Transporters/Interpreters
    - 13. Nursing Informatics/Education
- b. Medical Staff Excellence Committee
  - i. 7 Cases Reviewed/Discussed
  - ii. 4 Systems/Process Issues Identified

### **III.** Other Reports:

- a. Financial Performance Review March 2021
- b. Executive Update
- c. Summary of Executive Operations Committee Meetings
- d. Summary of Medical Staff Department/Committee Meetings
- e. Health Information Management Update
- f. Medical Staff Treasury
- g. Medical Staff Statistics
- h. HCAHPS Data

# IV. Order Sets Approved:

1	Acute Coronary Syndrome
2	Adm Pre Eclampsia
3	Bortezomib/Cyclophosphamide/Dexamethasone+Daratumumab Q28D
4	Bortezomib/Lenalidomide/Dex+ Daratumumab IV
5	Bortezomib/Lenalidomide/Dex+ Daratumumab SQ
6	CALGB: C10403 Delayed Intensification (Course IV)
7	Cardiac Surgery Immediate PO
8	CHOP (Cyclophos/DOXOrubicin/vinCRIStine/Pred)+Obinutuzumab (NMZL2)

9	Craniotomy Post Op
10	Dialysis Peritoneal
11	Endoscopy InPt Orders
12	ENT Thyroid- Parathy Post Op
13	Epidural Intrathecal Anesthesia
14	Fam-trastuzumab deruxtecan-nxki 6.4 mg/kg, Q21D (COL84)
15	Hip Replacment PostOp
16	Hospitalist ICU Adm
17	Intensivist ICU Admission
18	NICU Admission Orders
19	NM Treadmill Stress wPerfusion
20	PACU Anesthesia Orders Pediatrics – MT Test
21	PACU Peds Anesthesia Orders Adults
22	PACU Peds Anesthesia Orders Pediatric
23	Pre Term Labor Delivery
24	Pre-Eclampsia
25	Sepsis Admission
26	Sepsis Inpatient
27	Stress Echo w Exercise
28	Stroke Intracerebral Hemorrhage
29	Treadmill Stress Test
30	Trifluridine and Tipiracil+Bevacizumab-AWWB(Bs) 5 mg/kg, Q28D (COL85)
31	Venetoclax + Obinutuzumab, Q28D (CLL88)
32	Ventilator Orders
33	VinCRIStine 1.5 mg/m2, Q21D (BON62)
34	VinORELBine 25 mg/m2 + Gemcitabine 1000 mg/m2, Q21D (NSC57



#### Physician Assistant - Clinical Privileges /Practice Agreement

#### Applicant Name:

# To be eligible to apply for core privileges as a Physician Assistant (PA), the applicant must meet the following qualifications:

- Minimum formal training: Applicants must be able to demonstrate successful completion of a PA program accredited by the ARC-PA or its predecessors.
  - In addition, the PA applicant must meet the following requirements:
    - o Successful completion of the national certifying examination given by the NCCPA
    - o Possession of a current unrestricted California PA license
    - o Possession of adequate professional liability insurance
    - o Documentation of adequate physical and mental health to exercise the privileges requested
    - Agreement with a physician who is a member of the SVMHS Medical Staff in good standing with unrestricted privileges appropriate to the supervision of a PA to:
      - Assume responsibility for supervision or monitoring of the PA's practice as stated in the Advance <u>Practice Provider Rules and Regulations and be</u> available by telephone or other electronic communication at the time of patient examination.
      - Assume total responsibility for the care of any patient when requested by the PA, required by this practice agreement or in the interest of patient care
  - Required previous experience: Documentation of training and experience of requested practice prerogatives and 200 patient care activities for the PA providing services for patients for the preceding two (2) years.

New applicants will be required to provide documentation of the number and types of cases they were involved with during the past 24 months. Applicants have the burden of producing information deemed adequate by the medical staff and hospital for a proper evaluation of current competence, and other qualifications and for resolving any doubts.

#### Physician Assistant Core Privileges – Required for all applicants. Core privileges are defined on page 8.

Physician Assistant Core Privileges SVMH Outpatient Infusion Center (check box if requested)

#### Requested

To be eligible to apply for core privileges at the SVMH Outpatient Infusion Center, the applicant must meet all criteria for Physician Assistant Core Privileges noted above.

#### Physician Assistant Core Privileges in Emergency Medicine (check box if requested)

#### Requested

To be eligible to apply for core privileges as an Emergency Medicine Physician Assistant, the applicant must meet the following qualifications: Current <u>BLS\_ACLS\_and PALS certifications as well as documentation of training and</u> \_\_\_\_\_ current competency in the performance of history & physicals. *Core privileges are defined on page 8.* 

#### **Core Proctoring Requirements:**

Core proctoring requirements include direct observation or concurrent review as per proctoring policy contained in the Medical Staff General Rules and Regulations.

Core proctoring requirements for Emergency Medicine includes direct observation of the first two (2) shifts worked and the following: **3 lumbar punctures** 

#### Reappointment Criteria for Core Privileges:

Applicants must be able to document continued NCCPA certification and inpatient services for at least 50 patients annually over the reappointment cycle.

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# Medical Staff Excellence Committee Peer Review and Ongoing Professional Practice Evaluation Policy (Peer Review)

- 1. All peer review information is privileged and confidential in accordance with Medical Staff and Hospital Bylaws, state and federal laws, and regulations pertaining to confidentiality and non-discoverability.
- 2. The involved practitioner will receive provider-specific feedback on a routine basis.
- 3. The medical staff will use the provider-specific peer review results in making its recommendations to the hospital regarding the reappointment, credentialing and privileging process and, as appropriate, in its performance improvement activities.
- 4. Ongoing Professional Practice Evaluation (OPPE) is the routine monitoring and evaluation of current competency for current medical staff. These activities comprise one of the major functions of the ongoing peer review process.
  - <u>Responsibility for Reviewing Data</u>

Each provider's OPPE data (Practitioner Performance Report) will be reviewed by their Medical Staff Department's Chair and/or Executive Operating Committee (EOC). At the time of review, the Department Chair and/or EOC will determine if, based on the data contained in the performance report, that privileges will be continued. Decision resulting from the review by the Department Chair/EOC will be documented. If an individual provider improvement opportunity is identified, the procedure listed in OPPE Data decision-making will be followed. The Practitioner Performance Report will be shared with the respective provider.

- <u>Frequency of Data Review</u> The goal for frequency of OPPE data review will be every six to nine months.
- <u>Type of Data Collected</u>

Data may be obtained in the following manner:

- Periodic chart review
- Direct observation
- Monitoring of diagnostic and treatment techniques
- Risk adjusted rate based indicators relative to the provider's practice
- Performance related to Medical Staff Bylaws and/or Rules and Regulations
- Discussion with individuals involved in the care of each patient including consulting surgeons, assistants at surgery, nursing, and administrative data.
- Reports from individuals including other medical staff and/or hospital staff related to the individual provider's care of patients.
- Activity Reports
- Data from other hospital and medical staff committees (e.g. Pharmacy, Therapeutics and Infection Control; Utilization
- Activities from outside organizations (e.g. surgery centers, other hospitals)



#### **Telemedicine Credentialing Policy**

1. **PURPOSE:** To establish a policy and procedure for credentialing of applicants for telemedicine privileges as defined in the Medical Staff Bylaws Article 5.12 at Salinas Valley Memorial Healthcare System (SVMHS).

#### 2. **DEFINITIONS:**

a. "<u>Credentialing Acknowledgement</u>" – A PHYSICIAN CREDENTIALING AND PRIVILEGING AGREEMENT exists between SVMHS and the Telemedicine Entity. This agreement permits SVMHS to use the credentialing that the contracted service has performed, because the contracted service is a Joint Commission accredited or Medicare participating entity.

c. "<u>Telemedicine</u>" the practice of health care delivery, diagnosis, consultation, treatment, transfer of medical data, and education using interactive audio, video or data communications.

d. "<u>Interpretation Services</u>" shall consist of providing preliminary interpretations and official interpretations and/or reports, to SVMHS

3. **POLICY:** In addition to the requirements of its Medical Staff Bylaws, and all other applicable rules, regulations, and laws, SVMHS may utilize the credentialing information provided by the contracted Telemedicine service in making final privileging decisions

4. **TELEMEDICINE CREDENTIALING & PRIVILEGING:** As a Joint Commission accredited or <u>Medicare-participating</u> organization, the contracted Telemedicine service has credentialed, in accordance with all applicable <del>Joint Commission</del> standards, each individual providing Telemedicine services for SVMHS. Qualified providers will be granted privileges to provide services in affiliation with the appropriate corresponding SVMHS Medical Staff Department. As part of its credentialing process, the contracted Telemedicine Service has verified that each provider possesses the appropriate medical training, certification, and other credentials necessary to provide such services.

A. The contracted Telemedicine Service warrants and ensures that each provider:

- i. Identity is verified in accordance with The Joint Commission standards;
- ii. Has a clear and current license to practice medicine in the State of California;
- iii. Is specialty board certified and shall maintain such certification during the term of the contracted Telemedicine Service at SVMHS;
- Is credentialed and maintains active medical staff privileges at the contracted Telemedicine Service; and,
- v. R e n d e r s services within the scope of their privileges as granted by the contracted Telemedicine service and SVMHS.

# B. <u>SVMHS's (originating site) reliance on the Contracted Telemedicine Service's (distant site) Credentialing & Issuance of Privileges:</u>

i. The contracted Telemedicine Service (distant site) is a contractor of telemedicine services to SVMHS. The distant site furnishes services in a manner which permits SVMHS to be in compliance with the Medicare Conditions of Participation.

ii. All distant site telemedicine providers' credentialing and privileging processes satisfy, at a minimum, the Medicare Conditions of Participation and Joint Commission standards.

iii. The governing body of the distant site is responsible for adopting and implementing a process that is consistent with the credentialing and privileging requirements of the Joint Commission Medical Staff (MS) chapter or CMS Conditions of Participation.

iv. SVMHS may grant privileges to a distant site provider based on the recommendations of the SVMHS Medical Staff, consistent with the requirements of the SVMH Medical Staff Bylaws and will also rely on the contracted Telemedicine service's privileging and credentialing activities.

v. SVMHS is not obligated to issue privileges to those physicians the Telemedicine Service entity submits to it for consideration.

vi. The contracted Telemedicine Service will notify SVMHS of any disciplinary action taken against a contracted provider, including any matter that constitutes a reportable event to the State and or/the NPDB as described in 42 U.S.C. § 11133.

#### 5. PROCEDURE - INITIAL APPOINTMENT:

A. No later than thirty (30) business days before the addition of any new Telemedicine provider, the contracted Telemedicine service shall provide the following to the SVMHS Medical Staff:

i. Electronic copies of the complete application, credentialing materials, and other relevant evidence of the Practice and the Telemedicine Services entity's compliance with SVMHS standards, for each Telemedicine applicant;

ii. The Telemedicine Services approved Delineation of Privileges; and

iii. Evidence of current malpractice insurance coverage that is in effect for the contracted Telemedicine service.

B. <u>Application Processing</u>: Upon the receipt of the documentation referenced in section 5(A) (i-iii) above, the applicant's documents and information will be added to the SVMHS Medical Staff Credentialing Database.

#### C. Credentialing Review and Approval Process:

Telemedicine applicants will be forwarded to the D e p a r t m e n t C h a i r a n d Credentials or Interdisciplinary Practice Committee after all primary source verifications have been performed. The remainder of the approval process shall take place in accordance with the SVMHS Medical Staff Bylaws.

#### E. SVMHS Medical Staff Services shall:

- i. Update databases with the new appointment dates, etc.
- ii. Incorporate the Telemedicine service documentation and supplementary verifications and documentation into the applicant's credential file.
- iii. Notify the contracted Telemedicine service of the appointment dates.
- iv. SVMHS will be responsible for conducting inquiries into the NPDB, Medical Board of California, debarment from Federally funded programs and criminal background.

#### 6. PROCEDURE-REAPPOINTMENT

A. In the year of expiration, at least one hundred eighty (180) days prior to the expiration of Medical Staff membership and/or clinical privileges excluding temporary privileges, an application form for reappointment, consistent with Section 4.5 will be sent to the contracted Telemedicine Service. The renewal approval process by the contracted Telemedicine service shall follow the same process that applies to the granting of initial privileges. For each Telemedicine applicant, the Telemedicine Service will submit to SVMHS all credentialing materials and other relevant evidence of the Practice and the Telemedicine services entity's compliance with SVMHS standards. The Telemedicine service will also submit, for each provider scheduled for reappointment, a quality profile for the practitioner for the previous 24 months.

#### B. Primary Source Verifications:

i. Primary Source queries shall be completed by the contracted Telemedicine Service. Any outlying information will be reviewed by the SVMHS <u>Credentials or Interdisciplinary</u> <u>Practice Committee</u>, and the department chair.

ii. SVMHS will be responsible for conducting inquiries into the NPDB, Medical Board of California, and debarment from Federally funded programs.

#### C. Completed Re-Credentialing Review and Approval Process:

Telemedicine applicants will be forwarded to the Department Chair and Credentials <u>or</u> <u>Interdisciplinary Practice</u> Committee after all primary source verifications have been performed. The remainder of the approval process shall take place in accordance with the SVMHS Medical Staff Bylaws. Deleted: c

# EXTENDED CLOSED SESSION (if necessary)

(VICTOR REY, JR.)

# ADJOURNMENT – THE NEXT REGULAR MEETING OF THE BOARD OF DIRECTORS IS SCHEDULED FOR THURSDAY, JUNE 24, 2021, AT 4:00 P.M.