Salinas Valley Memorial Healthcare System
A Public Healthcare District

September 24, 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 **THURSDAY, SEPTEMBER 30, 2021, AT 3:30 P.M., IN THE DOWNING RESOURCE CENTER, ROOMS A, B & C AT SALINAS VALLEY MEMORIAL HOSPITAL, 450 E. ROMIE LANE, SALINAS, CALIFORNIA, OR BY PHONE OR VIDEO (Visit svmh.com/virtualboardmeeting for Access Information)**.

Please note: 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, SEPTEMBER 30, 2021
3:30 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 svmh.com/virtualboardmeeting for Access Information)

Please note: 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.	**Call to Order/Roll Call**	Victor Rey, Jr.
II.	**Closed Session** (See Attached Closed Session Sheet Information)	Victor Rey, Jr.
III.	**Reconvene Open Session/Closed Session Report** (Estimated time 5:00 pm)	Victor Rey, Jr.
IV.	**Education Program** ➢ Respiratory Care Presentation	Clement Miller Corina Clark
V.	**Report from the President/Chief Executive Officer**	Pete Delgado
VI.	**Public Input** This opportunity is provided for members of the public to make a brief statement, not to exceed three (3) minutes, on issues or concerns within the jurisdiction of this District Board which are not otherwise covered under an item on this agenda.	Victor Rey, Jr.
VII.	**Board Member Comments**	Board Members
VIII.	**Consent Agenda—General Business** (A Board 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, August 26, 2021
B. Financial Report
C. Statistical Report
D. Policies Requiring Board Approval:
   1. Obtaining and Documenting Informed Consent in Clinical Research Studies at SVMHS
   2. Iodinated Contrast Administration for Radiologic Procedures
   3. Radiation Safety
   4. Intravenous Lidocaine for Pain
   5. Compliance Sanctions Review Policy and Procedure
   6. Shipping of Hazardous Materials for Clinical Research Studies at SVMHS

7. Care for the Caregiver
8. Nebulized Tranexamic Acid Procedure

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

IX. Reports on Standing and Special Committees

A. **Quality and Efficient Practices Committee** — Juan Cabrera
Minutes from the September 27, 2021 Quality and Efficient Practices Committee meeting have been provided to the Board. Additional Report from Committee Chair, if any.

B. **Finance Committee** — Richard Turner
Minutes from the September 27, 2021 Finance Committee meeting have been provided to the Board. Additional Report from Committee Chair, if any.

C. **Personnel, Pension and Investment Committee** — Regina M. Gage
Minutes from the September 28, 2021 Personnel, Pension and Investment Committee meeting have been provided to the Board. One proposed recommendation has been made to the Board.

1. **Recommend Board Approval of Asset Allocation for Defined Benefit Pension Plan Change to 65% Equities / 35% Fixed Income, Effective Immediately**

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

D. **Corporate Compliance and Audit Committee** — Juan Cabrera
Minutes from the September 28, 2021 Corporate Compliance and Audit Committee meeting have been provided to the Board. Additional Report from Committee Chair, if any.

X. Report on Behalf of the Medical Executive Committee (MEC) Meeting of September 9, 2021, and Recommendations for Board Approval of the following: — Rachel McCarthy Beck, M.D.

A. From the Credentials Committee:
1. Credentials Committee Report

B. From the Interdisciplinary Practice Committee:
1. Interdisciplinary Practice Committee Report

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

XI. **Extended Closed Session** (if necessary) Victor Rey, Jr.
(See Attached Closed Session Sheet Information)

XII. **Adjournment** – The next Regular Meeting of the Board of Directors is scheduled for **Thursday, October 28, 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.

Notes: 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):
_____, or
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):_____
_____

[ ] THREAT TO PUBLIC SERVICES OR FACILITIES
(Government Code §54957)

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

[ ] PUBLIC EMPLOYEE APPOINTMENT
(Government Code §54957)

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

[ ] PUBLIC EMPLOYMENT
(Government Code §54957)

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

[ ] PUBLIC EMPLOYEE PERFORMANCE EVALUATION
(Government Code §54957)

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

[ ] PUBLIC EMPLOYEE DISCIPLINE/DISMISSAL/RELEASE
(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.)

[X] CONFERENCE WITH LABOR NEGOTIATOR
(Government Code §54957.6)

Agency designated representative: (Specify name of designated representatives attending the closed session):
Pete Delgado

Employee organization: (Specify name of organization representing employee or employees in question):
National Union of Healthcare Workers, California Nurses Association, Local 39, ESC Local 20, or

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

[ ] CASE REVIEW/PLANNING
(Government Code §54957.8)

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

[X] REPORT INVOLVING TRADE SECRET
(Government Code §37606 & Health and Safety Code § 32106)

Discussion will concern: (Specify whether discussion will concern proposed new service, program, or facility):

Trade Secrets, Strategic Planning, Proposed New Programs and Services

Estimated date of public disclosure: (Specify month and year): unknown

[X] HEARINGS/REPORTS
(Government Code §37624.3 & Health and Safety Code §§1461, 32155)

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

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

[ ] CHARGE OR COMPLAINT INVOLVING INFORMATION PROTECTED BY FEDERAL LAW (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.)

EDUCATION PROGRAM - RESPIRATORY CARE PRESENTATION

(VERBAL)

(MILLER/CLARK)

REPORT FROM THE PRESIDENT/ CHIEF EXECUTIVE OFFICER

(VERBAL)

(PETE DELGADO)

PUBLIC INPUT

BOARD MEMBER COMMENTS

(VERBAL)

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

THURSDAY, AUGUST 26, 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 svmh.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.

Present: President Victor Rey, Jr., Directors Regina M. Gage, Juan Cabrera, Joel Hernandez Laguna in person; Richard Turner by teleconference.

Also Present: Pete Delgado, President/Chief Executive Officer; Rachel McCarthy Beck, M.D., Chief of Staff, and Gary Ray, Esq., District Legal Counsel, in person.

A quorum was present and the meeting was called to order by President Victor Rey, Jr at 4:06 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) Conference with Labor Negotiator concerning the National Union of Healthcare Workers, California Nurses Association, Local 39 and ESC Local 20; (2) Report Involving Trade Secret – strategic planning, proposed new programs and services; (3) Hearings/Reports – Report of the Medical Staff Quality and Safety Committee, Report of the Medical Staff Credentials Committee and Interdisciplinary Practice Committee.

The meeting was recessed into Closed Session under the Closed Session Protocol at 4:08 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 5:00 p.m. President Rey announced that in Closed Session the Board discussed: (1) Conference with Labor Negotiator concerning the National Union of Healthcare Workers, California Nurses Association, Local 39 and ESC Local 20; (2) Report Involving Trade Secret – strategic planning, proposed new programs and services; (3) Hearings/Reports – Report of the Medical Staff Quality and Safety Committee and Report of the Interdisciplinary Practice Committee.

In Closed Session, the Board received and accepted the Medical Staff Quality and Safety Committee Report. No other action was taken by the Board.

Mr. Rey stated that an Extended Closed Session will be held.

Consider Resolution No. 2021-03 Honoring the Life Alfred Diaz-Infante

Pete Delgado, President/CEO, presented Resolution No. 2021-03 Honoring the Life of Alfred Diaz-Infante for the Board's consideration. Mr. Delgado read and presented the resolution to Mrs. Diaz-Infante and their three children. Mr. Delgado commented that Alfred was a dear friend and a pillar to the community. He was passionate and devoted to helping the underserved populations. He will deeply be missed.

Director Hernandez Laguna shared that when Alfred spoke, people listened. The dignity that Alfred brought to the families in our community provided them with a proper way to live. His devotion to CHISPA, Hartnell College Foundation and the Monterey Bay Economic Partnership to name a few. He thanked the family for supporting Alfred's dedication of his time to the community.

Director Rey commented that he was able to serve on the board with Alfred. Alfred is one of two board members who interviewed him and recommended him as a board member. Mr. Rey feels so honored that Alfred recommended him to the board. His passing has been impactful in the community, hospital, and board.

No Public Comment.

> MOTION: The Board of Directors adopts Resolution No. 2021-03 Honoring the Life of Alfred Diaz-Infante, as presented. Moved/Seconded/Roll Call Vote: Ayes: Turner, Hernandez Laguna, Cabrera, Gage, Rey; Noes: None; Abstentions: None; Absent: None; Motion Carried.

Education Program

Environmental Services (ES) Presentation: Anthony Duenas, ES Manager, introduced the ES team; Charles Gerhard, Jr., ES Supervisor, Daniel Duran, ES Supervisor, Stephen Drewry, ES Tech, Jesse Gonzalez, ES Tech, Annette Canchola, ES Aide to share the work they are doing within their department.

- Disinfection in Healthcare
  - Understanding the Difference between disinfecting a Hospital vs. Hotel
  - Terminal and Isolation Cleanings that include PPE and Disinfectant
  - Electrostatic Disinfection – Clorox Total 360 in patient rooms and COVID Emergency tents
  - UV Light Disinfection (Daylight Moonbeam 3) - used in COVID-19 vacancy cleanings, surgical suites and emergency rooms

- Making a Difference in the Environmental Services Department
  - Featured in the SVMHS Community Report 2020
  - Featured in the Monterey County Weekly
  - Featured in Mission Moment

- Morale and Team Building is very important in supporting, rewarding and recognizing staff
  - Conduct Milestone Celebrations
  - Performance Recognitions
  - Team kick-offs are really important and are done before their shift begins with music, stretching, trivia, jokes and information updates.
  - Proud to report FY 2021 Press Ganey Engagement Indicator of 4.36

- Environmental Services Patient Experience Committee, formed in the Spring of 2021
  - A group of individuals with a desire to effect positive change and growth to the patient experience and the continued success of the EVS department.
    - Leveraging ideas from the committee
      - Noise Reduction – finding ways to help reduce the noise
      - Role-play for increased confidence with various patient interactions
      - Healthcare Superhero stickers for kids, rubik's cubes or patients, crossword puzzles in English and Spanish, suduko and baby charms for patients from the ES team.
      - Participation of PM and Night shift staffing
    - Supervisor Engagement – Email and Starbucks coupon is given to staff who have been acknowledged for doing something good
    - Looking for Opportunity – Great way for staff to share testimonials they have experienced with the team
- CAHPS and Press Ganey Results for Cleanliness and Courtesy for 2018-Present
- Press Ganey: Patient Comments include Friendly, Excellent, Clean room, Housekeeper, Pleasant, Emotional, Very Good Listener, Polite, etc.

Mr. Duenas shared how proud he is of his team and closed their presentation with an African Proverb, "If you want to go fast, go alone. If you want to go far, go together".

Director Rey commented that finally a presentation that he can relate to. He works in the food sanitation field and it can be similar to cleaning a facility, it is pivotal for quality safety. Hats off to all the team, great presentation and keep up the good work. Your hard work doesn't go unnoticed.

Director Hernandez Laguna reported that many years ago he had a similar job experience and he knows how hard it is to work at 2am to 3am and stay awake to get the job done. He thanked them for all the service they do.

Dr. Beck thanked the staff and noted how amazing they are.

Director Cabrera liked their ideas and thanked them for sharing.

Mr. Delgado shared that he sent the Environmental Services mission moment that was presented at last month's Board Meeting to CEOs at other hospitals who were impressed by their dedication and hard work.

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 the procedure "TAVR". A summary of key highlights, centered around the pillars that are the foundation of the Hospital's vision for the organization, is as follows:

Hospital Foundation Check Presentation:

Jeff Wardwell, Chief Philanthropy Officer, Monica Tovar, Board President of Hospital Foundation and Sheri Dawes, Development Services Manager of Hospital Foundation presented a check to SVMHS in the amount of $2,109,932.20. Mr. Wardwell and Ms. Tovar noted the tremendous support the Hospital Foundation receives from the community.

- Service
  - Laurie Freed, RN, ICU, provided an overview of the Critical Care Practice Council and is comprised of 7 RNs from ICU, 5 Tower, 1 Main, Heart Center and OCU, a Director, 3 Clinical Managers, Shift Supervisor and a Clinical Nurse Educator.

  - She presented their current projects as follows:
    Unit Magnet® Data Displays
    - Strategies and interventions are used for improvement for each critical care unit.
      - Provide education on new medications
      - Update white boards and include patient's input on goals for care
      - Utilizing waffle overlay for at-risk patients
      - Checking under all devices to prevent skin breakdown
      - Encourage RNs to chart outside patient's room to prevent falls
    - Areas of improvement based on patient satisfaction surveys and Nurse Sensitive Indicators (NSI)
    - Data displays are posted on each unit for the quarter
      - They include both areas of excellence and areas of opportunity
      - The Critical Care Practice Council advocates sharing this information at huddle and referring to data display sheets
      - The data display sheets include a snapshot of quarterly scores

    Project Green:
    - Working with central supply to decrease the use of single-use plastic bags that are placed on "clean" equipment
      - Currently looking at different sticker options to place on "clean" equipment to replace the plastic bags
      - This project has been trialed in the Heart Center

Ms. Freed commented that the Unit Practice Council is unique because they are made up of five different units and follows the SVMH STAR Values:

- Support: We support each other to put our patients and families first
- Teamwork: Together we pursue excellence and exceptional performance with passion. Work well with other departments.
- Accountability: We take personal responsibility for our professional conduct in delivering results.
- Respect: We respect our patients, each other, the community and the environment by demonstrating integrity, honesty, fiscal responsibility in everything we do.

- Quality
  - SVMHS received awards from The American Heart Association "Get with the Guidelines" for Stroke, Heart Failure, STEMI Receiving Center and NSTEMI.

- Finance
  - Government Affairs: Federal Update
    - FDA gives full approval to Pfizer vaccine; will help increase vaccine intake
    - Advocacy continues for HHS to distribute remaining $40 billion in provider relief funding
  - Industry News
    - 8 recent hospital credit rating downgrades
    - 6 hospitals cutting inpatient care
    - 20 hospitals laying off workers

- Providence's operating loss shrinks to $94M through the first half of the year
- What comes next for Google in health? 9 things to know about the tech giant's healthcare push amid reorganizing

- Growth
  - The Mobile Health Clinic is now offering services at the Salinas Regional Soccer Complex every Sunday from 11am to 2pm.

- People
  - SVMHS staff received produce boxes for their hard work and service to our patients and the community. Produce boxes were purchased from Rancho Cielo to support their programs.
  - 1440 Multiversity - Healing Our Healthcare Heroes Program hosted a retreat on August 20, 21 and 22 and will provide a 12-month online wellness program. 45 participants plus one attended. Hospital Administration attended the evening reception on the first day of the retreat. This initiative is funded by the SVMH Foundation as well as the 1440 Foundation.

- Community
  - Ask the Experts: On August 26, a Facebook Live Event with Dr. Rene Colorado focused on Strokes in Spanish at 3:00pm and English at 4:30pm. The next Facebook Live Event with Dr. Joanna Oppenheim will take place on September 22, at 6:30pm, featuring Lifestyle and Metabolic Program at SVMHS.
  - Media coverage around COVID-19, Sleep Apnea in kids, Asthma Day Camp, Summer Health Institute, Alfred Diaz-Infante, Cherry's Jubilee and SVMHS achieves exemplary Magnet status.

Public Input

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.

Esther Fierros-Nunez, Cashier of Patient Financial Services and Chief Shop Steward of NUHW shared with the Board of Directors that bargaining negotiations have been going on for about one month. NUHW is trying to finalize a contract with SVMH. There has been a lot of delayed meetings and their contract will be expiring at the end of this month. NUHW has close to 900 members and have been dealing with COVID-19 for the last year. She stated that SVMH is proposing to increase their health insurance co-pay and modify their Leave of Absence and sick PTO pay. NUHW has submitted articles and tried to be open to finalize the contract. She noted that they want to continue to work at SVMH and thanked the Board of Directors.

Board Member Comments

Director Hernandez Laguna gave a huge shout out to The Blue Zones Project for their Drive-In Movie night last Sunday. He was able to speak to the staff and the community. He also commented that he is so happy to hear that the Mobile Clinic is now offering services in Greenfield, previous to that vaccines were not offered. For some people this is the only way people receive health care.

He also shared that he met with Andrea Cisneros, Children's Miracle Network Hospitals Program Coordinator regarding the remodel of the SVMH Pediatric playroom. He stated that this playroom means a lot to families who have their child in the hospital. It gives the children energy to want to play. He shared that he and his wife experienced this with their daughter when she was patient.

He also gave a huge shout out to Shannon Graham, Director, Volunteer and Health Career Services for all the great work she has done with the Summer Health Institute. It was great to see a lot of students interested in the medical field. He also shared that he enjoyed last month's Ask the Experts Facebook Live Event with Dr. Carla Rosal who focused on Back to School – Children & COVID-19.

Mr. Delgado shared that Mike Haynes, Community Member and part owner of Cinderella Carpet One is the donor of the remodel for the SVMH Pediatric playroom and has been very supportive for many years.

Director Gage thanked everyone for their continued hard work and for the public comments.

Director Rey was pleased to hear about the 1440 Multiversity Retreat. He has a couple of friends who were able to attend the retreat and shared how impactful their weekend was and looks forward to hearing about it more. He thanked the Foundation for offering this opportunity to our staff.

Consent Agenda – General Business

A. Minutes of the Regular Meeting of the Board of Directors, July 22, 2021
B. Financial Report
C. Statistical Report
D. Policies Requiring Board Approval
    1. Obtaining Daily Weights for Heart Failure Patients
    2. Newborn Pain, Agitation and Sedation Management
    3. Patient Safety Attendant Guidelines
    4. Hyperbilirubinemia-Infant Management & Treatment
    5. Block Charting: Titratable Medications
    6. Patient Classification System

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

No Public Comment.

MOTION: 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

Quality and Efficient Practices Committee

Juan Cabrera, Committee Chair, reported the minutes from the Quality and Efficient Practices Committee Meeting of August 23, 2021, were provided to the Board. The Committee received an Environmental Services Presentation, Patient Care Services Update and Financial Statistical Review. No action was taken by the Committee.

Finance Committee

Richard Turner, Committee Chair, reported the minutes from the Finance Committee Meeting of August 23, 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. **Recommend Board Approval of Healthcare Security Services (HSS) Contract Renewal**

   No Public Comment.

   MOTION: The Board of Directors approves the renewal of the Security and Valet Services Agreement between Salinas Valley Memorial Healthcare System and HSS, Inc., in the amount of $2,275,841 for the 1 year term, as presented. Moved/Seconded/Roll Call Vote: Ayes: Turner, Hernandez Laguna, Cabrera, Gage, Rey; Noes: None; Abstentions: None; Absent: None; Motion Carried.

2. **Recommend Board Approval of HealthStream (Learning Management System) Contract Renewal**

   No Public Comment.

   MOTION: The Board of Directors approves the renewal of the HealthStream (Learning Management System) Contract for the term of five years in the total amount of $457,719.50, as presented. Moved/ Seconded/Roll Call Vote: Ayes: Turner, Hernandez Laguna, Cabrera, Gage, Rey; Noes: None; Abstentions: None; Absent: None; Motion Carried.

3. **Recommend Board Approval to Continue Monthly Transfers from Operating General Account to Board Designated Restricted Account**

   No Public Comment.

   MOTION: The Board of Directors approves the continuation of making monthly transfers of $1,000,000 from operating general account to Board designated restricted account through fiscal year 2022, as presented. Moved/ Seconded/Roll Call Vote: Ayes: Turner, Hernandez Laguna, Cabrera, Gage, Rey; 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 August 24, 2021, were provided to the Board. The Committee had a Subject Expert Discussion, General HR Metrics and Financial Statistical Review. No action was taken by the Committee.

Community Advocacy Committee

Regina Gage, Committee Chair, reported the minutes from the Community Advocacy Committee Meeting of August 24, 2021, were provided to the Board. The Committee received an update from The Blue Zones Project, Mobile Clinic, Report from the Hospital Foundation and Hospital Service League. She shared that this is a fun meeting to attend because she gets to hear all the wonderful news.

Report on Behalf of the Medical Executive Committee (MEC) Meeting of August 12, 2021, and Recommendations for Board Approval of the following:

The following recommendations from the Medical Executive Committee (MEC) Meeting of August 12, 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. Bylaws and Policies:
   1. Consent to Surgery or Special Therapeutic or Diagnostic Procedure(s)
   2. Bylaws – Proposed deletion of Article 9.4.6

Dr. Beck commented on how important it is for pregnant women to get the COVID-19 vaccine. Pregnant women run the risk of early delivery and can cause severe illness to themselves and their baby. Dr. Beck strongly encourages the vaccine to her patients.

No Public Comment.

MOTION: The Board of Directors approves Recommendation (A) through (C) of the August 12, 2021, Medical Executive Committee Meeting, as presented. Moved/Seconded/Roll Call Vote: Ayes: Rey, Gage, Cabrera, Turner, Hernandez Laguna; Noes: None; Abstentions: None; Absent: None; Motion Carried.

Extended Closed Session

Board President Rey announced that the item to be discussed in the Closed Session is: Public Employee Performance Evaluation. The meeting was recessed into Closed Session at 6:30 p.m. The Board reconvened Open Session at 7:00 p.m. Mr. Rey announced that in Closed Session, the Board discussed Report Involving Trade Secret – Strategic Planning, Proposed New Services and Programs. No action was taken by the Board.

Director Cabrera left the meeting at 6:55 p.m.

Adjournment – The next Regular Meeting of the Board of Directors is scheduled for Thursday, September 30, 2021 at 4:00 p.m. There being no further business, the meeting was adjourned at 7:02 p.m.

Juan Cabrera
Secretary, Board of Directors

SALINAS VALLEY MEMORIAL HOSPITAL
SUMMARY INCOME STATEMENT
August 31, 2021

	Month of August,		Two months ended August 31,	
	current year	prior year	current year	prior year
Operating revenue:				
Net patient revenue	$ 50,527,025	$ 47,682,621	$ 98,046,847	$ 96,963,359
Other operating revenue	913,420	903,316	2,158,504	1,637,456
Total operating revenue	51,440,445	48,585,937	100,205,351	98,600,815
Total operating expenses	42,142,696	40,455,123	82,968,742	82,807,276
Total non-operating income	(1,134,115)	(1,206,977)	(3,712,828)	(2,815,154)
Operating and non-operating income	$ 8,163,633	$ 6,923,837	$ 13,523,781	$ 12,978,385

SALINAS VALLEY MEMORIAL HOSPITAL
BALANCE SHEETS
August 31, 2021

	Current year	Prior year
ASSETS:		
Current assets	$ 425,877,230	$ 391,962,173
Assets whose use is limited or restricted by board	145,675,896	132,935,132
Capital assets	242,436,011	261,210,063
Other assets	188,380,129	191,981,645
Deferred pension outflows	50,119,236	83,379,890
	$ 1,052,488,502	$ 1,061,468,903
LIABILITIES AND EQUITY:		
Current liabilities	130,468,528	161,562,454
Long term liabilities	14,556,513	14,780,831
	83,585,120	126,340,336
Net assets	823,878,341	758,785,282
	$ 1,052,488,502	$ 1,061,468,903

SALINAS VALLEY MEMORIAL HOSPITAL
SCHEDULES OF NET PATIENT REVENUE
August 31, 2021

	Month of August,		Two months ended August 31,	
	current year	prior year	current year	prior year
Patient days:				
By payer:				
Medicare	1,575	1,522	3,142	3,053
Medi-Cal	1,006	1,205	1,964	2,212
Commercial insurance	738	851	1,442	1,728
Other patient	126	115	273	272
Total patient days	3,445	3,693	6,821	7,265
Gross revenue:				
Medicare	$ 92,022,820	$ 73,692,528	$ 181,832,564	$ 153,257,385
Medi-Cal	58,046,182	54,151,800	114,281,809	104,801,847
Commercial insurance	46,776,796	47,799,019	98,894,465	101,154,013
Other patient	8,188,797	7,937,061	17,896,110	17,663,624
Gross revenue	205,034,595	183,580,408	412,904,948	376,876,869
Deductions from revenue:				
Administrative adjustment	297,324	477,667	494,412	660,047
Charity care	1,798,274	2,110,951	2,677,903	2,740,620
Contractual adjustments:				
Medicare outpatient	28,466,678	24,063,255	56,651,761	50,718,890
Medicare inpatient	35,954,117	33,452,246	73,118,138	66,546,919
Medi-Cal traditional outpatient	2,613,718	1,787,180	4,908,906	3,357,024
Medi-Cal traditional inpatient	6,995,705	8,142,897	11,803,120	15,467,408
Medi-Cal managed care outpatient	22,747,993	17,698,041	46,122,124	36,780,211
Medi-Cal managed care inpatient	19,944,312	18,466,582	41,928,697	35,583,346
Commercial insurance outpatient	15,112,176	14,406,677	32,785,474	31,342,630
Commercial insurance inpatient	16,735,540	12,217,017	34,635,416	28,292,799
Uncollectible accounts expense	3,670,707	3,413,870	7,769,507	7,279,931
Other payors	171,026	(338,594)	1,962,643	1,143,685
Deductions from revenue	154,507,570	135,897,787	314,858,101	279,913,510
Net patient revenue	$ 50,527,025	$ 47,682,621	$ 98,046,847	$ 96,963,359
Gross billed charges by patient type:				
Inpatient	$ 107,404,639	$ 99,684,280	$ 216,472,072	$ 200,273,347
Outpatient	70,186,240	62,330,868	141,297,959	133,425,234
Emergency room	27,443,716	21,565,260	55,134,917	43,178,288
Total	$ 205,034,595	$ 183,580,408	$ 412,904,948	$ 376,876,869

SALINAS VALLEY MEMORIAL HOSPITAL
STATEMENTS OF REVENUE AND EXPENSES
August 31, 2021

	Month of August,		Two months ended August 31,	
	current year	prior year	current year	prior year
Operating revenue:				
Net patient revenue	$ 50,527,025	$ 47,682,621	$ 98,046,847	$ 96,963,359
Other operating revenue	913,420	903,316	2,158,504	1,637,456
Total operating revenue	51,440,445	48,585,937	100,205,351	98,600,815
Operating expenses:				
Salaries and wages	15,800,754	16,147,849	31,260,761	31,919,329
Compensated absences	2,550,349	2,707,085	5,086,925	5,154,918
Employee benefits	7,652,176	6,466,444	15,296,605	15,502,767
Supplies, food, and linen	6,434,802	6,644,936	12,004,398	12,744,781
Purchased department functions	2,899,532	2,809,537	6,261,761	6,443,059
Medical fees	2,195,012	1,646,370	4,054,631	3,003,422
Other fees	1,136,907	1,110,088	2,348,840	2,295,305
Depreciation	1,759,187	1,755,382	3,568,103	3,532,465
All other expense	1,713,977	1,167,432	3,086,718	2,211,230
Total operating expenses	42,142,696	40,455,123	82,968,742	82,807,276
Income from operations	9,297,749	8,130,814	17,236,609	15,793,539
Non-operating income:				
Donations	166,667	166,667	333,333	333,333
Property taxes	333,333	333,333	666,667	666,667
Investment income	(187,030)	(102,991)	352,291	798,978
Taxes and licenses	0	0	0	0
Income from subsidiaries	(1,447,085)	(1,603,986)	(5,065,119)	(4,614,132)
Total non-operating income	(1,134,115)	(1,206,977)	(3,712,828)	(2,815,154)
Operating and non-operating income	8,163,633	6,923,837	13,523,781	12,978,385
Net assets to begin	815,714,708	751,861,445	810,354,560	745,806,898
Net assets to end	$ 823,878,341	$ 758,785,282	$ 823,878,341	$ 758,785,282
Net income excluding non-recurring items	$ 8,163,633	$ 6,923,837	$ 13,523,781	$ 12,978,385
Non-recurring income (expense) from cost report settlements and re-openings and other non-recurring items	0	0	0	0
Operating and non-operating income	$ 8,163,633	$ 6,923,837	$ 13,523,781	$ 12,978,385

SALINAS VALLEY MEMORIAL HOSPITAL
SCHEDULES OF INVESTMENT INCOME
August 31, 2021

	Month of August,		Two months ended August 31,	
	current year	prior year	current year	prior year
Detail of other operating income:				
Dietary revenue	$ 131,757	$ 123,923	$ 268,075	$ 262,160
Discounts and scrap sale	272,517	17	272,477	25,594
Sale of products and services	12,740	26,087	65,686	116,455
Clinical trial fees	0	0	6,976	39,404
Stimulus Funds	0	0	0	0
Rental income	161,292	164,793	320,613	314,062
Other	335,114	588,496	1,224,677	879,781
Total	$ 913,420	$ 903,316	$ 2,158,504	$ 1,637,456
Detail of investment income:				
Bank and payor interest	$ 140,754	$ 151,780	$ 204,942	$ 351,246
Income from investments	(380,958)	(254,771)	82,621	447,732
Gain or loss on property and equipment	53,174	0	64,728	0
Total	$ (187,030)	$ (102,991)	$ 352,291	$ 798,978
Detail of income from subsidiaries:				
Salinas Valley Medical Center:				
Pulmonary Medicine Center	$ (239,146)	$ 1,631,155	$ (397,808)	$ (436,444)
Neurological Clinic	(76,078)	(96,402)	(93,722)	(96,564)
Palliative Care Clinic	(35,498)	(101,315)	(146,532)	(135,768)
Surgery Clinic	(78,639)	(181,134)	(197,450)	(232,498)
Infectious Disease Clinic	(8,217)	(35,077)	(41,926)	(41,646)
Endocrinology Clinic	(103,658)	(341,510)	(214,864)	(305,522)
Early Discharge Clinic	0	0	0	0
Cardiology Clinic	(550,839)	(733,306)	(776,610)	(937,678)
OB/GYN Clinic	(374,547)	(227,656)	(704,568)	(305,954)
PrimeCare Medical Group	1,384,254	(605,465)	(699,410)	(912,563)
Oncology Clinic	(524,635)	(456,186)	(768,194)	(625,370)
Cardiac Surgery	(184,501)	(247,864)	(335,858)	(317,282)
Sleep Center	(14,434)	(163,122)	(56,524)	(76,958)
Rheumatology	(32,339)	(129,246)	(87,790)	(53,652)
Precision Ortho MDs	(430,217)	(416,153)	(529,016)	(596,464)
Precision Ortho-MRI	0	(11,435)	0	(27,840)
Precision Ortho-PT	(26,885)	41,938	(71,122)	27,260
Dermatology	(25,592)	(33,700)	(46,502)	(38,514)
Hospitalists	0	0	0	0
Behavioral Health	(50,214)	(169,640)	(125,722)	(138,962)
Pediatric Diabetes	(40,297)	(83,504)	(82,760)	(90,646)
Neurosurgery	(3,452)	(29,473)	(30,468)	(45,460)
Multi-Specialty-RR	(7,094)	(45,800)	3,620	(33,362)
Radiology	(275,168)	(302,693)	(550,628)	(316,016)
Salinas Family Practice	(173,270)	0	(212,232)	0
Total SVMC	(1,870,466)	(2,737,588)	(6,166,086)	(5,737,903)
Doctors on Duty	(603,234)	509,077	(196,087)	656,627
Assisted Living	0	(2,692)	0	(10,156)
Salinas Valley Imaging	0	6,570	0	(19,974)
Vantage Surgery Center	22,233	24,427	45,452	50,711
LPCH NICU JV	0	0	0	0
Central Coast Health Connect	0	0	0	0
Monterey Peninsula Surgery Center	958,377	110,225	1,129,204	229,382
Aspire/CHI/Coastal	(23,860)	(98,025)	(46,429)	(216,594)
Apex	14,052	(7,587)	31,941	7,049
21st Century Oncology	36,940	98,810	71,617	(68,026)
Monterey Bay Endoscopy Center	18,873	492,797	65,269	494,754
Total	$ (1,447,085)	$ (1,603,986)	$ (5,065,119)	$ (4,614,132)

SALINAS VALLEY MEMORIAL HOSPITAL
BALANCE SHEETS
August 31, 2021

	Current year	Prior year
A S S E T S		
Current assets:		
Cash and cash equivalents	$ 334,059,094	$ 296,092,077
Patient accounts receivable, net of estimated uncollectibles of $20,932,304	74,253,666	77,428,728
Supplies inventory at cost	8,200,689	8,590,999
Other current assets	9,363,781	9,850,369
Total current assets	425,877,230	391,962,173
Assets whose use is limited or restricted by board	145,675,896	132,935,132
Capital assets:		
Land and construction in process	34,572,681	54,158,906
Other capital assets, net of depreciation	207,863,330	207,051,158
Total capital assets	242,436,011	261,210,063
Other assets:		
Investment in Securities	144,640,143	147,540,548
Investment in SVMC	14,970,233	16,365,278
Investment in Aspire/CHI/Coastal	3,570,360	3,934,341
Investment in other affiliates	23,389,984	22,258,922
Net pension asset	1,809,409	1,882,556
Total other assets	188,380,129	191,981,645
Deferred pension outflows	50,119,236	83,379,890
	$ 1,052,488,502	$ 1,061,468,903
L I A B I L I T I E S A N D N E T A S S E T S		
Current liabilities:		
Accounts payable and accrued expenses	$ 54,249,539	$ 57,396,570
Due to third party payers	58,993,558	86,331,288
Current portion of self-insurance liability	17,225,431	17,834,596
Total current liabilities	130,468,528	161,562,454
Long term portion of workers comp liability	14,556,513	14,780,831
Total liabilities	145,025,041	176,343,285
Pension liability	83,585,120	126,340,336
Net assets:		
Invested in capital assets, net of related debt	242,436,011	261,210,063
Unrestricted	581,442,330	497,575,219
Total net assets	823,878,341	758,785,282
	$ 1,052,488,502	$ 1,061,468,903

SALINAS VALLEY MEMORIAL HOSPITAL
STATEMENTS OF REVENUE AND EXPENSES - BUDGET VS. ACTUAL
August 31, 2021

	Month of August,				Two months ended August 31,			
	Actual	**Budget**	**Variance**	**% Var**	**Actual**	**Budget**	**Variance**	**% Var**
Operating revenue:								
Gross billed charges	$ 205,034,595	$ 196,628,325	8,406,270	4.28%	$ 412,904,948	$ 393,256,651	19,648,297	5.00%
Dedutions from revenue	154,507,570	150,880,781	3,626,789	2.40%	314,858,101	301,942,307	12,915,794	4.28%
Net patient revenue	50,527,025	45,747,544	4,779,481	10.45%	98,046,847	91,314,344	6,732,503	7.37%
Other operating revenue	913,420	783,804	129,616	16.54%	2,158,504	1,558,116	600,388	38.53%
Total operating revenue	**51,440,445**	**46,531,348**	**4,909,097**	**10.55%**	**100,205,351**	**92,872,460**	**7,332,891**	**7.90%**
Operating expenses:								
Salaries and wages	15,800,754	15,920,490	(119,736)	-0.75%	31,260,761	31,493,739	(232,978)	-0.74%
Compensated absences	2,550,349	2,527,542	22,807	0.90%	5,086,925	5,291,111	(204,186)	-3.86%
Employee benefits	7,652,176	7,339,780	312,396	4.26%	15,296,605	14,668,980	627,625	4.28%
Supplies, food, and linen	6,434,802	5,938,499	496,303	8.36%	12,004,398	11,876,998	127,400	1.07%
Purchased department functions	2,899,532	3,006,925	(107,393)	-3.57%	6,261,761	5,952,178	309,583	5.20%
Medical fees	2,195,012	1,830,070	364,942	19.94%	4,054,631	3,660,140	394,491	10.78%
Other fees	1,136,907	931,400	205,507	22.06%	2,348,840	1,856,381	492,459	26.53%
Depreciation	1,759,187	1,772,243	(13,056)	-0.74%	3,568,103	3,565,376	2,727	0.08%
All other expense	1,713,977	1,455,868	258,109	17.73%	3,086,718	2,911,736	174,982	6.01%
Total operating expenses	**42,142,696**	**40,722,816**	**1,419,880**	**3.49%**	**82,968,742**	**81,276,638**	**1,692,104**	**2.08%**
Income from operations	**9,297,749**	**5,808,532**	**3,489,217**	**60.07%**	**17,236,609**	**11,595,822**	**5,640,787**	**48.64%**
Non-operating income:								
Donations	166,667	166,667	0	0.00%	333,333	333,333	(0)	0.00%
Property taxes	333,333	333,333	(0)	0.00%	666,667	666,667	0	0.00%
Investment income	(187,030)	(63,302)	(123,729)	195.46%	352,291	(126,603)	478,894	-378.26%
Income from subsidiaries	(1,447,085)	(4,215,213)	2,768,128	-65.67%	(5,065,119)	(8,383,837)	3,318,718	-39.58%
Total non-operating income	**(1,134,115)**	**(3,778,515)**	**2,644,399**	**-69.99%**	**(3,712,828)**	**(7,510,440)**	**3,797,613**	**-50.56%**
Operating and non-operating income	**$ 8,163,634**	**$ 2,030,017**	**6,133,617**	**302.15%**	**$ 13,523,781**	**$ 4,085,381**	**9,438,400**	**231.03%**

SALINAS VALLEY MEMORIAL HOSPITAL
PATIENT STATISTICAL REPORT
For the month of Aug and two months to date

	Month of Aug		Two months to date		
	2020	2021	2020-21	2021-22	Variance
NEWBORN STATISTICS					
Medi-Cal Admissions	51	43	101	91	(10)
Other Admissions	101	94	218	187	(31)
Total Admissions	152	137	319	278	(41)
Medi-Cal Patient Days	78	64	151	138	(13)
Other Patient Days	157	145	333	321	(12)
Total Patient Days of Care	235	209	484	459	(25)
Average Daily Census	7.6	6.7	7.8	7.4	(0.4)
Medi-Cal Average Days	1.5	1.5	1.5	1.5	0.0
Other Average Days	1.3	1.5	1.5	1.7	0.2
Total Average Days Stay	1.4	1.5	1.5	1.6	0.2
ADULTS & PEDIATRICS					
Medicare Admissions	318	329	655	630	(25)
Medi-Cal Admissions	298	248	479	503	24
Other Admissions	369	300	596	599	3
Total Admissions	985	877	1,730	1,732	2
Medicare Patient Days	1,395	1,338	2,739	2,665	(74)
Medi-Cal Patient Days	1,242	1,051	2,290	2,056	(234)
Other Patient Days	863	1,049	1,899	2,095	196
Total Patient Days of Care	3,500	3,438	6,928	6,816	(112)
Average Daily Census	112.9	110.9	111.7	109.9	(1.8)
Medicare Average Length of Stay	4.4	4.2	4.2	4.1	(0.1)
Medi-Cal AverageLength of Stay	4.1	3.7	3.9	3.2	(0.7)
Other Average Length of Stay	2.2	2.6	2.3	2.8	0.5
Total Average Length of Stay	3.5	3.4	3.3	3.3	(0.0)
Deaths	36	31	64	51	(13)
Total Patient Days	3,735	3,647	7,412	7,275	(137)
Medi-Cal Administrative Days	92	44	92	46	(46)
Medicare SNF Days	0	0	0	0	0
Over-Utilization Days	0	0	0	0	0
Total Non-Acute Days	92	44	92	46	(46)
Percent Non-Acute	2.46%	1.21%	1.24%	0.63%	-0.61%

SALINAS VALLEY MEMORIAL HOSPITAL
PATIENT STATISTICAL REPORT
For the month of Aug and two months to date

	Month of Aug		Two months to date		
	2020	2021	2020-21	2021-22	Variance
PATIENT DAYS BY LOCATION					
Level I	253	254	467	478	11
Heart Center	342	306	667	639	(28)
Monitored Beds	885	813	1,738	1,632	(106)
Single Room Maternity/Obstetrics	379	337	788	702	(86)
Med/Surg - Cardiovascular	677	604	1,339	1,315	(24)
Med/Surg - Oncology	199	277	358	557	199
Med/Surg - Rehab	405	430	811	835	24
Pediatrics	64	110	136	207	71
Nursery	235	209	484	459	(25)
Neonatal Intensive Care	193	77	337	159	(178)
PERCENTAGE OF OCCUPANCY					
Level I	62.78%	63.03%	57.94%	59.31%	
Heart Center	73.55%	65.81%	71.72%	68.71%	
Monitored Beds	105.73%	97.13%	103.82%	97.49%	
Single Room Maternity/Obstetrics	33.04%	29.38%	34.35%	30.60%	
Med/Surg - Cardiovascular	48.53%	43.30%	47.99%	47.13%	
Med/Surg - Oncology	49.38%	68.73%	44.42%	69.11%	
Med/Surg - Rehab	50.25%	53.35%	50.31%	51.80%	
Med/Surg - Observation Care Unit	0.00%	43.64%	0.00%	27.70%	
Pediatrics	11.47%	19.71%	12.19%	18.55%	
Nursery	45.94%	40.86%	23.66%	22.43%	
Neonatal Intensive Care	56.60%	22.58%	49.41%	23.31%	

SALINAS VALLEY MEMORIAL HOSPITAL
PATIENT STATISTICAL REPORT
For the month of Aug and two months to date

	Month of Aug		Two months to date		
	2020	2021	2020-21	2021-22	Variance
DELIVERY ROOM					
Total deliveries	159	141	320	274	(46)
C-Section deliveries	50	47	96	85	(11)
Percent of C-section deliveries	31.45%	33.33%	30.00%	31.02%	1.02%
OPERATING ROOM					
In-Patient Operating Minutes	16,644	21,010	54,711	44,428	(10,283)
Out-Patient Operating Minutes	22,513	24,231	35,455	49,948	14,493
Total	39,157	45,241	90,166	94,376	4,210
Open Heart Surgeries	12	13	27	27	0
In-Patient Cases	118	148	332	298	(34)
Out-Patient Cases	233	246	473	499	26
EMERGENCY ROOM					
Immediate Life Saving	34	51	47	90	43
High Risk	505	417	984	882	(102)
More Than One Resource	2,178	2,649	4,372	5,272	900
One Resource	1,797	1,885	4,371	3,365	(1,006)
No Resources	56	146	114	228	114
Total	4,570	5,148	9,888	9,837	(51)

SALINAS VALLEY MEMORIAL HOSPITAL
PATIENT STATISTICAL REPORT
For the month of Aug and two months to date

	Month of Aug		Two months to date		
	2020	2021	2020-21	2021-22	Variance
CENTRAL SUPPLY					
In-patient requisitions	12,674	15,765	25,745	31,883	6,138
Out-patient requisitions	9,126	9,388	20,325	18,817	-1,508
Emergency room requisitions	1,587	1,608	3,271	3,310	39
Interdepartmental requisitions	6,924	6,009	13,865	11,827	-2,038
Total requisitions	30,311	32,770	63,206	65,837	2,631
LABORATORY					
In-patient procedures	33,276	32,894	68,150	67,128	-1,022
Out-patient procedures	9,935	11,358	20,702	22,748	2,046
Emergency room procedures	8,525	11,159	16,706	22,405	5,699
Total patient procedures	51,736	55,411	105,558	112,281	6,723
BLOOD BANK					
Units processed	249	327	508	639	131
ELECTROCARDIOLOGY					
In-patient procedures	859	945	1,812	1,965	153
Out-patient procedures	397	389	822	827	5
Emergency room procedures	815	983	1,638	2,054	416
Total procedures	2,071	2,317	4,272	4,846	574
CATH LAB					
In-patient procedures	67	88	131	196	65
Out-patient procedures	77	98	158	199	41
Emergency room procedures	0	0	0	0	0
Total procedures	144	186	289	395	106
ECHO-CARDIOLOGY					
In-patient studies	287	333	558	685	127
Out-patient studies	168	223	361	480	119
Emergency room studies	1	1	4	2	-2
Total studies	456	557	923	1,167	244
NEURODIAGNOSTIC					
In-patient procedures	183	149	359	304	-55
Out-patient procedures	29	21	65	40	-25
Emergency room procedures	0	0	0	0	0
Total procedures	212	170	424	344	-80

SALINAS VALLEY MEMORIAL HOSPITAL
PATIENT STATISTICAL REPORT
For the month of Aug and two months to date

	Month of Aug		Two months to date		
	2020	2021	2020-21	2021-22	Variance
SLEEP CENTER					
In-patient procedures	0	0	0	0	0
Out-patient procedures	167	200	330	374	44
Emergency room procedures	0	0	0	0	0
Total procedures	167	200	330	374	44
RADIOLOGY					
In-patient procedures	1,286	1,217	2,596	2,460	-136
Out-patient procedures	700	457	1,434	885	-549
Emergency room procedures	1,108	1,237	2,236	2,538	302
Total patient procedures	3,094	2,911	6,266	5,883	-383
MAGNETIC RESONANCE IMAGING					
In-patient procedures	116	124	230	272	42
Out-patient procedures	150	112	289	242	-47
Emergency room procedures	8	4	21	11	-10
Total procedures	274	240	540	525	-15
MAMMOGRAPHY CENTER					
In-patient procedures	2,814	3,718	5,872	7,180	1,308
Out-patient procedures	2,801	3,695	5,845	7,119	1,274
Emergency room procedures	0	2	0	6	6
Total procedures	5,615	7,415	11,717	14,305	2,588
NUCLEAR MEDICINE					
In-patient procedures	11	10	27	27	0
Out-patient procedures	70	74	138	169	31
Emergency room procedures	1	2	1	2	1
Total procedures	82	86	166	198	32
PHARMACY					
In-patient prescriptions	83,124	86,567	164,824	168,780	3,956
Out-patient prescriptions	14,639	14,973	31,161	30,716	-445
Emergency room prescriptions	5,257	6,914	10,175	13,804	3,629
Total prescriptions	103,020	108,454	206,160	213,300	7,140
RESPIRATORY THERAPY					
In-patient treatments	19,015	19,566	36,776	36,359	-417
Out-patient treatments	462	1,049	904	2,112	1,208
Emergency room treatments	131	222	184	434	250
Total patient treatments	19,608	20,837	37,864	38,905	1,041
PHYSICAL THERAPY					
In-patient treatments	2,270	2,233	4,640	4,508	-132
Out-patient treatments	245	343	506	674	168
Emergency room treatments	0	0	0	0	0
Total treatments	2,515	2,576	5,146	5,182	36

SALINAS VALLEY MEMORIAL HOSPITAL
PATIENT STATISTICAL REPORT
For the month of Aug and two months to date

	Month of Aug		Two months to date		
	2020	2021	2020-21	2021-22	Variance
OCCUPATIONAL THERAPY					
In-patient procedures	1,243	1,612	2,407	3,300	893
Out-patient procedures	116	162	227	324	97
Emergency room procedures	0	0	0	0	0
Total procedures	1,359	1,774	2,634	3,624	990
SPEECH THERAPY					
In-patient treatments	399	397	784	905	121
Out-patient treatments	23	23	46	67	21
Emergency room treatments	0	0	0	0	0
Total treatments	422	420	830	972	142
CARDIAC REHABILITATION					
In-patient treatments	0	0	0	0	0
Out-patient treatments	390	700	816	1,263	447
Emergency room treatments	0	0	0	0	0
Total treatments	390	700	816	1,263	447
CRITICAL DECISION UNIT					
Observation hours	205	256	446	499	53
ENDOSCOPY					
In-patient procedures	96	89	198	196	-2
Out-patient procedures	48	39	65	73	8
Emergency room procedures	0	0	0	0	0
Total procedures	144	128	263	269	6
C.T. SCAN					
In-patient procedures	524	554	1,068	1,201	133
Out-patient procedures	505	345	1,098	842	-256
Emergency room procedures	467	579	887	1,182	295
Total procedures	1,496	1,478	3,053	3,225	172
DIETARY					
Routine patient diets	16,282	17,337	32,564	34,945	2,381
Meals to personnel	21,283	21,529	42,566	43,757	1,191
Total diets and meals	37,565	38,866	75,130	78,702	3,572
LAUNDRY AND LINEN					
Total pounds laundered	107,714	97,891	215,428	195,233	-20,195

Salinas Valley Memorial Healthcare System

Memorandum

To: Board of Directors

From: Allen Radner, M.D. CMO

Date: September 30, 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.	Obtaining and documenting Informed Consent in Clinical Research Studies at SVMHS	Updated Policy Statement moved verbiage to General Information section as this is a process. Added policy language for proxy consent. Updated Education Statement to standard verbiage. Updated Procedure section.	Clement Miller
2.	Iodinated Contrast Administration for Radiologic Procedures	Added new Pharmacy oversight process. Updated Policy Statement and Purpose Statement.	Clement Miller
3.	Radiation Safety	Updated Policy Statement. Updated General Information section.	Clement Miller
4.	Intravenous Lidocaine for Pain	New policy.	Clement Miller
5.	Compliance Sanctions Review Policy and Procedure	Updated Policy Statement moved some verbiage to General Information section. Updated Education Statement to standard verbiage. Updated References.	Augustine Lopez
6.	Shipping of Hazardous Materials for Clinical Research Studies at SVMHS	Updated Policy Statement as this is a procedure. Moved some of the content to General Information section. Updated Procedure Section. Updated Education Statement to	Clement Miller

		standard verbiage. Updated References section.	
7.	Care for the Caregiver	New policy.	Clement Miller
8.	Nebulized Tranexamic Acid Procedure	New policy.	Clement Miller

Salinas Valley Memorial Healthcare System

OBTAINING AND DOCUMENTING INFORMED CONSENT IN CLINICAL RESEARCH STUDIES AT SVMHS

Reference Number	2234
Effective Date	Not Approved Yet
Applies To	Clinical Research
Attachments/Forms	

I. POLICY STATEMENT:

A. N/A

~~I.~~II. PURPOSE:

A. To outline activities and procedures for obtaining and documenting informed consent for clinical research trials at SVMHS in accordance with Good Clinical Practice (GCP) and the SVMHS Human Research Protection Program Clinical Research.

~~II. POLICY~~

~~A. Informed consent in clinical research is a process that provides the prospective patient/subject or the subject's legally authorized representative with information pertaining to the research study and sufficient opportunity to consider whether or not to participate, thus minimizing the possibility of coercion or undue influence, ensuring the rights, safety and well-being of human subjects [21 CFR 50.20].~~

~~B. Applies to all personnel involved in the implementation and coordination of clinical research at SVMHS.~~

~~C. Informed consent is a process. This means it and may take place over more than one encounter with a subject or family. The information that is given to the subject or the representative shall be in language understandable to the subject or representative (21 CFR 50.20).~~

III. DEFINITIONS:

A. Informed consent in clinical research is a process that provides the prospective patient/subject or the subject's legally authorized representative with information pertaining to the research study and sufficient opportunity to consider whether or not to participate, thus minimizing the possibility of coercion or undue influence, ensuring the rights, safety and well-being of human subjects [21 CFR 50.20].

OBTAINING AND DOCUMENTING INFORMED CONSENT IN CLINICAL RESEARCH STUDIES AT SVMHS

~~A.~~B. CFR – Code of Federal Regulations

~~B.~~C. ICF – Informed Consent Form

~~C.~~D. GCP – Good Clinical Practice

~~D.~~E. HIPAA – Health Insurance Portability and Accountability Act

~~E.~~F. OHRP – Office for Human Research Protections

~~F.~~G. PI – Principal Investigator

~~G.~~H. IRB – Institutional Review Board

~~H.~~I. LAR – Legally Authorized Representative

OBTAINING AND DOCUMENTING INFORMED CONSENT IN CLINICAL RESEARCH STUDIES AT SVMHS

IV. GENERAL INFORMATION:

~~I.~~A. Informed consent is a process. This means it may take place over more than one encounter with a subject or family. The information that is given to the subject or the representative shall be in language understandable to the subject or representative (21 CFR 50.20).

B. Applies to all personnel involved in the implementation and coordination of clinical research at SVMHS.

~~IV.~~V. PROCEDURE:

A. Either the Principal Investigator (PI) or a sub-investigator will approach a subject about participating in a clinical trial. The investigator discussion will address the risks, benefits and alternatives of participation as well as the therapeutic options available to the subject. In doing so, the principal investigator or sub-investigator will provide a general overview of the clinical trial and its purpose. The overview will serve to introduce the clinical trial to the research subject, and may be part of a larger informed consent discussion involving any therapeutic procedure that will be performed as part of the clinical trial, to include an explanation of the patient's underlying condition, the proposed procedure, the anticipated benefits, the alternatives, and the risks or side effects.

B. The principal investigator, sub-investigator, or appropriate clinical research site personnel will obtain the informed consent of the research subject for participation in the clinical trial by presenting, explaining, and obtaining the research subject's signature on the prescribed consent form. The principal investigator may delegate the duty of obtaining the subject's informed consent to participate in the research project to appropriate clinical site research personnel (for example a qualified Research Coordinator) if permitted by the sponsor and IRB. The role of such personnel will be to review the consent form with the research subject in detail and to answer questions within their knowledge about the Informed Consent Form and the clinical trial. Clinical site research personnel shall refer any questions outside their area of expertise to the principal investigator or the appropriate sub-investigator. The PI will assure that all such personnel are knowledgeable about the study and the process of obtaining informed consent. Such personnel will receive training in accordance with Section VI.B below.

C. The content of the consent form will be written in compliance with GCP regulations/guidelines and IRB requirements. The content of an Informed Consent Form is divided into standardized sections. IC content is governed by

several entities, including the research study sponsor, the IRB, the research site, and both federal and state laws and regulations.

1. The only sections that SVMHS is permitted to modify are (1) the header, (2) the footer, (3) Page 1 section with SVMHS physician and research site contact information, and (4) the Subject Payment for Injury (legal) section.

~~C.~~2. The PI may delegate the ~~development and processing~~ modification of the SVMHS site-specific informed consent form to appropriate clinical research or regulatory personnel.

D. Only the current IRB-approved consent may be used to consent a research subject.

1. IRB-approved consents will contain all OHRP-required elements for informed consent.

~~1.~~2. The California Patient's Bill of Rights and research HIPAA Form: "Authorization for Use and Disclosure of Identifiable Health Information for Research." Note: it is the responsibility of the Covered Entity (SVMHS) to provide accurate, updated research HIPAA Form specific to each IRB-approved clinical trial. It is not the IRB's responsibility. SVMHS does not submit the HIPAA section of the Informed Consent Form for IRB-approval, but our policy requires that it be presented to and signed by the research subject along with the main Informed Consent Form.

E. Informed consent will be obtained for each research subject prior to any screening procedure(s) or altering a subject's care for the purpose of research.

F. In general, all adults, regardless of diagnosis or condition, should be presumed competent to consent to participation in research unless there is evidence of serious disability that would impair reasoning or judgment. In making the determination about whether it is appropriate for investigator's to utilize proxy consent, the IRB will take into consideration the following:

1. the rationale for the need to obtain proxy consent;

2. the criteria that will be used in determining whether a potential subject has decisional impairment sufficient to require the use of proxy consent, including any use of standardized assessment tools;

3. whether any additional methods are proposed to enhance subjects' ability to achieve decisional capacity with regard to the proposed study (e.g., reading of the consent form may not be sufficient and

use of other tools such as videos, educational materials, post-test, etc. might be considered to assist potential subjects in understanding what is involved with the research);

~~D.~~4. who will be approached, and in what order, to provide proxy consent.

~~E.~~G. **Legally Authorized Representative**: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

~~F.~~1. Upon identification of a potential study subject, the PI will identify who is legally authorized to provide consent. If the subject is physically or mentally unable to provide consent, and the reviewing IRB has approved the inclusion of such subjects in the clinical trial, then the legally authorized representative may be approached to give consent.

- The following are specific procedures that must be followed if proxy consent is utilized:

1. Persons with decision impairment may also have been adjudicated legally incapacitated by a court decision. If such persons are considered for enrollment in a research protocol, the only party who may provide proxy consent is the court-appointed guardian. The guardian may only provide proxy consent if the court order, appointing them guardian, specifically states that they have the authority to enroll the incapacitated person into a research protocol. For this category of subjects, a copy of the court order appointing the guardian and granting the guardian authority to enroll the person into a research study should be attached to the informed consent document.
2. Persons may also, through a health care proxy appointed by a power of attorney, designate a person to make decisions for them in the event that they are subsequently incapacitated. This person may give proxy consent for enrollment of a subject in research.
3. If a potential subject has neither a guardian, nor a health care proxy designated, the investigator may obtain the informed consent of the subject's legally authorized representative. Where neither a court-appointed guardian, nor a health care proxy exists, investigators may seek informed consent from the following individuals, in the order listed below:

- spouse, unless an action for divorce is pending, and the adult children of the principal are not the children of the spouse;
- adult child
- a parent (natural or adoptive);
- adult brother or sister;
- adult grandchild
- an adult who has knowledge of the principal's preferences and values, including, but not limited to, religious and moral beliefs, to assess how the principal would make health care decisions

H. Unable to Read Own Language: If the subject or the subject's legally authorized representative is unable to read, then the IRB-approved consent form or IRB approved summary statement must be read in its entirety in the presence of an impartial witness (someone not involved in the research study). This should be documented directly on the consent form and signed by the witness accordingly.

~~G.~~I. Unable to Write: If a subject is unable to write for any reason, but is deemed by the PI to be mentally competent, the subject may make their mark on the signature line and the person obtaining consent will write the date, ensuring all details of the modified consent process are documented in the Informed Consent Process Document.

~~H.~~J. If the subject ~~is unable to speak English~~prefers a language other than English, either an IRB-approved translated full consent or the IRB-approved **short form** consent will be provided per the reviewing IRB Standard Operating Procedures. ~~If the non-English speaking subject is unable to read, then the IRB-approved consent or IRB approved summary statement must be read in the subject's language in its entirety in the presence of an impartial witness (someone not involved in the research study). This should be documented directly onto the consent form and signed by the witness accordingly.~~ If a translated consent is not available, the IRB-approved **short form consent** and consent process are to be followed and documented per the reviewing IRB Standard Operating Procedures.

~~I.~~K. The PI or designee will fully inform the subject or the subject's legally authorized representative of all pertinent aspects of the trial including the written information as approved by the IRB. The process includes:

1. Giving the subject adequate information concerning the clinical investigation in language that is as non-technical as possible *(6th –*

8th grade reading level is recommended) including risks, benefits, alternatives and follow-up requirements of the clinical trial;

2. Providing ample time and opportunity for the subject or the subject's legally authorized representative to inquire about the details of the clinical trial and to decide whether or not to participate in the trial as well as to consider other available options, if any;

3. Responding to subject's questions; all questions about the trial should be answered to the satisfaction of the subject or the subject's legally authorized representative. The investigators must answer any medical questions that the Research Coordinator is not qualified to answer;

4. Ensuring that the subject has acknowledged review of the information contained in the informed consent document and has had time to ask questions;

5. Obtaining the subject's or subject's legally authorized representative's voluntary consent.

~~J.~~L. No informed consent may be obtained within 4 (four) hours following the subject receiving any sedative or amnesiac medications.

1. If the subject's legally authorized representative signs the consent, the research staff must re-consent the subject when possible. Once stable and sufficient time has elapsed (4 hours or more) from any narcotic, sedative or amnesiac drug, the research staff will assess the ability of the subject to participate in the informed consent process; this assessment is to be documented in the progress notes. If the subject is able to consent, the study personnel or investigator will re-consent the subject and document their continued willingness to volunteer for the study in the subject's medical record.

~~K.~~M. The written consent must be signed and personally dated by the subject or subject's legally authorized representative, and by the person who conducted the informed consent discussion. Each person's signature and date must be in his / her own handwriting. Time of signature must be documented ~~per the Sponsor's standards~~ if research-directed tests/procedures will occur the same day as signing the Informed Consent Form.~~applicable.~~ Other signatures must be provided as required by the

sponsor and/or IRB if specified on the IRB-approved consent form (such as witness or signature of person obtaining informed consent).

~~L.~~N. If vulnerable populations are to be involved in the clinical trial, additional protections are included in the informed consent process. The additional protections are defined by the regulations and approved by the IRB. SVMHS does not engage in clinical research involving prisoners.

~~M.~~O. The investigator or designee will file the original signed consent form in the subject's clinical research chart. A copy of the signed consent form will be provided to the ~~person signing the form~~subject at the time of consent. If the subject is unable to sign the consent, the research patient's ~~personal~~ legally authorized representative may sign in place of the subject.

~~N.~~P. The investigator or designee will document in the subject's case history / medical record that informed consent was obtained prior to participation in the investigation [21 CFR 312.62]. This documentation of the Informed Consent Process will include the following information:

1. persons present at the informed consent discussion *(i.e. patient and son)*;
2. telephone discussion(s) with family members (~~*only*~~ *if applicable*);
3. statement that subject had "adequate time to review the entire consent document";
4. statement that all questions from subject and family were answered;
5. statement that the subject agrees to all protocol required tests, procedures and follow-up;
6. statement that the subject voluntarily signed the informed consent;
7. statement that a signed and dated copy of the research consent is on the chart;
8. statement that a copy of the signed consent was given to the patient;
9. statement of whom the Principal Investigator is and his 24 hour phone number for all in-patients;

10. statement of whom to contact in the research office for questions and their contact phone number;

11. statement of what, if any, items/tests/procedures are promised free of charge to the subject as part of their participation;

12. any other cautions to be taken to ensure patient protection and safety. ~~(if applicable).~~

~~O.~~Q. The subject or the subject's legally authorized representative will be informed in a timely manner by the investigator or research personnel when new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. This may be done in writing by letter, revised ICF or in any manner approved by the reviewing IRB. The communication of this information should be documented in the medical record along with a copy of the information provided. [GCP 4.8.2].

R. Re-Consenting: If the written consent form is revised during the course of a subject's participation in the trial, the reviewing IRB panel shall determine when subjects must be re-consented by the principal investigator or designee with the revised IRB-approved consent form. The investigator or designee will file the newly obtained original signed consent form in the subject's clinical research chart. A copy of the consent form will be provided to the subject at the time of re-consent. Another copy will be filed in the subject's clinical research chart.

~~V.~~S. Order entry

~~A.~~1. ~~For all inpatients, a~~A copy of the signed Research Informed Consent ~~consent~~ will be placed in the ~~consent section of the~~ patient's electronic medical record. For investigational drug trials, nursing and pharmacy ~~can~~ review the patient's medical record to verify presence of signed consent form prior to administering study drug. ~~Following discharge, Health Information Management personnel will scan a copy of the completed ICF into the patient's electronic medical record. The Informed Consent Form is scanned into Meditech the EMR~~ [CP1]system.

2. The Research Informed Consent contains a companion HIPAA consent ("Authorization to Use or Disclose Identifiable Health Information for Research"), with detailed description of patient's additional permissions regarding the use and disclosure of their PHI with regard to that specific clinical trial participation.

T. Documentation

1. The Research Coordinator will document a narrative note in the patient's research chart and medical record describing the Informed Consent Process for each individual patient informed consent experience.

2. Informed Consent Form Document Control: a detailed procedure for Version Control document tracking can be found in the Research Program Standard Operating Procedures (SOPs).

U. Audits

1. In addition to audits performed by clinical research sponsors, SVMHS will perform periodic internal audits of consent forms and other research regulatory documentation to ensure that the requirements in this Policy, the Manual of Operations for the IRB of Record, and applicable laws and standards are being followed.

2. In the event that an external audit reveals deficiencies, SVMHS Research Manager or Clinical Research Coordinator will notify the IRB of Record and the SVMHS Research Oversight Committee, submit a written Corrective and Preventive Action p~~P~~lan, and take appropriate corrective measures.

~~B.~~

VI. **EDUCATION~~ and~~ TRAINING:**

~~A. Clinical research staff will read and acknowledge this Policy on an annual basis. In addition, all other staff intending to participate in clinical research at SVMHS will review this Policy as part of the institution's Human Research Protection Program.~~

~~B. All clinical research site personnel shall receive general education in GCP requirements for clinical trials, together with special training with regard to any specific clinical trial with which they will be involved.~~

~~C.~~A. ~~Designated clinical research site personnel will be assigned to monitor transmittals by the FDA, DHHS OHRP and other relevant agencies for new information regarding obtaining and documenting informed consent in clinical trials~~Education and/or training is provided as needed.

~~VII. DOCUMENTATION~~

~~A. The Research Coordinator will document a narrative note in the patient's research chart and medical record describing the Informed Consent Process for each individual patient informed consent experience.~~

~~B. Informed Consent Form Document Control: a detailed procedure for Version Control document tracking can be found in the Research Program Standard Operating Procedures (SOPs).~~

~~VIII. AUDITS~~

~~A. In addition to audits performed by clinical research sponsors, SVMHS will perform periodic internal audits of consent forms and other research regulatory documentation to ensure that the requirements in this Policy, the Manual of Operations for the IRB of Record, and applicable laws and standards are being followed. In the event that an audit reveals deficiencies, SVMHS will notify the IRB and the SVMH Research Committee, submit a written Corrective Action Plan, and take appropriate corrective measures.~~

~~IX.~~VII. **REFERENCES:**

A. The Belmont Report (1979)

B. The Code of Federal Regulations

- Title 21 CFR 50.20 - General Requirements for Informed Consent
- Title 21 CFR 50.23 - Exception from General Requirement
- Title 21 CFR 50.25 - Elements of Informed Consent
- Title 21 CFR 50.27 - Documentation of Informed Consent
- Title 21 CFR 50.40, 50.42, 50.44, 50.46, 50.48 - Protections Pertaining to Investigators Involving Prisoners as Subjects
- Title 45 CFR 46.116 - General Requirements for Informed Consent (when applicable)
- Title 45 CFR 46.408 - Requirements for Permission by Parents or Guardians and for Assent by Children (when applicable)

~~B.~~C. HIPAA Authorization for Research – Department of Health and Human Services Booklet

~~C.~~D. The Joint Commission: Rights & Responses of the Individual

Salinas Valley Memorial Healthcare System

OBTAINING AND DOCUMENTING INFORMED CONSENT IN CLINICAL RESEARCH STUDIES AT SVMHS

Salinas Valley Memorial Healthcare System

IODINATED CONTRAST ADMINISTRATION FOR RADIOLOGIC PROCEDURES

Reference Number	2443
Effective Date	Not Approved Yet
Applies To	ALL NURSING UNITS, OUTPATIENT NURSING UNITS, RADIOLOGY
Attachments/Forms	Attachment A: ACR Guidelines for Patients with Known Allergy to Iodinated Contrast Medication Attachment B: Recommended Treatment of Iodinated Contrast Extravasations Attachment C: Categories of Reactions Attachment D: Management of Acute Reaction in Adults Attachment E: Management of Acute Reaction in Pediatrics Attachment F: IV Injection Guidelines for CT Contrast Attachment G: ~~Algorythm~~Algorithm

I. POLICY STATEMENT:

A. Contrast media will be administered only by those individuals authorized by license, scope of practice, and organization policy to do so. The media will be administered in accordance with manufacturer instructions and/or in accordance with protocol(s) approved by ~~Pharmacy~~the Radiology Medical Director.

~~B. Personnel administering contrast media must be aware of the signs and symptoms of adverse effects involving contrast media.~~

~~C. A qualified physician, Registered Nurse or Radiologic Technologist may administer intravenous contrast material.~~

~~A. A Radiologic Technologist, under their scope of practice, may insert an IV for administration of contrast.~~

~~B. The person responsible for the injection, who may be a technologist or registered nurse, shall be aware of the signs and symptoms of an adverse effect and shall monitor the patient for the development of signs and symptoms throughout the examination.~~

~~D. Appropriate medications and resuscitation equipment shall be readily available to treat serious, potentially life-threatening adverse effects. In addition, the Radiologist, appropriate physician assigned to the patient and pharmacist will collaborate as appropriate on any needed treatment for the patient.~~

~~E. Appropriate screening of patients who take Metformin and Metformin containing medications shall be followed when undergoing procedures using intravascular contrast media.~~

~~F. Standard Metformin Screening Process:~~

~~A. Patient labs will be ordered by referring physician and/ or accessed prior to patient appointment~~

B. Radiology technologist or Registered Nurse will ask patient if they are taking Metformin containing medications prior to the procedure.

C. Medication reconciliation process will be done per hospital policy before exam by RN

G. Qualifications and Responsibilities of Personnel

A. Supervising Physician

a. The supervising physician shall be a licensed physician with the following qualifications:

a. Certification in Radiology, Diagnostic Radiology or Radiation Oncology by the American Board of Radiology or the American Osteopathic board of Radiology.

OR

b. Physicians whose training did not include the above may supervise the administration of contrast material (e.g. ER physician, Hospitalist). The supervising physician shall have sufficient knowledge of the pharmacology, indications and contraindications, and shallshall be familiar with the various contrast agents available and the indications for each, patient preparation for the examination, including necessary hydration or bowel preparation, and shall have an understanding about the volume and concentration of the appropriate contrast material required for a given examination. [1] (Refer to ACR Manual on Contrast Media Version 5.0 ACR Manual on Contrast Media.pdf)

b. The supervising physician or his or her physician designee shall be knowledgeable in the recognition and treatment of adverse effects of contrast materials (Ref. ACR Manual on Contrast Media.pdf; Tables 4, 5, 6 and 7 and the section on Contrast Reactions in Children.)

c. The supervising physician, who is a qualified health care professional, will review the appropriateness of the contrast medium for the patient based on their contrast history.

B. Radiologic Technologist

a. Qualifications for technologists performing intravenous injection of contrast material shall be documented in accordance with current ACR guidelines.

a. Prior written approval by the Medical Director of the Radiology Department shall be obtained for protocols and guidelines used in the department.

b. The technologist, technologist aide or registered nurse is responsible for obtaining the contrast history.

- Risk Factor Assessment and Process
  - Appropriate screening of patients who take Metformin and Metformin containing medications shall be followed when undergoing procedures using intravascular contrast media.
  - Patients will be screened for increased risk for acute kidney injury and post contrast induced nephropathy.
  - Patient labs will be ordered by referring physician and will be assessed prior to the patient's appointment depending on risk factors.

C. Information regarding patient risk can be obtained from the following sources:

a. The patient's referring physician

b. The patient's chart

c. The physician obtaining informed consent (invasive procedures)

d. All risk factors should be discussed with the patient by clinician interviewing the patient prior to the injection of the contrast media.

D. The supervising physician shall be made specifically aware of relative contraindications and pertinent risk factors.

E. The supervising physician shall be immediately available to respond to an adverse effect.

a. During normal operating hours the radiologist shall remain in the imaging department during procedures requiring intravenous contrast administration and shall be immediately available to respond to an adverse effect.

b. For after hours, emergent procedures, the supervising physician, emergency department physician, hospitalist or physician designee shall make him/herself immediately available to respond to an adverse effect.

H. Selection of Contrast Media

A. Contrast media selected for use in the organization must be approved by Pharmacy. Such media will be made part of the medication formulary (inventory).

I. Procurement of Contrast Media

A. Contrast media will be procured by Pharmacy, or by a department of the organization utilizing procurement procedures that have been approved by Pharmacy.

J. Delivery of Contrast Media

A. Contrast media may be delivered directly to the utilizing department so long as the media is delivered to a secure area and to an individual(s) authorized by scope of practice and organization policy to access medication.

K. Ordering of Contrast Media

A. Contrast media may be ordered only by those individuals authorized by license, scope of practice, and organization policy to order medications. Individuals ordering contrast media must be knowledgeable in the recognition and treatment of adverse events involving contrast media.

L. Monitoring of Patient Receiving Contrast Media

A. Patients will be monitored while receiving contrast media by staff sufficiently trained to recognize and respond to a significant reaction or adverse event. The nature and degree of monitoring is not prescribed, but rather is based on the individual clinical needs of each patient, the type of contrast media being used, and the procedure being performed.

M. Reporting of Errors and/or Adverse Reactions

A. Contrast media is considered a medication. As such, any incidence of an error or adverse reaction will be reported in accordance with established organization policy in these areas.

N. After Hours Use of Iodinated Contrast Media

A. Procedure for all inpatients, requiring injection of contrast media after normal business hours, when a Radiologist is not present.

a. The ED physician will be the LIP for all ED patients requiring after hours contrast media.

b. The on duty hospitalist will be the LIP for all inpatients requiring contrast media.

O. Storage of Contrast Media

A. Contrast media will be stored in accordance with manufacturer specifications for light, temperature, and shelf life. Pharmacy must approve all storage.

B. Oral and intravenous contrast material may be stored in the Imaging Department under locked security, allowing access only to appropriate staff.

P. Barium Sulfate suspension products may be refrigerated to improve taste, patient tolerance and patient compliance.

II. PURPOSE:

A. To guide the staff in the safe administration of intravascular iodinated media used for enhancing radiographic procedures. Also, reflected is how intravascular contrast agents are utilized appropriately to optimize imaging studies and to minimize risk to the patient.

B. To ensure that procedures requiring intravascular iodinated contrast media are safely and effectively administered.

to help prevent metformin-associated lactic acidosis/ contrast-induced nephropathy (CIN) in the susceptible patient.

III. DEFINITIONS:

A. Radiology Technologist (RT)
~~A.~~B. Registered Nurse (RN)
~~B.~~C. Peripherally Inserted Central Catheter (PICC)
~~C.~~D. Serum Creatinine (SCr)
~~D.~~E. Glomerular Filtration Rate (GFR)
~~E.~~F. LIP – Licensed Independent Practitioner
~~F.~~G. Pediatric patients (age 0 to 14 yrs)
~~G.~~H. Special Procedures (Angio)

IV. **GENERAL INFORMATION:**

A. A qualified physician, Registered Nurse or Radiologic Technologist may administer intravenous contrast material.

1. A RN/RT ~~Radiologic Technologist~~, under their scope of practice, may insert an IV for administration of contrast.

2. The person responsible for the injection, who may be a technologist or registered nurse, shall be aware of the signs and symptoms of an adverse effect and shall monitor the patient for the development of signs and symptoms throughout the examination.

B. Appropriate medications and resuscitation equipment shall be readily available to treat serious, potentially life-threatening adverse effects. In addition, the Radiologist, appropriate physician assigned to the patient and pharmacist will collaborate as appropriate on any needed treatment for the patient.

C. Qualifications and Responsibilities of Personnel

1. Supervising Physician

a. The supervising physician shall be a licensed physician with the following qualifications:

i. Certification in Radiology, Diagnostic Radiology or Radiation Oncology by the American Board of Radiology or the American Osteopathic board of Radiology.

OR

ii. Physicians whose training did not include the above may supervise the administration of contrast material (e.g. ER physician, Hospitalist). The supervising physician shall have sufficient knowledge of the pharmacology, indications and contraindications, shall be familiar with the various contrast agents available and the indications for each, patient preparation for the examination, including necessary hydration or bowel preparation, and shall have an understanding about the volume and concentration of the

appropriate contrast material required for a given examination. [1] (Refer to ACR Manual on Contrast Media Version 5.0 ACR Manual on Contrast Media.pdf)

b. The supervising physician or his or her physician designee shall be knowledgeable in the recognition and treatment of adverse effects of contrast materials.

~~(Ref. ACR Manual on Contrast Media.pdf; Tables 4, 5, 6 and 7 and the section on Contrast Reactions in Children.)~~

c. The supervising physician, who is a qualified health care professional, will review the appropriateness of the contrast medium for the patient based on their contrast history.

2. Radiologic Technologist

a. Qualifications for technologists performing intravenous injection of contrast material shall be documented in accordance with current ACR guidelines.

i. Prior written approval by the Medical Director of the Radiology Department shall be obtained for protocols and guidelines used in the department.

b. The technologist, technologist aide or registered nurse is responsible for obtaining the contrast history.

~~—~~Pharmacists are involved in reviewing intravenous contrast for appropriateness on inpatients. ~~in the listed capacity~~

~~— Reviewing the contrast dose is within the appropriate range~~

3. ~~Reviewing for contrast interactions, duplications, and allergies with electronically provided information.~~

B. Risk Factor Assessment and Process

1. Appropriate screening of patients who take Metformin and Metformin containing medications shall be followed when undergoing procedures using intravascular contrast media.

2. Patients will be screened for increased risk for acute kidney injury and post contrast induced nephropathy.

3. Patient labs will be ordered by referring physician and will be assessed prior to the patient's appointment depending on risk factors.

4. All risk factors should be discussed with the patient by clinician interviewing the patient prior to the injection of the contrast media.

5. The supervising physician shall be made specifically aware of relative contraindications and pertinent risk factors.
6. The supervising physician shall be immediately available to respond to an adverse effect.
    a. During normal operating hours the radiologist/supervising physician shall remain in the imaging department during procedures requiring intravenous contrast administration and shall be immediately available to respond to an adverse effect.
    b. For after hours, emergent procedures, the supervising physician, emergency department physician, hospitalist or physician designee shall make him/herself immediately available to respond to an adverse effect.

C. Selection of Contrast Media

1. Contrast media selected for use in the organization must be approved by Pharmacy. Such media will be made part of the medication formulary (inventory).

D. Procurement of Contrast Media

1. Contrast media will be procured by Pharmacy, or by a department of the organization utilizing procurement procedures that have been approved by Pharmacy.

E. Delivery of Contrast Media

1. Contrast media may be delivered directly to the utilizing department so long as the media is delivered to a secure area and to an individual(s) authorized by scope of practice and organization policy to access medication.

F. Ordering of Contrast Media

1. Contrast media may be ordered only by those individuals authorized by license, scope of practice, and organization policy to order medications. ~~Individuals ordering contrast media must be knowledgeable in the recognition and treatment of adverse events involving contrast media.~~

G. Monitoring of Patient Receiving Contrast Media

1. Patients will be monitored while receiving contrast media by staff sufficiently trained to recognize and respond to a significant reaction or adverse event. The nature and degree of monitoring is not prescribed, but rather is based on the individual clinical needs of each patient, the type of contrast media being used, and the procedure being performed.

H. Reporting of Errors and/or Adverse Reactions

1. Contrast media is considered a medication. As such, any incidence of an error or adverse reaction will be reported in accordance with established organization policy in these areas.

I. After Hours Use of Iodinated Contrast Media

1. Procedure for all inpatients, requiring injection of contrast media after normal business hours, when a Radiologist is not present.
    a. The ED physician will be the LIP for all ED patients requiring after hours contrast media.
    b. The on duty hospitalist will be the LIP for all inpatients requiring contrast media.

J. Storage of Contrast Media

1. Contrast media will be stored in accordance with manufacturer specifications for light, temperature, and shelf life. Pharmacy must approve all storage.
2. Oral and intravenous contrast material may be stored in the Imaging Department under locked security, allowing access only to appropriate staff.

K. Barium Sulfate suspension products may be refrigerated to improve taste, patient tolerance and patient compliance.

~~A. N/A~~

V. **PROCEDURE:**

A. Iodinated contrast media is used at SVMHS for the following diagnostic procedures: Special Procedures, CT, Cardiac Catheterizations and X-Ray.

B. Age Specific exams performed in Diagnostic Imaging.

1. Procedures done in Special Procedures will not be performed on pediatric patients, unless approved by performing Radiologist.

~~A.~~2. CT and Diagnostic Radiology will provide full services for adults, pediatric, and geriatric patients.

~~A.~~C. The RN/RT will evaluate all patients for sensitivities or allergies to intravenous contrast media agents, medication interactions, cumulative or previous doses of intravenous contrast media, and assess renal function based on current SCr and estimated GFR. The RN/RT will provide IV access as needed for diagnostic procedures requiring contrast media administration per the I.V. THERAPY - PERIPHERAL policy~~-~~.

~~B.~~D. The management of patients taking metformin should be guided by the following:

1. Patients taking metformin are not at higher risk than other patients for post-contrast acute kidney injury are.
2. Iodinated contrast is a potential concern for furthering renal damage in patients with acute kidney injury, and in patients with severe chronic kidney disease (stage IV or stage V).
3. There have been no reports of lactic acidosis following intravenous iodinated contrast medium administration in patients properly selected for metformin administration (ACR Committee on drugs and Contrast Media, 2020).

~~B.~~4. Patients taking medicines that contain metformin are classified into two categories:

a. Category I:

i. In patients with no evidence of AKI and with eGFR ≥45 mL / min/1.73m2, there is no need to discontinue metformin either prior to or following the intravenous administration of iodinated contrast media, nor is there an obligatory need to reassess the patient's renal function following the test or procedure.

~~A.~~ii. Obtain serum Cr and/or GFR within 30 days of study.~~Patients with normal renal function and no known comorbidities:~~

~~**a. Obtain serum Cr/GFR within 6 weeks of study if patient >60 years old**~~

~~**b. No need to discontinue metformin prior to IV contrast.**~~

~~**c. No need to reassess the patient's renal function following the IV contrast injection.**~~

~~**d. Patients will be encouraged to drink at least 32 ounces of water post procedure (unless patient is on a fluid restriction).**~~

b. Category II:

i. In patients taking metformin who are known to have acute kidney injury or severe chronic kidney disease (stage IV or stage V; i.e., eGFR< 45), or are undergoing arterial catheter studies that might result in emboli (atheromatous or other) to the renal arteries, metformin should be temporarily discontinued at the time of or prior to the procedure, and withheld for 48 hours subsequent to the procedure and reinstituted only after renal function has been re-evaluated and found to be normal.

~~B. Patients with multiple comorbidities who have acute kidney injury and/or severe chronic kidney disease or are undergoing arterial catheter studies that might result in emboli to the renal arteries.~~

~~a.~~ii. Obtain serum Cr and/~~and~~ or GFR within 1 week of study

~~b. Metformin should be discontinued at the time of the exam~~

~~c. Follow up Cr/GFR should be done 48 hours post exam before patient resumes taking Metformin~~

~~d.~~iii. A medication suspension form (7140-6934) is to be completed by an RT or RN, explained to and signed by the patient. A copy of this form will also be faxed to the referring physician.

~~e.~~iv. The signed medication suspension form will be scanned into the patient's chart and will be part of the medical record.

~~f.~~v. Patients will be encouraged to drink at least 32 ounces of water post procedure (unless patient is on a fluid restriction).

~~B.~~E. Pre-Procedure process for outpatients.

1. Order is faxed to scheduling department or ordered electronically. The ~~front desk of Diagnostic Imaging Department or Ryan Ranch CADI and/or Cardiac Cath Lab~~ order ~~to~~ should consist of the following items:
    a. Patient's name
    b. Patient's date of birth
    c. Patient's gender
    ~~a.~~d. Patient's height and weight
    ~~b.~~e. Allergies
    ~~b.~~f. Procedure to be done
    ~~c.~~g. Reason for procedure/Diagnosis/Signs and Symptoms
    ~~d.~~h. Previous reaction to Iodinated contrast media
    ~~e.~~i. Diabetic status and oral medications
    ~~f.~~j. History of taking metformin or metformin containing medications
    ~~g.~~k. Current SCr and/or estimated GFR per protocol ~~listed under section F~~.
2. All items should be included in the order. If information is incomplete, the diagnostic scheduler is to call the ordering physician's office and obtain the missing information.
3. Once the patient arrives for procedure, an RN will enter the following into the patients chart:
    a. allergies
    b. focused medication list (Metformin containing meds)
    c. height and weight
    d. labs for renal function, if indicated
4. The RN will order the contrast in MT.
5. Pharmacist will complete review and verify medication so it populates on the eMar.

~~1.~~6. The RN/RT will acknowledge the order and pull the contrast for the exam.

~~C. The RN will complete the Pre IV Contrast Notification in MT and submit to the Pharmacy for review.~~

~~D. The Pharmacy will review the order and verify:~~

~~E. If no contraindications Pharmacy will submit Okay to proceed in MT~~

~~F. If there are contraindications, the Pharmacy will call CT and enter Further review required in MT~~

~~C.~~F. Pre-procedure Process for Inpatients.

1. Ordering physician or designee inputs the order into the current computerized order entry system, order to consist of the following items:
    a. Patient's name
    b. Procedure to be done
    c. Reason/diagnosis/signs and symptoms
    d. Diabetes status and oral medications
2. The contrast order will reflux to Pharmacy for review
3. Pharmacist will complete review and verify medication so it populates on the eMar.
4. The RN/RT will acknowledge the order and pull the contrast for the exam.

~~d. ,Ordersenter, Further review needed in MT orders.~~

~~D. Current SCr or estimated GFR Age Specific exams performed in Diagnostic Imaging.~~

~~1. Procedures done in Special Procedures will not be performed on pediatric patients, unless approved by performing Radiologist.~~

~~2. CT and Diagnostic Radiology will provide full services for adults, pediatric, and geriatric patients.~~

~~E.~~G. Pre-Procedure ~~evaluation of all outpatients~~risk assessment prior to administration of Iodinated contrast media.

1. ~~Patients~~ Outpatients who have normal renal function determined by history or who are at low risk for renal insufficiency may have intravenous contrast media per SVMH contrast administration protocol.
2. Obtain baseline Current SCr and/~~and~~or estimated GFR.
    a. All inpatients receiving iodinated contrast media must have SCr and/~~and~~or estimated GFR within 24 hours of procedure unless emergent. ~~and/or a physician~~
3. All outpatients considered moderate to high risk for renal insufficiency and who are to receive Iodinated contrast media must have a baseline SCr and/~~and~~or GFR within 30 days of the procedure.
    a. Any patients with the following moderate to high risk factors will require a baseline Current SCr and/or estimated GFR:
        ~~e.~~i. Patients with known renal insufficiency
        ~~f.~~ii. Patients over the age of 60
        ~~g.~~iii. History of renal tumor, transplant or solitary kidney

~~h.~~iv. Metformin or Metformin containing drug combinations (refer to section V. D.)

~~i.~~v. Diabetes

vi. Diagnosis of multiple myeloma

vii. Scleroderma or systemic lupus erythematosus.

viii. Known hypertension with medical management

4. If the SCr and/or estimated GFR were obtained from an outside facility, the results are to be delivered or brought to the Diagnostic Imaging Department prior to admission for the imaging study.

~~a.~~5. If patient requires new labs for procedure they may be ordered using CPOE and then e-signed.

~~2.~~6. Any patients with the following high risk factors will be reviewed by a Radiologist before proceeding with the procedure:

a. Diagnosis of multiple myeloma

b. Scleroderma or systemic lupus erythematosus.

c. Known Allergy to Contrast

d. Pregnancy

~~3. Obtain baseline Current SCr or estimated GFR.~~

~~a. All inpatients receiving iodinated contrast media must have SCr or estimated GFR within 24 hours of procedure~~

~~b. All outpatients considered moderate to high risk for renal insufficiency and who are to receive Iodinated contrast media must have a baseline SCr or GFR and BUN within 30 days of the procedure.~~

~~c. If the SCr or estimated GFR were obtained from an outside facility, the results are to be delivered or brought to the Diagnostic Imaging Department prior to admission for the imaging study.~~

~~d. If patient requires new labs for procedure they may be ordered using CPOE and then e-signed.~~

~~4.~~ Obtain ~~Consent Form~~IV and Procedure Assessment form # 7140-6097. ~~Consent for Injection of Iodinated Contrast Media prior to the procedure per consent policy.~~

~~5.~~7. All patients scheduled for procedure requiring administration of Iodinated contrast media will include a focused medication list review prior to the administration of contrast.

~~6.~~8. Establish patient's identification using two patient identifiers, name, and date of birth.

~~7.~~9. Review physician order for the following: name of procedure to be completed, procedure to be completed with or without contrast.

~~8.~~10. RN/RT to assess gauge and patency of existing IV access to determine usability. If needed the RN or RT will obtain new IV access for procedure.

~~F.~~H. Contrast Protocol for safe administration of Iodinated contrast media for Adults and Children.

1. Determination to continue with procedure as ordered are based on the SCr and/or estimated GFR results and include:

2. If sCR and/~~or~~ or GFR is out of normal range, the radiologist will be notified.

   a. GFR is less than 45mL/min/1.73m2

   ~~2.~~b. sCR is 1.5 and above

3. *If the creatinine, ~~or~~ and the GFR are out of normal range, and the referring physician and radiologist have determined that a contrast-enhanced imaging study must be done to obtain critical medical information, the contrast may be given after considering the risks and benefits.* Contrast-enhanced procedures performed in the Radiology Department fall under the supervision of the Radiologist present or Emergency department physician after hours and do not require an order review by a Pharmacist. However, a list of current medications are obtained and reviewed prior to the administration of contrast.

   a. Prior review of non-emergent intravenous contrast media orders by a Pharmacist is not required if the Physician is in direct supervision of the patient. For the purposes of this policy, direct attendance by the Physician means that the Physician is in the Radiology Department, or is immediately available to respond to the Radiology Department within four minutes in the event of an adverse event involving the use of contrast media.

~~a.~~4. If the ordering physician or Radiologist deem contrast is necessary when the sCR and/or GFR are out of range, the physician's signature is required on the designated spot on Form 7140-6097, IV and Procedure Assessment.

~~4.~~5. IV, oral, and rectal contrast volume should be given per protocol (refer to ~~Attachment G~~Contrast Volumes per Protocol). If additional contrast is needed then a physician must be notified and an order must be obtained. The contrast volume must be documented in PACS so the radiologist can dictate the correct amount of contrast administered in the report.

~~5.~~6. New orders for oral and rectal contrast media do not require prior review by Pharmacy provided the following conditions are met:

   a. The oral media is ordered only by those individuals authorized by license, scope of practice, and organization policy to order medications, or in accordance with protocols approved by Pharmacy.

b. The oral media is administered only by those individuals authorized by license, scope of practice, and organization policy to do so.

c. The oral media is administered in accordance with manufacturer instructions and/or in accordance with protocol(s) approved by Pharmacy.

~~G.~~I. Hydration Pre-contrast with Renal Insufficiency

1. If the estimated SCr and/or GFR is ~~is~~ within normal range, and there are no contraindications, then the RT may proceed with the ordered procedure.

~~a.~~2. If the estimated SCr (1.5 and above) and/or the GFR is out of normal range GFR (less than 45mL/min/1.73m^2~~t~~), then the following considerations are to be evaluated by a Radiologist and/or referring physician:

~~i.~~a. Is the decreased renal function temporary? Can the contrast portion of the procedure be delayed?

~~ii.~~b. Study should be monitored and the need to administer iodinated contrast should be reviewed with the non-contrast portion on the procedure.

~~iii.~~c. If contrast is found to be necessary by the radiologist or ordering physician, refer to electronic order set **Hydration Pre-con w Renal Insufficiency**.

~~iv.~~d. The Radiologist should state in the report that the Iodinated contrast was deemed necessary and was administered.

~~2.~~J. Protocol for safe administration of Iodinated contrast media for patients with known allergy to Iodinated contrast media refer~~s~~ to **Attachment A.**

~~3.~~K. Label contrast syringes with name of contrast, concentration of contrast and amount of contrast, date, and initials if not immediately administered.

~~4.~~L. Radiologist ~~will~~ order required if contrast media dose is outside of these protocols.

~~H.~~M. Assess IV site for power injection (see Attachment F)

1. A 20 gauge or larger catheter is preferable for flow rates of 3 ml/sec.
2. An antecubital or large forearm vein is the preferred venous access site.
3. If saline can be injected through the catheter without abnormal resistance, Iodinated contrast media can be administered through the catheter safely.
4. If a more peripheral venipuncture site is used (hand or wrist) a lower contrast flow rate may be more appropriate.
5. Intravenous site will be assessed. If pain, redness, swelling, abnormal resistance or discomfort is encountered, an alternative access will be obtained by RN/RT.
6. A critical step in preventing significant extravasation is performing a test injection then direct monitoring of the venipuncture site by palpation during the initial injection.

7. If administering contrast via a PICC or Central Venous Catheter (CVC) line, only power-injectable rated PICCs or CVCs are to be used. Power-injectable rated PICCs are identified by purple color. Power-injectable rated CVC line' flow rate is located on clamp of each lumen.
8. Only power-injected rated Port-A-Catheter can be used with injector.
    a. Port-A-Catheter is to be accessed by a Radiologist or RN with training.
    b. Non-Power rated Port-A-Catheter requires only hand injection.
9. If hand injection is warranted:
    a. 22 – 24 gauge needle is sufficient.
    b. 5 – 10 ml normal saline is needed for pre and post injection flush.

~~I.~~N. Administration of contrast media with a power injector:

1. Iodinated contrast media should be administered by power injector through a flexible plastic cannula.
2. Careful preparation of the power injector is essential to minimize the risk of Iodinated contrast media extravasation or air embolism.
3. Standard procedures should be used to clear the syringe of air.
4. 30 ml normal saline will be injected as a test with power injector prior to contrast injection.
5. RT to observe for signs of extravasation of contrast media throughout the injection.
6. 30 ml of normal saline flush will follow contrast bolus through power injector.
7. If extravasation is detected the injection is stopped immediately.
8. Communication between the RT and patient via an intercom or television will be maintained throughout the examination.
9. If extravasation is detected, refer to Attachment B for recommended treatment.
10. If extravasation occurs, outpatients will be evaluated by a Radiologist or supervising physician prior to discharge from the department.

~~J.~~O. Assessment of patient during and after iodinated contrast injection.

1. If a patient becomes in distress, the RT will promptly notify the RN to evaluate that patient for signs of venous air embolism, air hunger, dyspnea, cough, chest pain, pulmonary edema, tachycardia, hypotension, or expiratory wheezing and respond appropriately
2. Air Embolism.
    a. Immediate treatment for suspected air embolism includes administration of 100% oxygen, place patient in left lateral decubitus position (left side down), initiate CPR if warranted and activate a Rapid Response Team

(RRT) or Code Blue response according to policy CODE BLUE, CODE WHITE, CODE WHITE NEONATAL

3. Contrast Reaction.
    a. RN/RT to monitor patient throughout the procedure for signs of adverse reaction.
    b. Stop contrast infusion at the first sign of contrast adverse reaction.
    c. Stay with patient and call for assistance.
    d. Identify the severity of the reaction refer to Attachment C.
    e. Activate code blue system for severe life-threatening reaction to Iodinated contrast reaction according to policy CODE BLUE, CODE WHITE, CODE WHITE NEONATAL ~~.~~
4. If adverse reaction is detected refer to Attachment D American College of Radiology (ACR) Guidelines for management of acute reactions in adults or Attachment E, ACR guideline for pediatric treatment.
5. If adverse reaction is detected RN/RT to complete Adverse Drug Reaction (ADR) Reporting form 7170-9050 and complete an Occurrence Report.
6. RN to document allergy into current computerized documentation system.
7. Instruct patient regarding sensitivity to contrast and need for pre-medication prior to any future Iodinated contrast media injection in the future.
8. RN to document in electronic medical record type of reaction and treatment provided
9. Outpatient to be assessed by Radiologist or Primary physician prior to discharge following Iodinated contrast reaction.

~~K.~~P. Injection of Contrast after Hours when a Radiologist is not on site.

1. The ER physician will be LIP for all ER patients requiring iodinated contrast media injection.
2. The Hospitalist on site will be LIP for all stat in- house patients requiring contrast injection for CT procedures.

~~L.~~Q. Post-Procedural Patient Care and Education.

1. Outpatient intravenous access to be discontinued prior to patient being discharged.
2. Women that are breastfeeding should be advised to pump breast milk and discard for 24 hours after receiving Iodinated contrast media.
3. GLUCOSE MONITORING AND MEDICATION COVERAGE WHILE METFORMIN IS ON HOLD

4. Primary physician must be contacted for blood glucose monitoring and possible coverage with insulin or another agent while patient is not able to take Metformin. (See Attachment A)
5. The primary physician orders the sCR and/or GFR to be drawn forty-eight (48) hours after the procedure when indicated. The primary physician is ultimately responsible for follow-up and continuation of Metformin when clinically safe.

~~G.~~R. Documentation:

1. Electronic documentation in Pyxis and MAR.
2. Patient will receive discharge instruction sheet on Medication Suspension Information Form #7140-6934.
3. Patient assessment will be completed on *IV and Procedure Assessment* Form #7140-6097 (English) or 7140-6098 Spanish).

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[CP1].

VII. REFERENCES:

A. American College of Radiology: Manual on Contrast Media ~~Version 10.3 2018~~2020.
   1. Management of acute reactions in Adults and Children - pg. 105-120
   2. Patient Selection and Preparation Strategies – pg. 6.
   3. Extravasation Of Contrast Media – pg. 17
   4. Guidelines for Safe Practice with Patients taking Metformin. – pg. 48.
   5. Post-Contrast Acute Kindy Injury and Contrast Induced Nephropathy in Adults – pg. 33.

B. Journal of Radiology Nursing, Adverse Drug Reaction Prevention, Renal Failure.

ATTACHMENT A

ACR GUIDELINES FOR PATIENTS WITH KNOWN ALLERGY TO IODINATED CONTRAST MEDIA

ATTACHMENT B

RECOMMENDED TREATMENT OF IODINATED CONTRAST EXTRAVASATIONS

SIGNS & SYMPTOMS	TREATMENT	GUIDELINES
Initial: Swelling Tightness Stinging or Burning pain **Visual Examination Signs and Symptoms** Edamatous Erythematous Outpatients will be releases from the department only after assessment by the Department Radiologist and initial signs and symptoms improved and no new symptoms have developed	Most extravasations are limited to immediately adjacent soft tissue (typically the skin and subcutaneous tissue) Elevation of the affected extremity above the level of the heart Apply cold compress as ordered Apply warm compress as ordered	Elevation decreases hydrostatic pressure and thereby promotes re-absorption of extravagated fluid. Cold compresses have been found to be helpful in relieving pain at the injection site. Warm compresses have been found to be helpful in improving absorption of the extravasation.

ATTACHMENT C

CATEGORIES OF REACTIONS

Mild

Signs and symptoms are self-limited without evidence of progression. Mild reactions include:

Allergic-like	Physiologic
Limited urticaria / pruritis	Limited nausea / vomiting
Limited cutaneous edema	Transient flushing / warmth / chills
Limited "itchy" / "scratchy" throat	Headache / dizziness / anxiety / altered taste
Nasal congestion	Mild hypertension
Sneezing / conjunctivitis / rhinorrhea	Vasovagal reaction that resolves spontaneously

Moderate

Signs and symptoms are more pronounced and commonly require medical management. Some of these reactions have the potential to become severe if not treated. Moderate reactions include:

Allergic-like	Physiologic
Diffuse urticaria / pruritis	Protracted nausea / vomiting
Diffuse erythema, stable vital signs	Hypertensive urgency
Facial edema without dyspnea	Isolated chest pain
Throat tightness or hoarseness without dyspnea	Vasovagal reaction that requires and is Responsive to treatment
Wheezing / bronchospasm, mild or no hypoxia	

Severe

Signs and symptoms are often life threatening and can result in permanent morbidity or death if not managed appropriately. Cardiopulmonary arrest is a nonspecific end-stage result that can be caused by a variety of the following severe reactions, both allergic-like and physiologic. If it is unclear what etiology caused the cardiopulmonary arrest, it may be judicious to assume that the reaction is/was an allergic-like one.

Pulmonary edema is a rare severe reaction that can occur in patients with tenuous cardiac reserve (cardiogenic pulmonary edema) or in patients with normal cardiac function (noncardiogenic pulmonary edema). Noncardiogenic pulmonary edema can be allergic-like or physiologic; if the etiology is unclear, it may be judicious to assume that the reaction is/was an allergic like one.

Severe reactions include:

Allergic-like	Physiologic
Diffuse edema, or facial edema with dyspnea	Vasovagal reaction resistant to treatment
Diffuse erythema with hypotension	Arrhythmia
Laryngeal edema with stridor and/or hypoxia	Convulsions, seizures
Wheezing / bronchospasm, significant hypoxia	Hypertensive emergency
Anaphylactic shock (hypotension + tachycardia)	

ATTACHMENT D
MANAGEMENT OF ACUTE REACTION IN ADULTS

Urticaria

a. Discontinue injection if not completed.
b. No treatment needed in most cases
c. Give H_1 – receptor blocker: Diphenhydramine (Benadryl) PO/IM/IV 25 to 50 mg.

If severe or widely disseminated: give alpha agonist (arteriolar and venous constriction): epinephrine SC (1:1,000) 0.1 to 0.3 ml (=0.1 to 0.3 mg) (if no cardiac contraindications).

Facial or Laryngeal Edema

1. Give O_2 6 to 10 liters/min (via mask).
2. Give alpha agonist (arteriolar and venous constriction): epinephrine SC or IM (1:1,000) 0.1 to 0.3 ml (=0.1 – 0.3 mg) or especially if hypotension evident, epinephrine (1:10,000) slowly IV 1-3 ml (=0.1–0.3 mg). Repeat as needed up to a maximum of 1 mg.

If not responsive to therapy or if there is obvious acute laryngeal edema, seek appropriate assistance (e.g cardiopulmonary arrest response team).

Bronchospasm

1. Give O_2 6 to 10 liters/min (via mask). Monitor: electrocardiogram, O_2 saturation (pulse oximeter), and blood pressure.
2. Give beta-agonist inhalers (bronchiolar dilators) or albuterol (Proventil® or Ventolin®) 2 to 3 puffs; repeat as necessary. If unresponsive to inhalers, use SC, IM, or IV epinephrine.
3. Give epinephrine SC or IM (1: 1,000) 0.1 to 0.3 ml (=0.1 – 0.3 mg). Repeat as needed up to a maximum of 1 mg.

Call for assistance (e.g., cardiopulmonary arrest response team) for severe broncospasm or if O_2 saturation < 88% persists.

Hypotension with Tachycardia

1. Legs elevated 60º or more (preferred) or Trendelenburg position.
2. Monitor: electrocardiogram, pulse oximeter, blood pressure
3. Give O_2 6 to 10 liters/min (via mask).
4. Rapid intravenous administration of large volumes of Ringer's lactate or normal saline.
   If poorly responsive: epinephrine) 1:10,000) slowly IV 1 ml (=0.1 mg)
   Repeat as needed up to a maximum of 1 mg
   If still poorly responsive, seek appropriate assistance (e.g., cardiopulmonary arrest response team).

Hypotension with Tachycardia (Anaphylactic Shock)

1. Secure airway and give O_2 6 to 10 liters/min (via mask). Monitor: electrocardiogram, O_2 saturation (pulse oximeter), and blood pressure.
2. Legs elevated 60º or more (preferred) or Trendelenburg position.
3. Keep patient warm.
4. Give rapid infusion of IV or IO normal saline or Ringer's lactate.

5. If severe, give alpha agonist: epinephrine IV (1:10,000) 0.1 mL/kg slow push over 2 – 5 min., up to 3 mL per dose. Repeat in 5 -30 minutes as needed.

If not responsive to therapy, call for assistance (e.g., cardiopulmonary arrest response team).

Hypotension with Bradycardia (Vagal Reaction)

1. Secure airway and give O_2 6 to 10 liters/min (via mask).
2. Monitor vital signs
3. Legs elevated 60º or more (preferred) or Trendelenburg position.
4. Secure IV access: rapid administration of Ringer's lactate or normal saline.
5. Give atrophine 0.6 - 1 mg IV slowly if patient does not respond quickly to steps 2, 3, and 4.
6. Repeat atropine up to a total dose of 0.04 mg/kg (2-3 mg) in adult.
7. Ensure complete resolution of hypotension and bradycardia prior to discharge.

Hypertension, Severe

1. Give O_2 6 to 10 liters/min (via mask).
2. Monitor: electrocardiogram, O_2 saturation (pulse oximeter), and blood pressure.
3. Give nitroglycerine 0.4 mg tablet, sublingual (may repeat x 3); or topical 2% ointment, apply 1 inch strip.
4. If no response, consider labetalol 20 mg IV, then 20 to 80 mg IV every 10 minutes up to 300 mg.
5. Transfer to intensive care unit or emergency department.
6. For pheochromocytoma: phentolamine 5 mg IV (may use labetalol if phenotolamine is not available).

Seizures or Convulsions

1. Give O_2 6 to 10 liters/min (via mask).
2. Consider Lorazepam (Ativan) 2 mg IV (or more, as appropriate) or midazolam (Versed®) 0.5 to 1 mg IV.
3. If longer effect needed, obtain consultation; consider phenytoin (Dilantin®) infusion – 15-18 mg/kg at 50 mg/min.
4. Careful monitoring of vital signs required, particularly of O_2 because of risk to respiratory depression with Benzodiazepine administration.
5. Consider using cardiopulmonary arrest response team for intubation if needed.

Pulmonary Edema

1. Give O_2 6 to 10 liters/min (via mask).
2. Elevate torso.
3. Give diuretics: furosemide (Lasix®) 20 – 40 mg IV, slow push.
4. Consider giving morphine (1-3 mg IV).
5. Transfer to intensive care unit or emergency department.

Abbreviations: IM = intramuscular
IV = intravenous
SC = subcutaneous
PO = orally

ATTACHMENT E

MANAGEMENT OF ACUTE REACTIONS FOR PEDIATRICS

Urticaria

1. No treatment needed in most cases
2. Give H1-receptor blocker: Diphenhydramine (Benadryl) PO/IM/IV 1 to 2 mg/kg, up to 50mg.
3. If severe or widely disseminated: give alpha agonist: epinephrine SC (1:1,000) 0.01mL/kg.

Facial Edema

1. Give O2 6-10 liters/min (via mask, face tent, or blow-by stream). Monitor: electrocardiogram, O2 saturation (pulse Oximeter), and blood pressure.
2. Give alpha agonist: epinephrine SC or IM (1:1,000) 0.01 mL/kg, up to 0.3 mL/dose. Repeat in 15 to 30 minutes as needed.
3. Give H1-receptor blocker: Diphenhydramine (Benadryl®) IM/IV 1 to 2 mg/kg, up to 50 mg.

If not responsive to therapy, seek appropriate assistance (e.g., cardiopulmonary arrest response team).

Laryngeal Edema or Bronchospasm

1. Give O2 6 to 10 liters/min (via mask, face tent, or blow-by stream). Monitor: electrocardiogram, O2 saturation (pulse Oximeter), and blood pressure.
2. Give beta-agonist inhalers [bronchiolar dilators, such as metaproterenol (Alupent®), terbutaline (Brethaire), or albuterol (Proventil) or (Ventolin®)] 2 to 3 puffs; repeat as necessary.
3. Give epinephrine SC or IM (1:1,000) 0.01 mL/kg , maximum 0.3 mL/dose OR epinephrine (1:10,000) IV 0.1 mL/kg, maximum 3mL/dose. Repeat in 3 to 5 minutes as needed.

Call for assistance (e.g., cardiopulmonary arrest response team) for severe Bronchospasm or if O2 saturation < 88% persists.

Pulmonary Edema

1. Give O2 6 to 10 liters/min (via mask, face tent, or blow-by stream). Monitor: electrocardiogram, O2 saturation (pulse Oximeter), and blood pressure.
2. Give diuretic – furosemide (Lasix®) IV 1 to 2 mg/kg.
3. Elevate torso

Call for assistance (e.g., cardiopulmonary arrest response team.

ATTACHMENT E – CONTINUED

MANAGEMENT OF ACUTE REACTION FOR PEDIATRICS

Hypotension with Tachycardia

1. Give O2 6 to 10 liters/min (via mask). Monitor: electrocardiogram, O2 saturation (pulse oximeter), and blood pressure.
2. Legs elevated 60° or more (preferred) or Trendelenburg position.
3. Keep patient warm.
4. Give IV or IO normal saline or Ringer's lactate 20 mL/kg over 5 to 10 minutes. Bolus infusion over 10 to 20 minutes in patients with myocardial dysfunction.

Seek appropriate assistance (e.g., cardiopulmonary arrest response team).

Hypotension with Bradycardia (Vagal Reaction)

1. Give O2 6-10 liters/min (via mask). Monitor: electrocardiogram, O2 saturation (pulse oximeter), and blood pressure.
2. Legs elevated 60° or more (preferred) or Trendelenburg position.
3. Keep patient warm.
4. Give IV or IO normal saline or Ringer's lactate 20 mL/kg over 5 to 10 minutes. Give infusion over 10 to 20 minutes in patients with myocardial dysfunction.
5. Give atropine IV 0.02 mg/kg if patient does not respond quickly to steps 2, 3, and 4. Minimum initial dose of 0.1 mg. Maximum initial dose of 0.5 mg (infant/child), 1.0 mg (adolescent).
6. Atropine dose may be doubled for second administration.

Seek appropriate assistance (e.g., cardiopulmonary arrest response team).

Abbreviations: IM= intramuscular
IO= intraosseous
IV=intravenous
SC=subcutaneous
PO=orally

ATTACHMENT F
SVMHS Department of Radiology
IV INJECTION GUIDELINES FOR CT CONTRAST

The type of IV access required for CT examinations varies by the rate/volume of contrast required for specific protocols. IV contrast is usually administered using a power injector so that a constant rate of contrast can be administered and to make sure that it is precisely timed to the CT image acquisition. Some contrast-enhanced CT examinations require a faster rate and larger volume of intravenous contrast injection than other exams. In general, these include angiographic studies, such as studies of the aorta, head/neck and extremity arteries and cardiac CT studies as well as tumor/organ perfusion studies. For these examinations, a large bore peripheral IV is needed to obtain a diagnostic quality study, while other methods will render the study non-diagnostic. Even for non-angiographic CT examinations, such as a routine CT of the abdomen, contrast is administered using a power injector at a uniform rate through a good peripheral IV, which will result in a better quality study than if only a hand injection through a port/central line is possible. There are an increasing number of PICC and central lines available to which power injectors can be attached and safely used, as described in the specifications from the manufacturer, as detailed below. As a general rule, "non-purple" central lines must be hand injected.

TYPE OF LINE	**POWER vs HAND INJECTION**	**INJECTION RATES**	**LINE ACCESSED/INJECTE BY:**
Peripheral IV	Power or hand injection Hand inject only>>>>>>>>>>	18 g up to 6 cc/sec 20 g up to 4 cc/sec 22 g up to 2.5 cc/sec 24 g up to 1cc/sec	CT tech, RN, MD, PA
Midlines	Power inject or hand inject	5 cc/sec	CT tech, RN, MD, PA
Purple PICC, accessed Smart(power) Port and purple central lines	a. Power injection or b. Hand injection	a. up to 5 cc/sec or b. Test flush for ease of flushing and proper flow to achieve bolus injection no more than 5 cc/sec	a. CT tech can only acce Purple PICC; **all others must b accessed by** b. RN, MD, PA
Central lines (non-purple lines) including Tunnel caths, PICC's, Hickman and internal jugular	Hand injection only Hand injection only with Radiologist approval. Last resort.	Test flush for ease of flushing and proper flow to achieve at least 1 cc/sec bolus	RN, MD, PA
Regular accessed (non-purple) port and other ports used on pediatric patients	Hand injection only: not for rapid bolus of contrast exams such as CT angio studies or coronary studies. Follow 10 cc syringe/double stopcock method of injection.	Test flush for ease of flushing and proper flow to achieve at least 1 cc/sec bolus	RN, MD, PA
Groin lines	Hand injection only		RN, MD, PA

~~ATTACHMENT G~~

~~CONTRAST VOLUMES PER PROTOCOL~~

~~Adult Exams~~	~~Non-Ionic contrast concentration~~	~~IV contrast volume in mL~~	~~Oral contrast volume in mL~~	~~Rectal Contrast volume in mL~~
~~Head with IV~~	~~300~~	~~100~~	~~-~~	~~-~~
~~Angio head~~	~~*320 - 370~~	~~100~~	~~-~~	~~-~~
~~CTA cerebral blood perfusion~~	~~*320 - 370~~	~~80~~	~~-~~	~~-~~
~~Stealth Head with IV~~	~~300~~	~~100~~	~~-~~	~~-~~
~~CTA head & neck~~	~~*320 - 370~~	~~100~~	~~-~~	~~-~~
~~Soft Tissue Neck with IV~~	~~300~~	~~100~~	~~-~~	~~-~~
~~Angio Carotid~~	~~*320 - 370~~	~~100~~	~~-~~	~~-~~
~~C, T, L, Spine with IV~~	~~300~~	~~100~~	~~-~~	~~-~~
~~Chest with IV~~	~~300~~	~~100~~	~~-~~	~~-~~
~~Angio Chest~~	~~*320 - 370~~	~~100~~	~~-~~	~~-~~
~~Chest, Abdomen, Pelvis with IV~~	~~300~~	~~100~~	~~-~~	~~-~~
~~Chest, Abdomen, Pelvis with oral~~	~~-~~	~~-~~	~~30 mL gastroview (Diatrizoate Meglumine and Diatrizoate Sodium) Solution per 900 mL water~~	~~-~~

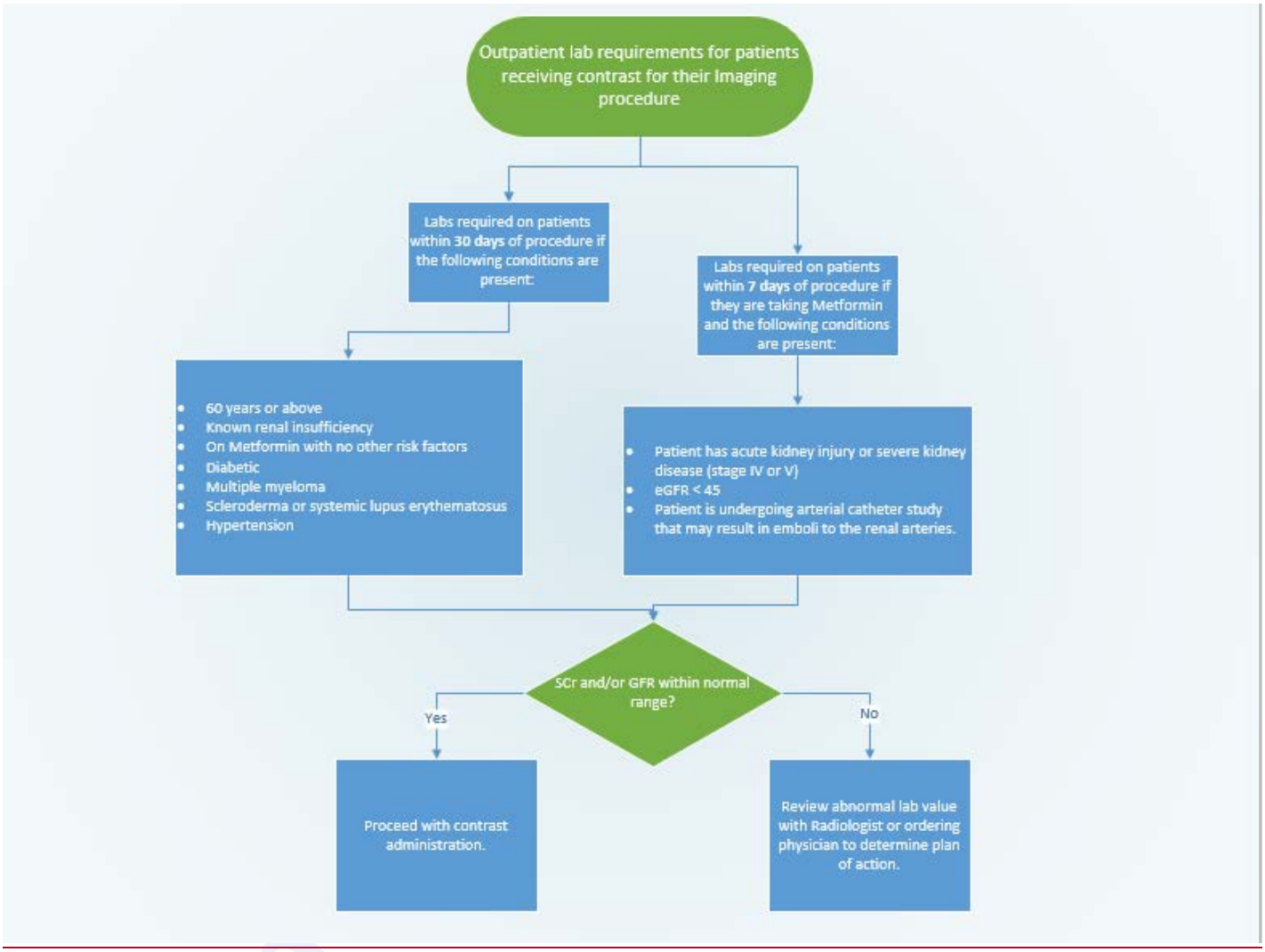
~~Chest, Abdomen, Pelvis with oral & rectal~~	~~-~~	~~-~~	~~30 mL gastroview (Diatrizoate Meglumine and Diatrizoate Sodium) Solution per 900 mL water~~	~~30 mL gastroview (Diatrizoate Meglumine and Diatrizoate Sodium) Solution per 1000 mL water~~
~~Chest, Abdomen, Pelvis with IV, oral & rectal~~	~~300~~	~~100~~	~~30 mL gastroview (Diatrizoate Meglumine and Diatrizoate Sodium) Solution per 900 mL water~~	~~30 mL gastroview (Diatrizoate Meglumine and Diatrizoate Sodium) Solution per 1000 mL water~~
~~CTA Coronary Arteries~~	~~*320 - 370~~	~~80 - 100~~	~~-~~	~~-~~
~~Pulmonary vein/heart/ CTA C-A-P (TAVR)~~	~~*320 - 370~~	~~160 - 180~~	~~-~~	~~-~~
~~Abdomen with IV~~	~~300~~	~~100~~	~~-~~	~~-~~
~~Abdomen with oral~~	~~-~~	~~-~~	~~30 mL gastroview (Diatrizoate Meglumine and Diatrizoate Sodium) Solution per 900 mL water~~	~~-~~
~~Abdomen with IV & oral~~	~~300~~	~~100~~	~~30 mL gastroview (Diatrizoate Meglumine and Diatrizoate Sodium) Solution per 900 mL water~~	~~-~~
~~Abdomen Pelvis with IV~~	~~300~~	~~100~~	~~-~~	~~-~~

~~Abdomen Pelvis with oral~~	~~-~~	~~-~~	~~30 mL gastroview (Diatrizoate Meglumine and Diatrizoate Sodium) Solution per 900 mL water~~	~~-~~
~~Abdomen Pelvis with oral & rectal~~	~~-~~	~~-~~	~~30 mL gastroview (Diatrizoate Meglumine and Diatrizoate Sodium) Solution per 900 mL water~~	~~30 mL (Diatrizoate Meglumine and Diatrizoate Sodium) Solution per 1000 mL water~~
~~Abdomen Pelvis with IV, oral, rectal~~	~~300~~	~~100~~	~~30 mL gastroview (Diatrizoate Meglumine and Diatrizoate Sodium) Solution per 900 mL water~~	~~30 mL (Diatrizoate Meglumine and Diatrizoate Sodium) Solution per 1000 mL water~~
~~Abdomen / Adrenals with IV~~	~~300~~	~~100~~	~~-~~	~~-~~
~~Biphasic/Triphasic abdomen with IV~~	~~300~~	~~100~~	~~-~~	~~-~~
~~IVP~~	~~300~~	~~120~~	~~-~~	~~-~~
~~Angio Abdomen Pelvis~~	~~*320--370~~	~~100~~	~~-~~	~~-~~
~~Angio Runoff~~	~~*320--370~~	~~100-200~~	~~-~~	~~-~~
~~Extremeities with IV~~	~~300~~	~~100~~	~~-~~	~~-~~
~~Enterography~~	~~300~~	~~100~~	~~-~~	~~-~~
~~**Infant & Children patients**~~	~~**300**~~	~~**1.5 – 2 mL/kg**~~	~~-~~	~~-~~

~~* Dependent on vendor supply~~				

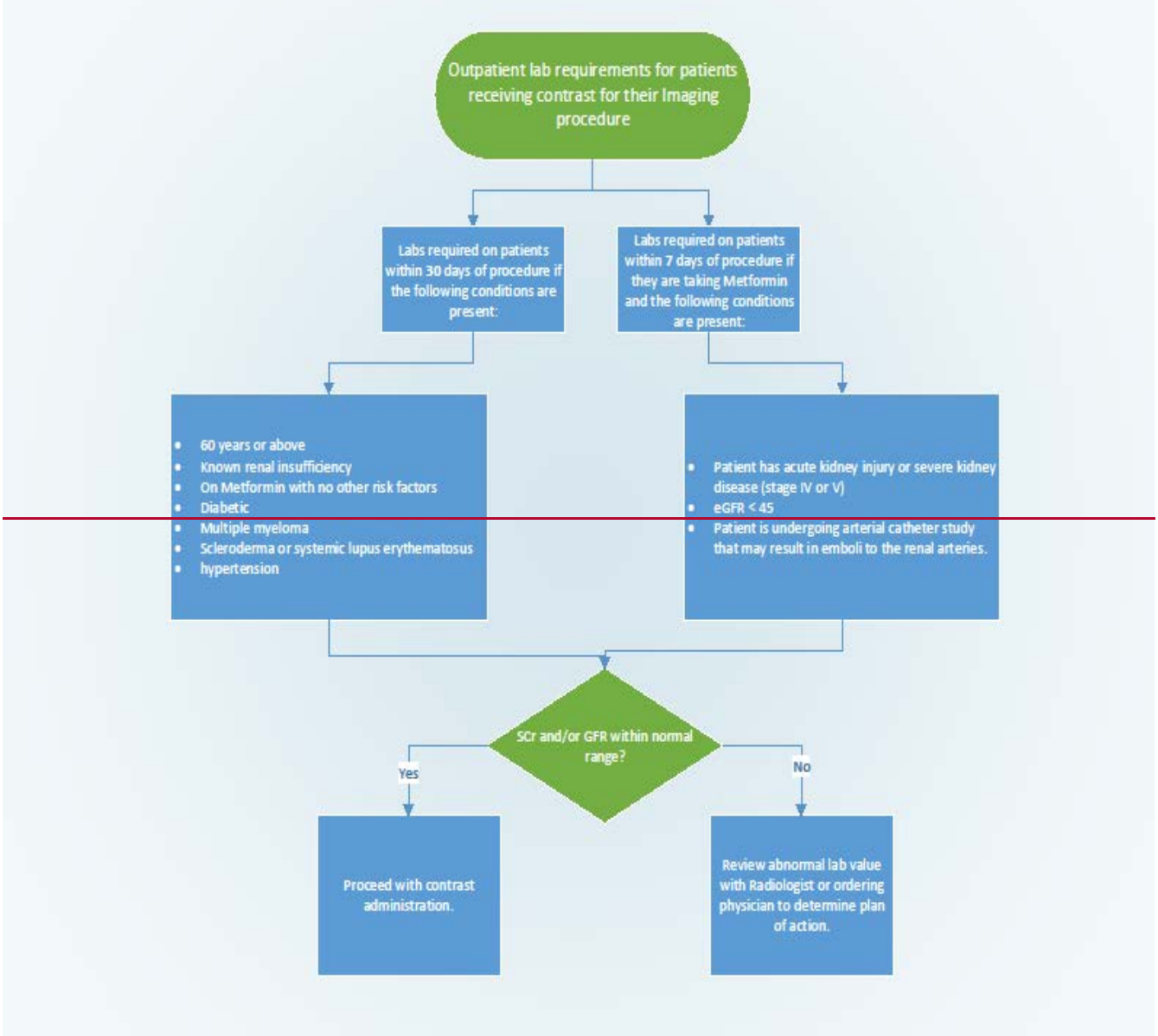
~~A~~AATTACHMENT ~~HH~~G

IODINATED CONTRAST ADMINISTRATION FOR RADIOLOGIC PROCEDURES



Salinas Valley Memorial Healthcare System

IODINATED CONTRAST ADMINISTRATION FOR RADIOLOGIC PROCEDURES



Salinas Valley Memorial Healthcare System

RADIATION SAFETY

Reference Number	2660
Effective Date	Not Approved Yet
Applies To	SVMH, MAMMOGRAPHY CENTER, TAYLOR FARMS FAMILY HEALTH & WELLNESS CENTER, CDOC, AND CADI.
Attachments/Forms	Attachment A: Exposure Action Levels

~~I. PURPOSE~~

~~A. To guide staff regarding radiation safety requirements. in the Diagnostic Imaging Department.~~

~~II.~~I. **POLICY STATEMENT:**

A. Salinas Valley Memorial Healthcare System (SVMHS) will continually review the radiation safety program, including ALARA considerations. The review will cover operation procedures and past dose records, inspections of equipment, and recommendations of the radiation safety staff or consultants.

B. All ionizing equipment and related instrumentation will be checked and used by appropriately trained and licensed personnel, following state and federal regulatory guidelines.

~~B. All ionizing equipment and related instrumentation will be checked and used by appropriately trained and licensed personnel, following state and federal regulatory guidelines.~~

~~C. ALARA will be practiced in all areas where ionizing radiation is used.~~

~~C. Salinas Valley Memorial Healthcare System (SVMHS) will continually review the radiation safety program, including ALARA considerations. The review will cover operation procedures and past dose records, inspections of equipment, and recommendations of the radiation safety staff or consultants.~~

II. **PURPOSE:**

A. To guide staff regarding radiation safety requirements.

III. **DEFINITIONS:**

RADIATION SAFETY

A. **TITLE 17**-California Code of Regulations Title 17

~~A.~~B. **California Department of Health, Radiologic Health Branch** (CDPH-RHB), enforces the laws and regulations addressing ionizing radiation including radioactive material, designed to protect the public, workers, and the environment.

~~B.~~C. **ALARA**-The guiding principle behind radiation protection is that radiation exposures should be kept "As Low as Reasonably Achievable (ALARA)" This common-sense approach means that radiation doses for both worker and the public are typically kept lower than their regulatory limits.

~~C.~~D. **Dose:** The mean energy per unit mass imparted to any matter by ionizing radiation.

~~D.~~E. **Rad:** The common unit of absorbed dose.

~~E.~~F. **mRem:** The common unit of effective dose.

~~F.~~G. **Radiation Safety Committee (RSC):** See RSC Charter.

H. **Radiation Safety Officer (RSO)/ alternate Radiation Safety Officer (aRSO):** Monitor, and review, exposure badge reports quarterly and perform a quarterly review of occupational radiation. The Radiation Safety Officer is "an individual with the responsibility for the overall radiation safety program on behalf of the licensee and who meets the requirements of 10 CFR § 34.42."

I. **National Counsel on Radiation Protection and Measurements (NCRP)**

IV. GENERAL INFORMATION:

A. All individuals working in or frequenting any portion of a controlled area of radiation will be instructed in the following.

1. Required Regulatory Competency for Radiation Safety.
2. Radiological safety procedures will be explained on an individual basis and correlates to the employees' respective duties. This information will include, but is not limited to, appropriate response to emergency or unsafe conditions. If any person notices what appears to be an unsafe practice or condition, in regard to radiation safety, notification should be given immediately to the Diagnostic Imaging Department Management or Radiation Safety Officer.
3. Prior to new equipment being placed into service, instruction of staff will be by the manufacturer's application specialists.

B. ALARA will be practiced in all areas where ionizing radiation is used.

~~IV.~~V. PROCEDURE:

Salinas Valley Memorial Healthcare System

RADIATION SAFETY

A. SVMHS will adhere to the following Radiation Safety guidelines.

1. California Title 17
2. CFR –Title 10 Part 20 and 35
3. California Department of Health – Standards for Protection Against Radiation
4. ALARA

B. Principles of Mitigation of External Radiation Exposures:

1. Time: Minimize the time of exposure.
2. Distance: Personnel should be at locations as far from the primary x-ray field as possible
3. Shielding: Personnel shall use appropriate equipment available to reduce radiation exposure.
4. Patient immobilization: Immobilization equipment should be used to immobilize patients for x-ray procedures. If immobilization equipment is not adequate then a family member or caregiver of the patient should be utilized. If a family member/caregiver or other individual is not available then an x-ray tech can be used as a last resort to hold the patient. Anybody holding a patient for an x-ray examination should wear protective gloves and apron with a minimum 0.25 millimeters lead equivalent. Under no circumstance should individual's holding or supporting a patient have any part of their body directly in the primary beam. Healthcare personnel must avoid exposing any body parts to direct x-ray beam exposure.

~~3.~~5. Collimation: Technologists must collimate the x-ray beam to the area of interest whenever possible. Collimation reduces the overall dose to the patient and improves the image quality.

C. Equipment:

1. Radiation Producing Equipment: all radiation producing equipment should be calibrated annually by a qualified physicist and maintained per manufacturers guidelines. Use storage and shielding of all radioactive materials shall comply with the California radiation control regulations.
2. Lead Aprons: A lead apron or lead equivalent shall be worn during radiation exposure.
3. Lead Glasses: Lead glasses are available upon request. The glasses are required to use for personnel that perform > 3 hrs of fluoroscopy per week.
4. Thyroid Shields: A thyroid shield shall be worn at all times while radiation equipment is in use.

5. Shielding: Full-length lead shields, lead apron shall be used during radiation exposure.
6. Dosimetry program: Dosimetry badges shall be worn in accordance with state regulation to measure levels of exposure to ionizing radiation. All occupationally exposed employees shall wear dosimeters (personal monitors). Dosimeters are to be exchanged quarterly. Body monitors are to be worn at chest level outside of protective devices. (Title 17 recommends personal monitoring device should always be positioned on the collar above the protective apron on top of the protective apron itself).
    a. The Radiation Safety Office (RSO) shall review all dosimetry results and report any excessive exposure to Radiation and Safety Committee and the effected individual with particular attention to instances, in which the investigational levels in Table 1 are exceeded, see ATTACHMENT A.
    b. Badges should be left in the work area in a low background area when not in use. Badges are not to be taken home.
    c. Control badges are kept for each group and will be placed in a non-radiation use area.
    ~~d.~~ Lost or damaged dosimetry badges are to be reported to the RSO or aRSO as soon as possible. ~~immediately.~~
    ~~e.~~d. Doses from previous readings should be added to the lifetime totals carried by this institution.
    ~~f.~~e. Dosimetry badges are not to be shared.
    ~~g.~~f. Readings that fall below the minimum reportable dose will be reported as ND (Not Detectable).
7. Warning Signs: "X-Ray in Use" signs illuminated during procedure to inform anyone in the vicinity that a procedure requiring the use of ionizing radiation is in progress. "Radiation area" and "Radioactive material" signs will be posted as appropriate to help safeguard the general public.
8. Mobile Radiographic Procedures. The operator must stand at least 6 feet from the patient and well away from the beam. Only individuals required for the radiographic procedure shall be in the room during exposure, and except for the patient all persons in the room shall be equipped with appropriate protective devices. The CRT will announce when the exposure is going to take place.
9. Gonadal shielding of not less than 0.5 mm lead equivalent shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the direct beam, except for cases in which this would interfere with the diagnostic procedure.

RADIATION SAFETY

D. ~~D.~~ Annual Occupational Dose Limits per policy:

:PREGNANT WORKER and PATIENT - RADIATION SAFETY

1. 5 rems: Whole body total effective dose equivalent
2. 50 rems: Any individual organ or tissue will be the sum of the deep-dose equivalent and the committed dose equivalent.
3. 15 rems: Lens of the eye
4. 50 rems: Skin of the whole body or any extremity

Declared Pregnant Worker: The dose equivalent to the unborn child during the entire pregnancy due to the occupational exposure of a declared pregnant woman is 0.5 rems.

5.

E. Patient Exposure to Ionizing Radiation:

1. Patient dose information is posted at the consoles. Exposure (dose) is specified at the patient's skin surface where the primary beam enters. These levels are measured by the physicist each year. Patient doses should be kept to a minimum; all studies should be done in a manner to produce the best image quality utilizing the lowest amount of Ionizing Radiation should be considered in patient set-up.
2. X-ray - collimation to the area of interest must be utilized whenever possible to reduce radiation dose to the patient.
3. Fluoroscopy -Short fluoroscopy time, short acquisition time, larger intensifier modes, additional collimation, short distance between the intensifier and patient are factors that reduce dose.

F. Radiation Monitoring:

1. When fluoroscopy is used during an examination, the fluoro time will be recorded in PACS and/or a copy of the dose report from the modality will be sent to PACS with the acquired images.
2. The imaging technologist will notify the RSO or aRSO when any procedure involves a patient exposure of equal to or greater than 3,000 mGy.
3. The RSO or aRSO will notify the performing physician, in writing ~~(certified return receipt requested)~~ any patient that has a single field exposure of greater than 3,000 mGy (NCRP recommendation) or 5,000 mGy of exposure for a procedure that involves multiple fields. The operating physician should institute a clinical follow up plan for the patient. A check for deterministic effects; which may be performed by patient, family or referring physician based on the providers follow up plan.

4. Per The Joint Commission guidelines, any single field exposure of 15,000 mGy or more shall be considered a sentinel event.

    a. Please refer to hospital policy regarding sentinel events ADVERSE EVENTS - REPORTABLE.

5. Copies of the letter will be documented and reviewed at the next scheduled RSC meeting.

6. The RSO, aRSO, or designee will report the ~~occurrence~~ high exposure cases to the Medical Physicist if deemed appropriate by the RSO~~.~~

~~D.~~G. Personnel:

1. Prior to the start of each procedure, Diagnostic Imaging staff (RNs, CRTs, CVTs) may position the patient on the exam table. Once the procedure begins only staff possessing and x-ray and or fluoroscopy license may position the x-ray/fluoroscopy equipment, select dosages, reset x-ray alarms and manipulate the exam table.

~~E.~~H. Monitoring Radiation:

1. Certified Radiologic Technologist performs weekly fluoroscopy checks. Any inconsistencies are reported to the physicist.
2. The Radiation Safety Officer, or designated alternate, reviews results of personnel monitoring each quarter and reports to the Radiation Safety Committee each quarter.
3. Quality control testing will be completed annually by a medical ~~medial~~ physicist.
4. Preventive maintenance of fluoroscopic, x-ray equipment will be completed at least, but not limited to, annually.
5. Annual lead checks are performed by a CRT. Any lead that fails the lead check is removed from service per policy PROTECTION DEVICE INSPECTIONS and REMOVAL

~~F.~~I. ~~–~~Employees Right to Know:

1. All employees have the right to know about possible exposure to radiation.
2. The employee has the right to be notified of any violation involving radiological working conditions or any order issued pursuant to radiation control law on the Title 17, Section 30346.
3. For Exposure and action levels for deep dose limits See Attachment A.

J. Documentation:

1. A radiation badge log will be kept on all staff exposed to radiation.
2. A protective device log will be kept and monitored yearly on all protective devices.

3. A fluoroscopy log book will be kept and monitored weekly by x-ray staff.

~~V.~~VI. **EDUCATION/TRAINING:**

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

~~A. All individuals working in or frequenting any portion of a controlled area of radiation will be instructed in the following.~~

~~• Required Regulatory Competency for Radiation Safety annually in e-learning, provided by SVMHS.~~

~~• Radiological safety procedures will be explained on an individual basis and correlates to the employees' respective duties. This information will include, but is not limited to, appropriate response to emergency or unsafe conditions. If any person notices what appears to be an unsafe practice or condition, in regard to radiation safety, notification should be given immediately to the Vice President, Strategic Management & Planning. Manager of the Diagnostic Imaging Department Management or Radiation Safety Officer.~~

~~• Prior to new equipment being placed into service, instruction of staff will be by the manufacturer's application specialists.~~

~~VI. DOCUMENTATION~~

~~A. A radiation badge log will be kept on all staff exposed to radiation.~~

~~B. A protective device log will be kept and monitored yearly on all protective devices.~~

~~C. A fluoroscopy log book will be kept and monitored weekly by x-ray staff.~~

~~and yearly by physicist.IF NOT APPLICABLE, TYPE N/A.~~

VII. **REFERENCES:**

A. California Department of Public Health. *Standards for protection against radiation: Notice to Employees:* ~~*5/22/09*~~*2016*.

B. California Government Programs. California Code of Regulations (CCR), Title 17, Div. 1, Chapter 5. Retrieved from: ~~11/15/2010~~2017.

ATTACHMENT A

Salinas Valley Memorial Healthcare System

INTRAVENOUS LIDOCAINE FOR PAIN

Reference Number	6891
Effective Date	Not Approved Yet
Applies To	PHARMACY
Attachments/Forms	

I. POLICY STATEMENT:

A. Intravenous Lidocaine for Pain policy is to provide evidence-based recommendations for the dosing, administration and monitoring of parenteral lidocaine for the treatment of pain at Salinas Valley Memorial Healthcare System.

II. PURPOSE:

A. The purpose of this policy is to assure safe administration of lidocaine for pain management in select patients.

III. DEFINITIONS:

A. N/A

IV. GENERAL INFORMATION:

A. Lidocaine is a local amide anesthetic and class Ib antiarrhythmic medication that decreases pain through the blockade of sodium channels in nerve fibers. Intravenous lidocaine has been shown to be effective in postoperative, neuropathic, and opioid-refractory cancer related pain. Lidocaine levels are not reflective of pain control, therefore are not monitored during short term lidocaine use for pain management.

V. PROCEDURE:

A. Patients are screened for exclusion criteria by the prescriber, unless indicated for end of life

1. Exclusion criteria:
    a. Pediatric patients
    b. Patients allergic to amide anesthetics

c. Patients with heart block

d. Patients with cardiovascular instability or concomitant use of antiarrhythmics medications (e.g. amiodarone, sotalol, flecainide, phenytoin)

e. Patients with low potassium or magnesium levels

f. Patients who have received regional anesthesia or epidural in the prior 48 hours, or liposomal bupivacaine in the prior 72 hours

B. Lidocaine orders

1. Physician will order using the Lidocaine for Pain Management orderset.
2. Palliative Medicine physician approval is required. Ordering physician must contact the palliative medicine physician for an approval.
3. Lidocaine infusion
   a. Optional loading dose of 1-1.5 mg/kg IV bolus from bag over 10 minutes, maximum dose of 100 mg.
   b. Range of 1-1.5 mg/kg/hr. (approximately 2 mg/min) with a maximum of 2 mg/kg/hr.
4. Lidocaine therapy must be reordered every 24 hours and will not exceed 48 hours in duration. For patients admitted for greater than 14 days, therapy may be repeated if needed after 14 days.
5. If lidocaine is transitioned by the prescriber to mexiletine, as is done in some comfort care patients, the suggested regimen is as follows:
   a. Decrease lidocaine infusion by 50% and start mexiletine 150mg orally every 12h. Discontinue the infusion the following day and increase mexiletine to 150mg every 8h.

C. Monitoring and Care:

1. Patient must be on cardiac monitor for the duration of the lidocaine administration, unless use is indicated for comfort care at end of life.
2. Magnesium and potassium levels checked prior to initiation, replaced prior to initiation, if low; and checked the following morning x1 while on lidocaine infusion (excludes patients at end of life/comfort care)
3. Vital signs per unit standard of care
4. Pain assessment is completed at a minimum of every 4 hours while on lidocaine infusion

a. Symptoms requiring prescriber notification with possible dose reduction or discontinuation include perioral numbness or tingling, altered or metallic taste, ringing or buzzing in the ears, dizziness or lightheadedness.

b. Symptoms requiring immediate discontinuation of lidocaine infusion followed by prescriber notification include new symptoms of systolic blood pressure less than 100 mmHg, heart rate less than 50 bpm, confusion, altered or blurred vision, muscle twitching, numbness of extremities, or tremor.

c. Symptoms requiring a RRT/Code Blue include seizures, life threatening cardiac arrhythmias, or loss of consciousness. (excludes patients at end of life/comfort care).

VI. EDUCATION/TRAINING:

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

VII. REFERENCES:

A. Bartlett, EE, Hutserani O. Xylocaine for the relief of postoperative pain. *Anesth Analg* 1961; 40:296-304

B. Kranke P, Jokinen J, Pace NL, et al. Continuous intravenous perioperative lidocaine infusion for postoperative pain and recovery. *Cochrane Database Syst Rev* 2015:CD009642

C. Challapalli V, Tremont-Lukats IW, McNicol ED, Lau J, Carr DB. Systemic administration of local anesthetic agents to relieve neuropathic pain. *Cochrane Database Syst Rev*. 2005;4:CD003345

D. Lee JT, Sanderson CR, Xuan W, et al. Lidocaine for Cancer Pain in Adults: A Systematic Review and Meta Analysis. *L Palliat Med* 2019 Mar;22(3):326-344

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J. Atayee R, Naidu D. Geiger-Hayes J, et al. A multi-centered case series highlighting the clinical use and dosing of lidocaine and mexiletine for refractory cancer pain. *J Pain Palliat Care Pharmacother*. 2020

Salinas Valley Memorial Healthcare System

COMPLIANCE SANCTIONS REVIEW POLICY AND PROCEDURE

Reference Number	1047
Effective Date	Not Approved Yet
Applies To	All Departments
Attachments/Forms	

I. POLICY STATEMENT:

~~A. Federal and California law enforces civil monetary penalties against organizations that employ or contract with an individual or entity that the person/organization knows or should know is excluded from participation from the provision of items or services for which payment may be made under a federal health care program or debarred from receiving federal funds [42 U.S.C. § 1320a-7a(6); 42 C.F.R. § 1003.102(a)(2); Welfare and Institutions Code § 14043.61].~~

~~B. SVMHS conducts sanction screenings of its providers, employees, volunteers, independent contractors (including but not limited to travelers and registry) and vendors.~~

~~C. SVMHS takes all reasonable efforts to verify that information provided by applicants and business partners is correct. Responsibility for completion of pre-employment screening, verification, and resolution lies with the Human Resources Department for Hospital employees, travelers and registry. See~~ BACKGROUND CHECKS POLICY~~.~~

~~D.~~A. Any individual or contracting agency identified by SVMHS as being on a governmental sanctions or suspension list may not work for SVMHS, serve on its Medical Staff, occupy Allied Health Professional status, volunteer, or work as a vendor or contractor. Said individual(s) or agency(ies) will be suspended until such time as such sanctions/suspensions are lifted or rescinded. Orders for such non-staff referring providers shall not be acted upon and their ordering status suspended.

II. PURPOSE:

A. Salinas Valley Memorial Healthcare System (SVMHS) demonstrates its commitment to high quality patient care and service through its financial and business management. SVMHS screens providers, employees, volunteers, independent contractors and vendors to ensure they have not been excluded from participating in federal health care programs (including Medi-Cal) or debarred from receiving federal funds.

III. DEFINITIONS:

COMPLIANCE SANCTIONS REVIEW POLICY AND PROCEDURE

For the purposes of this policy the following definitions apply.

A. Allied health professionals are health professionals who do not independently diagnose and prescribe treatment, but provide diagnostic procedures, therapeutic services, and patient care. Examples include respiratory therapists, radiation therapists, occupational therapists, physical therapists, and others.

B. Exclusions are actions taken to bar or prevent participation in a state or federally funded health care program.

C. Resolution includes review of the items identified in a screening to determine if they apply to the individual submitted and if so, ensuring that SVMHS does not employ, contract, or utilize an individual or organization that has been identified as being sanctioned.

D. Sanctions are government actions taken to bar or exclude an individual or organization from participation in a federal health care program (including Medi-Cal) or from receiving federal funds.

E. Screening includes submission to the applicable application or website (e.g., as described in Section V.E. and the references section of this policy) that identifies whether the prospective individual or organization has any sanctions.

F. Verification is selecting a sample of individuals and organizations to identify whether they have been screened and resolved or reviewing documentation provided by the department responsible or the application that performs the check.

IV. GENERAL INFORMATION:

A. ~~N/A~~ Federal and California law enforces civil monetary penalties against organizations that employ or contract with an individual or entity that the person/organization knows or should know is excluded from participation from the provision of items or services for which payment may be made under a federal health care program or debarred from receiving federal funds [42 U.S.C. § 1320a-7a (6); 42 C.F.R. § 1003.102(a)(2); Welfare and Institutions Code § 14043.61].

B. SVMHS conducts sanction screenings of its providers, employees, volunteers, independent contractors (including but not limited to travelers and registry) and vendors.

~~A.~~C. SVMHS takes all reasonable efforts to verify that information provided by applicants and business partners is correct. Responsibility for completion of pre-employment screening, verification, and resolution lies with the Human Resources Department for Hospital employees, travelers and registry. See BACKGROUND CHECKS POLICY.

COMPLIANCE SANCTIONS REVIEW POLICY AND PROCEDURE

V. **PROCEDURE:**

A. The following table identifies the monitoring department responsible for initial and periodic screening:

Population	Initial Check	Monthly Check
Employees	Human Resources (HR)	Human Resources
Privileged Physicians and Allied Health Professionals and Non-Staff Referring Providers	Medical Staff Services	Medical Staff Services
Allied Health Professionals not Privileged with Hospital	Cypress	Cypress
Travelers	Human Resources	Human Resources
Contracted Physicians	Medical Staff Services	Medical Staff Services
Contractors (contracted party/company, not employees)	Contracts Administrator	Vendor Manager
Vendors Coming Onsight	Vendor Mate	Vendor Mate
Other Vendors with no contract	Contracts Administrator	Vendor Manager
Volunteers	Volunteer Office	Volunteer Office

B. Vendor companies coming on site will be checked for sanctions prior to providing items or services to SVMHS. Vendor representatives will be required to register in Vendormate, which will be used to check for sanctions.

C. Screenings will be performed initially before an individual's first date on site or date of service to the organization, and on a monthly basis thereafter by the applicable monitoring department identified in Section V.A. of this policy.

D. Screening processes will include (at a minimum) checking against the Department of Health and Human Services' Office of Inspector General's (OIG) List of Excluded Individuals/Entities (LEIE), the General Services Administration (GSA)

Debarment list, California Medi-Cal Suspended and Ineligible Provider List, as noted in the reference section below.

E. Should an individual or organization be identified with a sanction, the Compliance Officer will be advised immediately by the monitoring department identified in Section V.A. of this policy so that the appropriate action may be taken. Appropriate action may include communication to appropriate stakeholders and suspension of services performed by the individual or organization.

F. In the event SVMHS receives payment for items or services furnished by any excluded individual or entity, SVMHS will refund all associated payments within 60 days of discovery.

G. Periodic verification will be performed by the Internal Audit/Compliance Office and will include review of files for individuals and entities required to have a check to ensure that (a) initial screenings have been performed and (b) resolutions have been completed.

H. The individual performing the screening will advise the Compliance Officer when a sanction is lifted. The Compliance Officer will then advise the respective department head.

I. Documentation:

1. Documentation of all initial and periodic sanctions screening will be maintained by the applicable department identified in Section V.A.1. of this policy.

2. Documentation of actions taken based on sanctions identified will be maintained by the Compliance Officer and, in the case of employees, also by the Human Resources Department.

VI. EDUCATION/TRAINING:

~~A. Education regarding sanctions review is provided on at least an annual basis to the monitoring departments.~~

~~B. Education is provided to individual department leadership and Executive Leadership in accordance with the needs of this policy.~~

~~C. Education about sanctions is provided during periodic Ethics and Compliance Training.~~

A. and/or training is provided as needed.

VII. REFERENCES:

COMPLIANCE SANCTIONS REVIEW POLICY AND PROCEDURE

~~A. SVMHS Background Check Policy~~

~~B.~~A. Exclusion of certain individuals and entities from participation in Medicare and State health care programs, 42 U.S. Code § 1320a–7 http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXI-partA-sec1320a-7.pdf

~~C.~~B. Office of the Inspector General: Basis for civil money penalties and assessments http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-sec1003-102.pdf

~~D.~~C. Welfare and Institutions Code § 14043.61 http://ca.regstoday.com/law/wic/ca.regstoday.com/laws/wic/calaw-wic_DIVISION9_PART3_CHAPTER7.aspx#14043.61

~~E.~~D. 2010 Federal Sentencing Guidelines Manual, Chapter 8, Part B.2

~~F.~~E. U.S. Federal Register, Vol. 63, No. 35, ~~Monday,~~ 2018~~February 23, 1998~~, "Notices", pp. 8987-8993

~~G.~~F. U.S. Federal Register, Vol. 70, No. 19, Monday, January 31, 2005, "Notices", pp. 4874-4875

~~H.~~G. Medicare Managed Care Manual, Chapter 21, Compliance Program Guidelines

~~I.~~H. OIG Special Advisory Bulletin dated May 8, 2013

~~J.~~I. HCCA-OIG, "Measuring Compliance Program Effectiveness: A Resource Guide", March 27, 2017

~~K.~~J. Office of the Inspector General List of Excluded Individuals/Entities at https://oig.hhs.gov/fraud/exclusions.asp

~~L.~~K. General Services Administration Debarment List at https://www.sam.gov

L. California Medi-Cal Suspended and Ineligible Provider List at http://www.medi-cal.ca.gov/references.asp

~~M.~~

Salinas Valley Memorial Healthcare System

SHIPPING OF HAZARDOUS MATERIALS FOR CLINICAL RESEARCH STUDIES AT SVMHS

Reference Number	2469
Effective Date	Not Approved Yet
Applies To	HR, Pathology, Research Department
Attachments/Forms	

I. POLICY STATEMENT:

A. N/A

~~A. The hazardous materials transportation regulations are located in 49 CFR § 171 through 173. The regulations for shipping by air are different than for ground transportation. The regulations for air shipments are the strictest.~~

~~B. For the purpose of this SOP, the terms dangerous goods, hazardous materials and infectious substances (blood and blood products) have the same meaning. Dangerous Goods are articles or substances which are capable of posing a significant risk to health, safety or property when transported.~~

~~C. It is the Research Site's responsibility to assure that employees are adequately trained. Staff who will be dealing with the shipment of hazardous materials must complete appropriate education prior to engaging in the packaging and shipment of hazardous materials.~~

~~D. Research staff shall not transport unpackaged hazardous materials in private vehicles, facility-owned vehicles or via any other mode of transportation.~~

II. PURPOSE:

A. To describe the requirements for shipping of dangerous goods/hazardous materials.

~~B. Applies to all clinical research personnel who handle, prepares for transport, or transports dangerous goods or causes dangerous goods to be transported. [IATA 1.2.1, TDGR 9.2].~~

III. DEFINITIONS:

A. Dangerous goods, hazardous materials and infectious substances (blood and blood products) have the same meaning. Dangerous Goods are articles or substances which are capable of posing a significant risk to health, safety or property when transported including infectious substances, diagnostic specimens (including

excreta, secreta, blood, blood components, tissue and tissue fluids), biologic products and dry ice.

~~A. Dangerous Goods – articles or substances which are capable of prosing risk to health including infectious substances, diagnostic specimens (including excreta, secreta, blood, blood components, tissue and tissue fluids), biologic products and dry ice.~~

~~B. HAZMAT – Hazardous Materials~~

~~C.~~B. DOT – Department of Transportation

~~D. PHMSA – Pipeline and Hazardous Materials Safety Administration~~

~~E.~~C. IATA – International Air Transportation Association – the trade association of the major airlines. ~~http://www1.iata.org/cargo/dg/primer/dghaz6.htm .~~

~~F. ICAO – International Civil Aviation Organization. This is the body of the United Nations that governs all international civil aviation and publishes the Technical Instructions for the Safe Transport of Dangerous Goods by Air. http://www.icao.int/~~

~~G.~~D. DGR – Dangerous Goods Regulations

~~H. SOP – Standard Operating Procedure~~

E. CFR – Code of Federal Regulations

~~I.~~F. Class 6, Division 6.2 Definitions are found at 49 CFR §173.134

- Class 6, Division 6.2, ~~**RC/CRC – Research Coordinator/Clinical Research Coordinator**~~**Category B** - An infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes. A Category B infectious substance must be described as "Biological substance, Category B" and assigned identification number **UN 3373**.

~~J.~~• Class 6, Division 6.2, **Category A**: An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. SVMHS DOES NOT CONDUCT CLINICAL TRIALS INVOLVING Category A Infectious Substances.

Salinas Valley Memorial Healthcare System

SHIPPING OF HAZARDOUS MATERIALS FOR CLINICAL RESEARCH STUDIES AT SVMHS

IV. GENERAL INFORMATION:

A. This process applies to all clinical research personnel who handle, prepare for transport, or cause dangerous goods to be transported. Research staff shall not transport unpackaged hazardous materials in private vehicles, facility-owned vehicles or via any other mode of transportation.

B. It is the Research Site's responsibility to assure that employees are adequately trained. Staff who will be dealing with the shipment of hazardous materials must complete appropriate education prior to engaging in the packaging and shipment of hazardous materials.

~~IV.~~V. **PROCEDURE:**

A. Prior to conducting the clinical investigation, the principal investigator and/or staff will be trained and certified for shipment of Class 6.2 hazardous goods. Employees who package substances classified by the Department of Transportation as Class 6.2 Category B ~~INFECTIOUS SUBSTANCES~~Infectious Substances for shipment receive training consistent with the applicable regulations (~~[~~49 CFR §171-180, 42 CFR 72). SVMHS does not conduct clinical trials involving Category A Infectious Substances, but Clinical Research Coordinators are required to be trained for shipment of BOTH and able to differentiate the two classes.~~].~~

~~B.~~ Only personnel who have completed approved educational programs may perform this function. ~~[49CFR 172.700, IATA 1.5].~~ Documentation of required education shall be maintained in the Research Department staff education file. ~~and in the employees Human Resources education file.~~

~~C.~~ During the site initiation or training for a new study, the Research Manager / designee ~~or Lead RC/CRC~~Clinical Research Coordinator will obtain from the Sponsor any information specific to the handling of hazardous materials for the study, including the procurement and shipping of dangerous goods, and / or specimens or materials that require dry ice. ~~This includes the proper shipping name (IATA DGR 4.2), UN Number, and information necessary to complete the 14 item Identification for all shipments.~~

~~D.~~B. The Research Manager / Designee ~~or Lead RC/CRC~~Clinical Research Coordinator will obtain ~~from the Sponsor~~ the proper packaging or shipping materials, containers, labels and account numbers that meet the requirements of the regulations. In most cases, the study Sponsor will provide the specimen

collection and shipping materials. Alternatively, the clinical trial agreement (such as NCI sponsored trials with ECOG-ACRIN) may require that SVMHS Research Program provide the specimen collection and shipping materials.

~~E.~~C. The shipper of hazardous materials (in this case, the Salinas Valley Memorial Healthcare System Research Department) will classify, identify, package, mark, label and document shipments for transport by air or surface according to the regulations.

~~F.~~D. The principal investigator or Clinical Research Coordinator ~~designee,~~ will maintain appropriate records by keeping copies of the Shipper's Declaration and Waybill in the study files for each shipment.

E. If dry ice is needed, it will be ordered through ~~the~~ SVMH Materials Management, with a minimum of 24 ~~hours notice~~hours' notice prior to the anticipated shipment date. All routine research specimen shipments will be made Monday through Thursday, via an overnight courier such as FedEx or UPS.

~~G.~~F. The Clinical Research Coordinator will arrange for and track the specimen shipment through Delivery and maintain such documentation in the research participant's investigative site file.

~~H.~~G. Documentation:

- Study related roles and duties will be documented in Delegation of Authority Logs and Signature Logs as required by individual studies/protocols.
- Records related to shipping of hazardous materials shall be maintained per CFR 49 and local guidelines in addition to study protocol requirements.
- Copy of all shipping documents will be kept with study materials.

~~V.~~VI. EDUCATION/TRAINING:

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

~~A. Annual review by Clinical Research Staff.~~Manager.

~~B. Reviewed by all staff intending to participate in clinical research~~Clinical Research Coordinators at SVMHS as part of protocol approval ~~training~~process.

~~C. Completion of certification every 2 years~~ from an ~~per IATA approved provider validated by the SVMHS Research Manager, such as: guidelines from:~~

- ~~Mayo Clinic Dangerous Goods Dangerous Training www.mayomedicallaboratories.com/education/online/dangerousgoods/index.html~~
- ~~SafTPak Dangerous Goods Training (1-800-814-7484) http://www.saftpak.com/training.asp~~
- ~~Other SVMHS recognized training as appropriate or required by study protocol.~~

~~VI.~~ REFERENCES:

VII. ~~Hazardous material shipping is in accordance with the following regulatory requirements and industry guidelines - Retrieved April 20, 2010 from~~ http://www.gpoaccess.gov/cfr/index.html

- ~~49 CFR 172.700 – Pipeline and Hazardous Materials Safety Administration, Department of Transportation, Subchapter C – Hazardous Materials Regulations~~

~~B.~~ ~~US Department of Transportation PHMSA. 49 CFR §173.199 Category B Infectious substances. Retrieved February 24, 2010~~June 21, 2021 ~~from: https://www.govinfo.gov/content/pkg/CFR-2010-title49-vol2/pdf/CFR-2010-title49-vol2-sec173-199.pdf http:/www.phmsa.dot.gov/hazmat~~

~~C.~~ ~~IATA Manual. Retrieved February 24, 2010 from:~~http://wwwl.iata.org/cargo/dg/primer/dghaz6.htm

~~D.~~ ~~ICAO Technical Instructions. Retrieved February 24, 2010 from: http://www.icao.int/~~

A. US Department of Transportation PHMSA. 49 CFR§17 - §173.199 Category B Infectious substances. Retrieved June 21, 2021 from: https://www.govinfo.gov/content/pkg/CFR-2010-title49-vol2/pdf/CFR-2010-title49-vol2-sec173-199.pdf

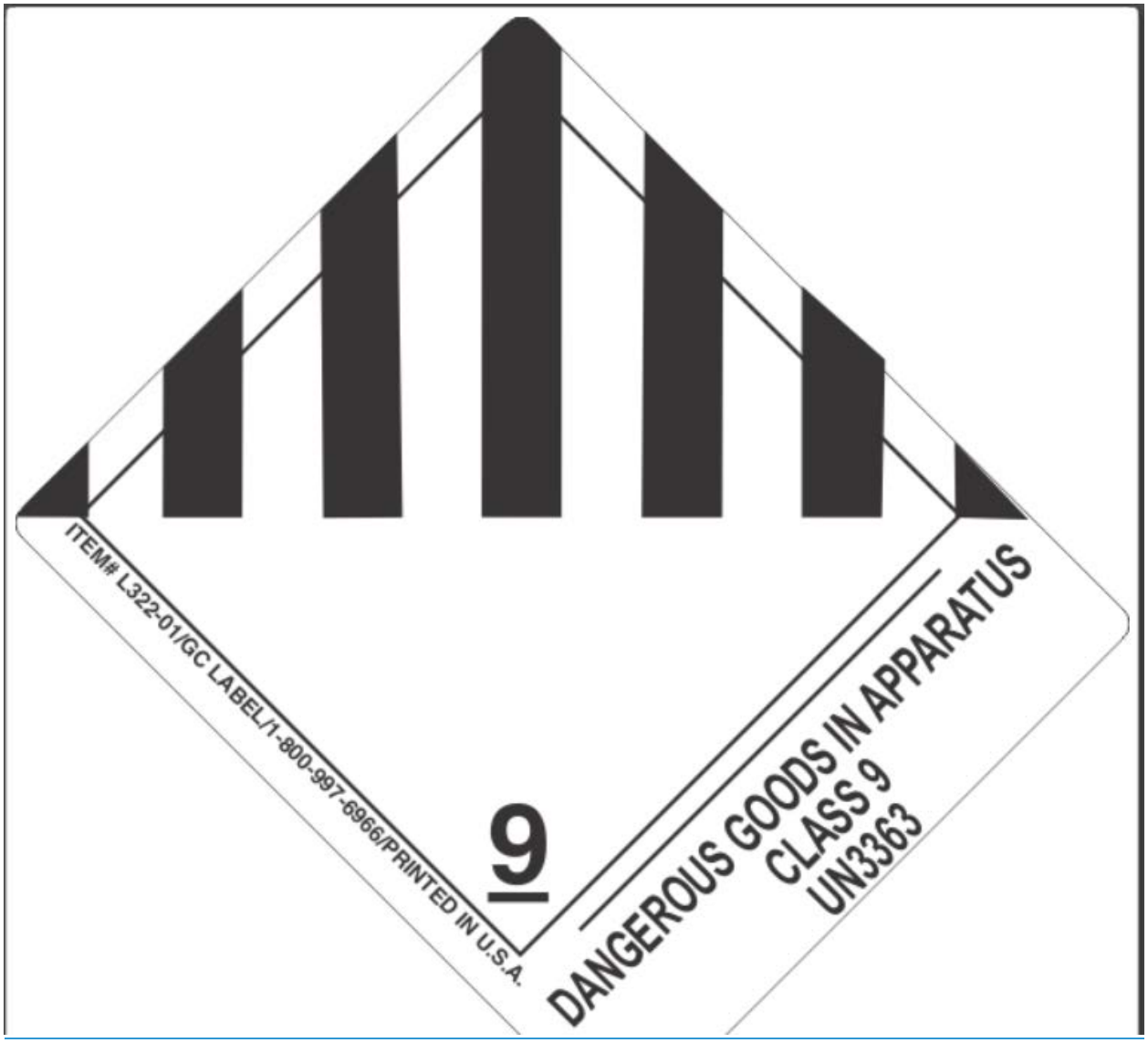
Salinas Valley Memorial Healthcare System

SHIPPING OF HAZARDOUS MATERIALS FOR CLINICAL RESEARCH STUDIES AT SVMHS

Table 1. Sample of required UN3363 Label for Category B Shipping box:

Salinas Valley Memorial Healthcare System

SHIPPING OF HAZARDOUS MATERIALS FOR CLINICAL RESEARCH STUDIES AT SVMHS



Salinas Valley Memorial Healthcare System

CARE FOR THE CAREGIVER

Reference Number	6899
Effective Date	Not Approved Yet
Applies To	All Departments
Attachments/Forms	

I. POLICY STATEMENT:

A. NA

II. PURPOSE:

A. To provide guidelines and structure for offering emotional first aid and support for staff and physicians after an unanticipated/adverse harm or traumatic event.

B. To develop and implement a 24/7 support system inclusive of all staff, providers and contracted staff of Salinas Valley Memorial Hospital, which acknowledges and identifies difficult situations.

C. To develop a program that is grounded in a philosophy of healing, empathy, support, compassion, trust and confidentiality that respects and maintains the integrity of those impacted.

III. DEFINITIONS:

A. **Adverse/Harm event:** An unanticipated event that may have, or did result in, harm.
B. **Care for caregiver**: Emotional first aid provided to a person who is involved in an unexpected health care or other emotionally traumatic event.
C. **Debriefing:** Process of holding a post-event discussion about what happened during the event. The discussion may include input from participants regarding what occurred, what worked well, what could be improved, or personal feelings associated with the event. The scope and purpose of the debriefing should be established in the opening comments. A debriefing is not an investigation and is separate and apart from a peer supporter interaction.
D. **Harm:** Any measurable amount of physical, discernable, or financial injury
E. **Peer supporter:** A trained member of the Care for the Caregiver Peer Support Team who is available to respond to physicians or personnel to offer and provide emotional first aid following a harm, adverse, or emotionally traumatic event

F. **Traumatic event:** An experience in the workplace that causes emotional upheaval or has the potential to impact the well-being of staff in the work environment. Examples of a traumatic event include but are not limited to, the following:

- Workplace violence event
- Severe injury or death to a patient, staff, or visitor
- Medical error
- Unanticipated patient harm or death (especially when the age or other characteristics remind the individual of a family member or loved one)
- Sudden loss of a co-worker
- Collective, significant personal loss
- Multiple deaths in a clinical area
- Seriously troubled staff creating havoc with multiple staff members
- Actual suicidal or homicidal attempts by a patient, staff, or visitor
- Unanticipated patient death (Pediatric)

G. **Triggering event:** An adverse, unanticipated, or traumatic event.

IV. GENERAL INFORMATION:

A. SVMH recognizes the potential emotional and psychological impact that, harm and emotionally traumatic events can have on persons. To that end, this organization is committed to providing support and care for our caregivers; staff and physicians, impacted by emotionally traumatic events.

B. The Care for the Caregiver process is part of the Beta HEART program. As such, all program related referrals and encounters are maintained in a confidential manner and as part of the patient safety work product. The effectiveness and evaluation of the Care for the Caregiver program is reported in accordance with the Quality Oversight Structure

V. PROCEDURE:

A. Care for the Caregiver program can be activated by anyone in response to a harm or emotionally traumatic event that triggers the need for emotional support.

B. Activation of the program will be accomplished through communication to the Care for Caregiver Intake Coordinator.

1. The Critical Care and Emergency Department Director functions as Care for Caregiver Intake Coordinator. The Care for the Caregiver Intake Coordinator can be reached via telephone and/or secure texting. In the event the Intake Coordinator is unavailable, the Patient Experience Team should be contacted. After hours, contact should go

to the Administrative Supervisor who will then contact the appropriate people for response.

2. Upon activation, the Care for Caregiver Intake Coordinator may need to contact the involved individual or their Director/Manager to determine the level of post event support and resources needed. Resources and referrals may include but are not limited to Care for the Caregiver Peer Support Team member, Staff Assistance Program, Chaplain/Pastoral Services, or external access to a higher level of psychological support.
3. Tier One Activation: Department/Unit level support will be provided by unit Director/Manager, fellow team member/colleague, supervisor, or department chair. Support includes:
    a. Connect with affected individual(s)
    b. Provide one-on-one reassurance and/or professional support
    c. Reaffirm confidence in individual
    d. Assist with contacting the Care for Caregiver Intake Coordinator, to determine if additional resources are needed
    e. Assist individual to temporarily leave unit and go to the designated 'Safe Space' or other suitable area to process the event.
    f. Consider relieving involved individuals of duties for balance of shift and longer if necessary through collaboration with Administrative Nursing Supervisor and Department Leader.
    g. Check on staff member regularly after initial interaction
    h. Notify individual of next steps, if any
4. Tier Two Activation: Upon receipt of notification, the Intake Coordinator will gather initial information, triage the call, and provide a handoff report to a trained peer supporter or resource as needed.
    a. Intake information includes: Date and time of request, name of involved staff member, unit, type of event, effectiveness of tier one support, any special concerns, etc.
    b. Trained peer supporter may receive request for peer support from anyone; however, the peer supporter should notify the Intake Coordinator if the request is made outside of the formal activation process,
    c. The peer supporter will respond by phone to provide support to involved staff/physician; and be prepared to respond to the unit if immediate personal response is needed
5. Peer supporter will (in addition to support provided in Tier One):
    a. Provide one-on-one crisis intervention
    b. Demonstrate active listening techniques
    c. Offer support

d. Redirect conversation as needed to focus on individual rather than event
e. "Be there" for the staff member
f. Evaluate and determine the need for referral to Tier 3 support for additional assistance as needed
g. Document on the Peer Support Encounter form
h. Participate in ongoing team meetings and education

6. Tier Three Support may be triggered by the peer supporter, Director/Manager, a colleague or the individual when needed. Additional resources include but are not limited to:
    a. Staff Assistance Program
    b. Social Work
    c. Chaplain
    d. Clinical Psychologist
    e. Other as designated by organization
7. Individuals manifesting signs consistent with impairment will be managed according to the organization's process for evaluating potentially impaired physicians/staff. The peer supporter shall notify Director/Manager immediately when it is believed the individual may be affected to the point of impairment regardless of when the concern arises in the recovery process

VI. PROGRAM EVALUATION:

A. Peer supporters will complete a confidential Peer Support Encounter form and submit to the Care for the Caregiver Intake Coordinator within 72 hours of interaction.
B. Staffs and physicians participating in Care for the Caregiver program interactions will be asked to complete a confidential program evaluation
C. Evaluation of the Care for the Caregiver program will be achieved through volume statistics (number and frequency of encounters) as well as qualitative analysis through post-event surveys.
D. Program statistics will be reported up through the Quality Oversite Structure.
E. Data detailing the effectiveness of the Care for the Caregiver program will be shared within the Care for The Caregiver Steering Committee and Quality Oversite Structure. Overall program effectiveness will be shared as appropriate at Leadership and Staff Venues.

VII. EDUCATION/TRAINING:

A. Education and/or training is provided as needed

Salinas Valley Memorial Healthcare System

NEBULIZED TRANEXAMIC ACID PROCEDURE

Reference Number	6911
Effective Date	Not Approved Yet
Applies To	RESPIRATORY CARE
Attachments/Forms	

I. POLICY STATEMENT:

A. N/A

II. PURPOSE:

A. To guide staff on the proper administration of Nebulized Tranexamic Acid

III. DEFINITIONS:

A. N/A

IV. GENERAL INFORMATION:

A. **Indications:**
- Patient is ≥ 18 years of age
- Non-massive hemoptysis **(expectorated blood ≤ 200 mL/24 hrs.)**

B. **Contraindications**
- Hypersensitivity to Tranexamic acid
- Massive hemoptysis (expectorated blood > 200 mL/24 hrs.)
- Respiratory instability
- Renal failure
- Pregnancy
- Hemodynamic instability

V. PROCEDURE:

A. **Dosing**:
- Per Physician order

B. **Administration**:
- Remove Tranexamic acid from vial using a syringe and place in nebulizer undiluted
- Administer via Aerogen nebulizer over 2-7 minutes

- If bronchospasm occurs, stop nebulization and administer albuterol 2.5-5 mg nebulized once

C. **Monitoring Requirements**

- Signs of bronchospasm
- Continued bleeding
- Allergic reactions

VI. EDUCATION/TRAINING:

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

VII. REFERENCES:

A. Komura, S., Rodriguez, R. M., & Peabody, C. R. (2018). Hemoptysis? Try Inhaled Tranexamic Acid. The Journal of Emergency Medicine, 54(5). https://doi.org/10.1016/j.jemermed.2018.01.029

B. Wand, O., Guber, E., Guber, A., Epstein-Shochet, G., Israeli-Shani, L., & Shitrit, D. (2018). Inhalations of Tranexamic Acid for Hemoptysis: A randomized controlled trial. Airway Pharmacology and Treatment. https://doi.org/10.1183/13993003.congress-2018.pa4409

QUALITY AND EFFICIENT PRACTICES COMMITTEE

Minutes from the September 27, 2021 meeting of the Quality and Efficient Practices Committee will be distributed at the Board Meeting

(JUAN CABRERA)

FINANCE COMMITTEE

Minutes from the September 27, 2021 meeting of the Finance Committee will be distributed at the Board Meeting

(RICHARD TURNER)

PERSONNEL, PENSION AND INVESTMENT COMMITTEE

Minutes from the September 28, 2021 meeting of the Personnel, Pension and Investment Committee will be distributed at the Board Meeting

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

(REGINA M. GAGE)

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

Consider Recommendation for Board Approval of Asset Allocation for Defined Benefit Pension Plan Change to 65% Equities / 35% Fixed Income, Effective Immediately

(LOPEZ /KJAR & SALB OF LOCKTON INVESTMENT ADVISORS, LLC)

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

CORPORATE COMPLIANCE AND AUDIT COMMITTEE

Minutes from the September 28, 2021 meeting of the Corporate Compliance and Audit Committee will be distributed at the Board Meeting

(JUAN CABRERA)

Medical Executive Committee Summary
September 9, 2021

Items for Board Approval:

Credentials Committee

Initial Appointments:

APPLICANT	SPECIALTY	DEPT	PRIVILEGES
Baker, Steven, MD	Pathology	Surgery	Pathology: Core
Morneau, Leonard, MD	Radiology	Surgery	Remote Radiology: Core
Smith, Diana, MD	Psychiatry	Medicine	Tele-Psychiatry: Core

Reappointments:

APPLICANT	SPECIALTY	DEPT	PRIVILEGES
Baker-Leyva, Sa Vanna, DO	Family Medicine	Family Medicine	Family Medicine – Active Community
Carrillo, Raymond, MD	Nephrology	Medicine	Nephrology General Internal Medicine
Coll, Jonathan, MD	Tele-Radiology	Surgery	Remote Radiology
Dacus, James, MD	Internal Medicine	Medicine	General Internal Medicine Cardiac Diagnostic Outpatient Center (CDOC)
Hay, Sunthara, DO	OB Hospitalist	Ob/Gyn	Obstetrical Hospitalist Gynecology Hospitalist
Hosohama, B. Misa, MD	Diagnostic Radiology	Surgery	Diagnostic Radiology Center for Advanced Diagnostic Imaging (CADI)
Hotchkiss, John, MD	Tele-Radiology	Surgery	Remote Radiology
Karachalios, Michael, MD	Tele-Radiology	Surgery	Remote Radiology
Klick, Anastasia, MD	Family Medicine	Family Medicine	Family Medicine Adult Pediatric and Well Newborn Category I Obstetrical Category II Obstetrical
Krishna, Gopal, MD	Nephrology	Medicine	Nephrology General Internal Medicine
Lappen, Rhonda, MD	Pediatric Cardiology	Pediatrics	Remote Pediatric Cardiology
Litman, David, MD	Pathology	Surgery	Pathology
Lieberman, Marc, MD	Rheumatology	Medicine	Rheumatology
Lin, Michael, MD	Tele-Radiology	Surgery	Remote Radiology
Lotan, Roi, MD	Tele-Radiology	Surgery	Remote Radiology
Ramirez, Edward, MD	Gynecology	Ob/Gyn	Gynecology
Strauchler, Daniel, MD	Tele-Radiology	Surgery	Remote Radiology
Thomson, Matthew, MD	Tele-Radiology	Surgery	Remote Radiology
Trieu, Chuyen, MD	Pediatrics	Pediatrics	Pediatrics
Wahl, Gerald, MD	Neurology	Medicine	Neurology

Modification and/or Addition of Privileges:

NAME	SPECIALTY	RECOMMENDATION
Jani, Atul, MD	General Surgery	Voluntarily relinquishing Use of Radiofrequency for interruption of veins.
Khieu, William, MD	Ob/Gyn	Voluntarily relinquishing Laparoscopic or

		Supracervical Hysterectomy privileges.

Staff Status Modifications:

NAME	SPECIALTY	RECOMMENDATION
Calzetta, Juan, MD	Thoracic Surgery	Emeritus Staff effective 10/01/2021
Arnold, Cody, MD	Neonatology	Advance to Active Staff Status
Sakopoulos, Andreas, MD	Cardiac, Thoracic and Vascular Surgery	Advance to Active Staff Status
Choi, Lillian, MD	Gastroenterology	Leave of Absence effective 08/31/2021
Dutaret, Claudine, MD	Tele-Neurology	Resignation effective 07/19/2021
Khera, Tanvir, MD	Internal Medicine	Resignation effective 08/31/2021

Interdisciplinary Practice Committee

Reappointments:

APPLICANT	SPECIALTY	DEPT	PRIVILEGES/SUPERVISOR
O'Brien, Kaitlyn, PA-C	Physician Assistant	Emergency Medicine	Physician Assistant Clinical Privileges Emergency Medicine Rakesh Singh, MD

Modification/Addition of Privileges:

NAME	SPECIALTY	PRIVILEGES	RECOMMENDATION
Devencenzi, Amanda, PA-C	Physician Assistant Surgery	Taylor Farms Family Health & Wellness Center Physician Assistant – Ambulatory Care	Recommend granting core privileges as requested.
Tran, Katherine, PA-C	Physician Assistant Surgery	Taylor Farms Family Health & Wellness Center Physician Assistant – Ambulatory Care	Recommend granting core privileges as requested.

Other Items: *(Attached)*

Dept of Surgery: Physician Assistant – Clinical Pathway Agreement Surgical Assisting – New	Recommend approval of new privilege form as submitted.
Physician Assistant Clinical Privileges/Practice Agreement – Emergency Medicine	Recommend approval of revision to criteria for Physician Assistant – Emergency Medicine with the elimination of required BLS certification. Requirements for ACLS and PALS certification remain unchanged.

Bylaws and Policies: ***None***

Informational Items:

The following items were approved/accepted as appropriate:

I. Committee Reports:

Quality and Safety Committee:

- **i.** Code Blue/RRT Report
- **ii.** Sepsis Committee Report
- **iii.** Patient Experience Report
- **iv.** Critical Care Services
- **v.** Respiratory Care

II. Medical Staff Leadership Changes October 1, 2021:

a. Officers:

i. Chief of Staff: Ted Kaczmar, MD
ii. Vice Chief of Staff: Rakesh Singh, MD
iii. Secretary Treasurer: Tarun Bajaj, MD
iv. MEC Member-at-Large: Richard Rupp, MD
v. MEC Member-at-Large: Mahendra Poudel, MD

b. Department Chairs:

i. Anesthesiology: Max Thompson, MD
ii. Emergency Medicine: Misty Navarro, MD
iii. Family Medicine: James Lew, MD
iv. Surgery: Matthew Romans, MD

III. Other Reports:

a. Financial Performance Review – July 2021
b. Executive Update
c. Summary of Executive Operations Committee Meetings
d. Summary of Medical Staff Department/Committee Meetings
e. Medical Staff Treasury
f. Medical Staff Statistics
g. Foundation Update
h. HCAHPS Update September 9, 2021
i. Medical Staff Lifetime Achievement Award 2021 – June Dunbar, MD

IV. Order Sets Approved:

Salinas Valley Memorial Healthcare System

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:
  - Successful completion of the national certifying examination given by the NCCPA
  - Possession of a current unrestricted California PA license
  - Possession of adequate professional liability insurance
  - 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 Practice Provider Rules and Regulations and be 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 ~~BLS,~~ ACLS and PALS certifications as well as documentation of training and 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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Physician Assistant – Clinical Pathway Agreement
Surgical Assisting

Applicant Name: _____

Qualifications:

To be eligible to apply for this clinical pathway, the applicant must meet the following qualifications:

- Current and unrestricted core Physician Assistant clinic privileges at Salinas Valley Memorial Hospital.
- Documentation of at least one qualified physician preceptor with current and unrestricted surgical privileges at Salinas Valley Memorial Hospital

Clinical Pathway Requirements:

This Clinical Pathway must be completed at Salinas Valley Memorial hospital.

The Clinical Pathway shall be composed of the following elements, which must be completed within 3 months. weeks/months of initial approval:

- Surgical Assisting 25 surgical cases
- Surgical Skin Closure 25 of cases
- Provide pre- and postoperative surgical care
- Cleanse and debride wounds and suture lacerations and remove sutures and staples
- The ability to demonstrate proficiency in the following:
    - Assessment and evaluation of patients in pre-op and post-op settings to include preoperative clearance
    - Ability to scrub, don sterile garb and maintain sterile field while in the operating room

Acknowledgment of Physician Assistant Practice Agreement

I acknowledge that I am responsible for knowing the scope of my practice, the scope of this Surgical Preceptorship and clinical functions, which are defined in this clinical pathway.

I understand that my designated preceptor physician must be with me at all times when I am performing services under this clinical pathway.

I understand that this Preceptorship shall not be deemed complete until my Preceptor Evaluation(s) are complete and approved by the Department Chair, Interdisciplinary Practice Committee, Medical Executive Committee and the Board of Directors.

I will comply with all the Hospital policies and procedures.

_____ _____
Physician Assistant Signature Date

_____
Physician Assistant Printed Name

Physician Assistant
List of Preceptor Physicians

As a Preceptor Physician, my signature below is attestation of my commitment to:

- Assume responsibility for supervision or monitoring of the PA's practice as stated in the Advance Practice Provider Rules and Regulations and be 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
- Complete competency assessment documentation following completion of this Surgical Pathway.

Preceptor Physician's Name	Signature
Preceptor Physician's Name	Signature
Preceptor Physician's Name	Signature
Preceptor Physician's Name	Signature

*****Department Chair's Recommendation*****

□ Recommend approval:
□ Recommend approval with the following conditions/modifications:
□ Approval withheld for the following reasons:

Department Chair Signature	Date

EXTENDED CLOSED SESSION
(if necessary)

(VICTOR REY, JR.)

ADJOURNMENT – THE NEXT REGULAR MEETING OF THE BOARD OF DIRECTORS IS SCHEDULED FOR THURSDAY, OCTOBER 28, 2021, AT 4:00 P.M.