AMENDED

TRI-CITY HEALTHCARE DISTRICT
AGENDA FOR A REGULAR MEETING
November 14, 2024 – 3:30 o'clock p.m.
Assembly Rooms 2 & 3 – Eugene L. Geil Pavilion
4002 Vista Way, Oceanside, CA 92056

The Board may take action on any of the items listed below, unless the item is specifically labeled "Informational Only"

	Agenda Item	Time Allotted	Requestor
1	Call to Order	3 min.	Standard
2	Report from Chairperson on any action taken in Closed Session (Authority: Government Code, Section 54957.1)	2 min.	Chair
3	Roll Call / Pledge of Allegiance		
4	Approval of Agenda	2 min	Standard
5	Public Comments – Announcement Members of the public may address the Board regarding any item listed on the Board Agenda at the time the item is being considered by the Board of Directors. Per Board Policy 19-018, members of the public may have three minutes, individually, to address the Board of Directors. NOTE: Members of the public may speak on any item not listed on the Board Agenda, which falls within the jurisdiction of the Board of Directors, immediately prior to Board Communications.	2 min.	Standard
6	Special Recognition: a) Honoring Marvin Mizell for his service on the TCHD Board of Directors – February 2022 – November 2024	5 min.	Chair
7	Foundation Report – Jennifer Paroly, President	10 Min	Chair
8	September 2024 Financial Statement Results	10 min.	CFO
9	New Business – a) Consideration to approve the terms of the contract with SEIU-UHW per the terms tentatively agreed to on September 30, 2024 and ratified by SEIU-UHW Bargaining Unit on October 21, 2024. b) Consideration to approve the terms of the contract with the California Nurses Association (CNA) per the terms tentatively agreed to on October 29, 2024 and ratified by CNA on November 7, 2024.	5 min. 5 min.	CEO CEO

Note: This certifies that a copy of this agenda was posted in the entrance to the Tri-City Medical Center at 4002 Vista Way, Oceanside, CA 92056 at least 72 hours in advance of the meeting. Any writings or documents provided to the Board members of Tri-City Healthcare District regarding any item on this Agenda is available for public inspection in the Administration Department located at the Tri-City Medical Center during normal business hours.

Note: If you have a disability, please notify us at 760-940-3348 at least 48 hours prior to the meeting so that we may provide reasonable accommodations.

	Agenda Item	Time Allotted	Requestor
	c) Consideration to approve 2025 Employee Benefits as recommended by the Benefits Committee.	5 min.	CEO
	d) Consideration to approve retaining a Consulting Firm to provide Affiliation Advisory Services. *(Summary Included)*	10 min.	CEO
10	Old Business – None	--	--
11	Chief of Staff – *No Credentialing Actions this month.*	--	
12	Consent Calendar (1) Board Committee **(a) Finance, Operations & Planning Committee** **Director Younger, Committee Chair** *No meeting due to lack of quorum* (2) Consideration to approve the renewal of an agreement with Gehaan D'Souza, M.D. as the Medical Director for Plastic Surgery Consultative and Procedural Services for a term of 12 months beginning October 1, 2024 and ending September 30, 2025, for a total term cost of $33,840. (3) Consideration to approve the renewal of an agreement with David Amory,M.D., James Andry, M.D., Andrew Hartman, M.D., Serge Kaska, M.D., Hannah Kirby, M.D., Grant Seiden, M.D., Morgan Silldorff, M.D., Erilk Stark, M.D., Braden McKnight, M.D., James Layson, M.D. and Nicholas Kusnezov, M.D. to provide ED On-Call Coverage Panel for Orthopedics-General and Foot & Ankle, for a term of 24 months, beginning November 1, 2024, and ending October 31, 2026, for an annual cost of $746,725 and a total term cost of $1,493,450. (4) Consideration to approve the renewal of an agreement with Dr. Emad Tadros, M.D., For Emergency Room and Inpatient Units Unfunded, Underfunded and Denied Patients consultation services, for a term of 21 months, beginning October 1, 2024 and ending June 30, 2026, for an annual cost of $120,972 and a total term cost of $211,701. (5) Consideration to approve the renewal of an agreement with Quoc Tran, M.D. and Zhong Zhao, M.D. as Co-Medical Directors of the Utilization Review and DRG Oversight program for a term of 12 months, beginning October 1, 2024 and ending September 30, 2025, for an annual and total term cost not to exceed $102,000. (6) Consideration to approve the renewal of an agreement with Coastal Surgeons, a California Medical Corporation, to provide a comprehensive general surgicalist program for a term of 24 months, beginning December 1, 2024 and ending November 30, 2026, at a daily rate of $2,900, for an annual cost of $1,058,500 and a total term cost of $2,117,000. (7) **Administrative Policies & Procedures** **a) Patient Care Services** 1) Duty to Warm Potential Victims Policy 2) Infusion Pump Infusion System with Guardrails Procedure 3) Insulin, Use of Concentrated 4) Obstetrical Hemorrhage (RETIRE) 5) Outpatient Post Anesthesia Procedure Discharge	10 min.	Chair

	Agenda Item	Time Allotted	Requestor
	Transportation Guidelines Policy 6) Radiation Safety Policy 7) Standards of Care Adult 8) Stroke Code, In-House **b) Administrative** 1) 340B Outpatient Drug Pricing 295 ~~2) Alcohol and Drug Testing for Employees Policy – 429~~ 3) Diversity – 471 (RETIRE) 4) Equal Employment Opportunity – 418 **c) Emergency Department** 1) Ketamine for Pain **d) Employee Health & Wellness** ~~1) Alcohol and Drug Testing Guidelines (RETIRE)~~ **e) Laboratory General/Pathology** 1) Chain of Custody for Forensic Specimens or Foreign Objects Removed from Patients 2) Individualized Quality Control Plan Policy 3) Laboratory Infection Prevention and Control 4) Pathology Staff Professional Competency Policy **f) Medical Staff** 1) Unintended Intraoperative Awareness During General Anesthesia 8710-546 **g) Outpatient Behavioral Health Services** 1) Psychotropic Medications Policy **h) Pharmacy** 1) Drug Supply Chain Security Act 2) General and Concentrated Electrolytes Policy 3) Licensure and Professional Standards 4) Pharmaceutical Representatives Policy 5) Unlabeled Uses of FDA-Approved Medications **I) Pulmonary** 1) Respiratory Medication Administration **j) Surgical Services** 1) Admission-Discharge Criteria Policy 2) Discharge of Post Anesthesia and Post Sedation Patients to Inpatient Units Policy **k) Telemetry** 1) Orientation of Registry Staff 8) Minutes a) Special Meeting – September 26, 2024 b) Regular Meeting – September 26 2024 (9) Reports – (Discussion by exception only) a) Building Lease Report – (September, 2024) b) Reimbursement Disclosure Report – (September, 2024)		

	Agenda Item	Time Allotted	Requestor
13	Discussion of Items Pulled from Consent Agenda	10 min.	Standard
14	Comments by Members of the Public NOTE: Per Board Policy 19-018, members of the public may have three (3) minutes, individually and 15 minutes per subject, to address the Board on any item not on the agenda.	5-10 minutes	Standard
15	Comments by Chief Executive Officer	5 min.	Standard
16	Board Communications	18 min.	Standard
17	Total Time Budgeted for Open Session	1.5 hour	
18	Adjournment		

New For 2025!

Health Reimbursement Account (HRA)

Outside of preventive care, each medical plan requires the member to pay their share of the covered visit either through a copay, coinsurance and/or deductible. When an employee is enrolled in a Tri-City Medical Center medical plans, they can access the HRA funds provided to them to help pay or be reimbursed for eligible out-of-pocket expenses. Expenses must be for those covered under the medical plan. As a reminder, the medical plan does not cover expenses out-of-network and the HRA plan cannot be used for reimbursement for non-eligible expenses. The HRA account is 100% funded by Tri-City Medical Center.

For ease, enrolled employees are issued a debit card which can be used at the point-of-sale such as paying for an office visit copay at their doctor's office. HRA funds are available at the beginning of each plan year. Funds left unused do not roll over into the next plan year. Employees that leave employment cannot take the funds with them. The administrator of the HRA is Benefit Coordinators Corporation, commonly referred to as **BCC.**

For 2025, Tri-City Medical Center will fund HRA accounts based on the medical plan enrolled in and if dependents are enrolled in the plan. Read carefully through the next few pages to understand the medical plan coverage and how the HRA works with each plan.

SAVE YOUR RECEIPTS

No matter how you access your HRA funds, be sure to keep your receipts to validate your reimbursements for eligible expenses.

MEDICAL HMO PLAN

❖ To locate healthcare providers please visit myuhc.com

MEDICAL HMO OPTION AT-A-GLANCE			
	UHC HMO	**HRA Pays**	**You Pay**
FEATURES	SIGNATURE VALUE ADVANTAGE	$2,500 Individual / $5,000 Family	
Annual Deductible	**$2,500 individual / $5,000 family**	**100% up to HRA available balance**	**You pay for covered services after max HRA balance used, up to plan out of pocket maximum**
Annual Out-of-Pocket Maximum	**$5,000 individual / $10,000 family**	**100% up to HRA available balance**	**$2,500 individual / $5,000 family**
OUTPATIENT SERVICES			
Office Visit PCP/Specialist	**$25 / $50 copay**	**100% up to HRA available balance**	**You pay for covered services after max HRA balance used, up to plan out of pocket maximum**
X-Ray & Lab Services	**$25 copay**	**100% up to HRA available balance**	
Complex Imaging	**$150 copay**		
Outpatient Surgery	**30% after deductible**	**100% up to HRA available balance**	
EMERGENCY & URGENT CARE SERVICES			
Emergency Room Visit	**30% coinsurance after deductible**	**100% up to HRA available balance**	**You pay for covered services after max HRA balance used, up to plan out of pocket maximum**
Urgent Care Visit	**$50 copay**	**100% up to HRA available balance**	
MENTAL HEALTH SERVICES			
Office Visit	**$50 copay**	**100% up to HRA available balance**	**You pay for covered services after max HRA balance used, up to plan out of pocket maximum**
CHIROPRACTIC / ACUPUNCTURE			
Office Visit (20 visits max)	**$20 copay**	**Not Covered**	**100%**
INPATIENT SERVICES			
Hospital Services	**30% coinsurance after deductible**	**100% up to HRA available balance**	**You pay for covered services after max HRA balance used, up to plan out of pocket maximum**

MEDICAL PPO PLAN

❖ To locate healthcare providers please visit myuhc.com

MEDICAL PPO OPTION AT-A-GLANCE			
	UHC PPO	**HRA Pays**	**You Pay**
FEATURES	Select Plus Network In-Network	$2,500 Individual / $5,000 Family	
Annual Deductible	**$3,000 individual $6,000 family**	**100% up to HRA available balance**	**You pay for covered services after max HRA balance used, up to plan out of pocket maximum**
Annual Out-of-Pocket Maximum	**$7,150 individual / $14,300 family**	**100% up to HRA available balance**	**$4,650 individual / $9,300 family**
OUTPATIENT SERVICES			
Office Visit PCP/Specialist	**$35 / $70 copay**	**100% up to HRA available balance**	**You pay for covered services after max HRA balance used, up to plan out of pocket maximum**
X-Ray & Lab Services Complex Imaging	**20% coinsurance****	**100% up to HRA available balance**	
Outpatient Surgery	**20% coinsurance****	**100% up to HRA available balance**	
EMERGENCY & URGENT CARE SERVICES			
Emergency Room Visit	**20% coinsurance****	**100% up to HRA available balance**	**You pay for covered services after max HRA balance used, up to plan out of pocket maximum**
Urgent Care Visit	**$50 copay**	**100% up to HRA available balance**	
MENTAL HEALTH SERVICES			
Office Visit	**$35 copay**	**100% up to HRA available balance**	**You pay for covered services after max HRA balance used, up to plan out of pocket maximum**
CHIROPRACTIC			
Office Visit (24 visits)	**20% coinsurance****	**Not Covered**	**100%**
INPATIENT SERVICES			
Hospital Services	**$350+20% coinsurance****	**100% up to HRA available balance**	**You pay for covered services after max HRA balance used, up to plan out of pocket maximum**

NEW in 2025

YOUR HRA WITH YOUR UHC MEDICAL HMO AND PPO PLANS

Tri-City Medical Center funds the HRA account so that most of your out-of-pocket expenses will be covered.

Prescription drugs covered in your UHC medical plans are Not HRA-qualified and your BCC HRA Debit card will be turned off so that you can't use it for point-of-sale transactions.

Your HRA Fund on the HMO Plan

TCMC will fund your BCC HRA account with the following on January 1, 2025:

- **Employee Only:**

$2,500

- **Employee + Dependent(s):**

$5,000

Your HRA Fund on the PPO Plan

TCMC will fund your BCC HRA account with the following on January 1, 2025:

- **Employee Only:**

$2,500

- **Employee + Dependent(s):**

$5,000

USE YOUR HRA TO PAY FOR COVERED OUT-OF-POCKET ELIGIBLE EXPENSES

- **Deductible**
- **Copay**
- **Coinsurance**

- **Rx Prescriptions**
- **Chiropractic**
- **Acupuncture**

The HRA fund that is given to you is for eligible expenses that were processed through your TCMC medical plan.

You must process your medical services through your TCMC medical plan to avoid any issues that may result in you paying back the HRA fund.

Ineligible Expenses: This is a brief list of the most common ineligible expenses submitted to the HRA fund that cause a delay in reimbursement for true HRA-qualified expenses.

- Rx Prescriptions
- Chiropractic and Acupuncture
- Dental and Vision
- Elective cosmetic surgery, spa treatments
- Expenses with a non-network provider
- Expenses reimbursed by another insurance plan
- Expenses reimbursed by your FSA
- Expenses incurred outside of the Plan Year
  - > Your 2025 HRA fund is for eligible expenses incurred from January 1, 2025, through December 31, 2025

https://benefitcc.wealthcareportal.com **1-800-685-6100** BCC

JUNIPER ADVISORY LLC
110 NORTH WACKER DRIVE | STE 2500
CHICAGO, IL 60606

November 11, 2024

Dr. Gene Ma, MD, FACEP
President & CEO
Tri-City Medical Center
4002 Vista Way
Oceanside, CA 92056

Dear Dr. Ma:

Thanks for speaking this morning. We appreciate being notified of the Board affiliation subcommittee's decision to recommend the selection of Juniper Advisory as the firm engaged to assess strategic alignment opportunities. We are enthusiastic to bring our expertise to Tri-City Healthcare District as a trusted source of advisory services to the hospital industry for over 35 years, and as the only investment banking firm that focuses exclusively on providing nonprofit health systems with mergers and acquisitions advice. Comprised of the largest and most experienced team in the industry specializing in advising local government-owned hospitals, having completed over 300 nonprofit health system assignments across 45 states including 25 in California, and a 100% track record of success achieving regulatory approval, we are uniquely positioned to ensure Tri-City's success.

Following the proposal of October 1, and per our more recent conversations, the terms of the engagement are as follows:

- Monthly retainer fee: $20,000, TCMC free to terminate at anytime
- Transaction fee: 1.25% of Aggregate Consideration, fully contingent on successful closing
- Minimum transaction fee: $500,000
- Maximum transaction fee: $3,000,000

Please let us know if you need anything else in preparation for the meeting this Thursday, November 14.

All the best,

Rex Burgdorfer
Partner

Chris Benson
Executive Director

Ansley Geary
Associate

Tri-City Medical Center

TCHD BOARD OF DIRECTORS
DATE OF MEETING: November 14, 2024
MEDICAL DIRECTORSHIP AGREEMENT FOR PLASTIC SURGERY - CONSULTATIVE & PROCEDURAL SERVICES

Type of Agreement	X	Medical Directors		Panel	X	Other: Consulting & Procedural Services
Status of Agreement		New Agreement		Renewal – New Rates	X	Renewal – Same Rates

Physician's Name: Gehaan D'Souza, M.D.

Area of Service: Hospital Inpatient, Observation & Outpatient Units

Term of Agreement: 12 months, Beginning, October 1, 2024 – Ending, September 30, 2025

Maximum Totals: Within Hourly and/or Annualized Fair Market Value: YES

Rate/Hour	Hours per Month	Hours per Year	Monthly Cost	12 month Term Cost
$235	12	144	$2,820	**$33,840**

Position Responsibilities:

- Physician to provide Plastic Surgery Services (Consultative and Procedural) for registered TCMC Hospital patients (inpatient, observation, and outpatient units)
- Provide medical direction and services for plastic, wound care and reconstructive surgery
- Recommend to the medical staff that patients receive evidence-based plastic, wound and reconstructive care
- Participate in in-service training, utilization review, and service as a liaison for the community

Document Submitted to Legal for Review:	X	Yes		No
Approved by Chief Compliance Officer:	X	Yes		No
Is Agreement a Regulatory Requirement:		Yes	X	No
Budgeted Item:	X	Yes		No

Person responsible for oversight of agreement: Jeremy Raimo, Chief Operating Officer

Motion:
I move that the TCHD Board of Directors approve the renewal of the agreement with Gehaan D'Souza, M.D., as the Medical Director for Plastic Surgery Consultative and Procedural Services, for a term of 12 months beginning October 1, 2024 and ending September 30, 2025, for a total term cost of $33,840.

Tri-City Medical Center

TCHD BOARD OF DIRECTORS
DATE OF MEETING: November 14, 2024
NAME OF AGREEMENT: ED ON-CALL COVERAGE – ORTHOPEDICS - General, Foot & Ankle

Type of Agreement		Medical Directors	X	Panel		Other:
Status of Agreement		New Agreement		Renewal – New Rates	X	Renewal – Same Rates

Physician's Name: David Amory, M.D., James Andry, M.D., Andrew Hartman, M.D., Serge Kaska, M.D., Hannah Kirby, M.D., Grant Seiden, M.D., Morgan Silldorff, M.D., Erik Stark, M.D., Braden McKnight, M.D., James Layson, M.D., Nicholas Kusnezov, M.D.

Area of Service: Emergency Department On-Call: Orthopedics

Term of Agreement: 24 months, Beginning November 1, 2024 – Ending October 31, 2026

Maximum Totals: Within Hourly and/or Annualized Fair Market Value: YES
Shared Call agreement with Entire ED call panel for Orthopedic Surgery

Service	Coverage Days	Rate	Panel Days During Term	Total Term Panel Cost
General	Monday - Friday Saturday/Sunday/Holidays	$1,750 $1,800	507 days 223 days	$887,250 $401,400
Foot & Ankle	Monday - Friday Saturday/Sunday/Holidays	$250 $350	507 days 223 days	$126,750 $ 78,050
			Total Term Cost	**$1,493,450**

Description of Services/Supplies:

- Provide 24/7 patient coverage for all Orthopedics specialty services in accordance with Medical Staff Policy #8710-520 (Emergency Room Call: Duties of the On-Call Physician)
- Complete related medical records in accordance with all Medical Staff, accreditation, and regulatory requirements.

Document Submitted to Legal for Review:	X	Yes		No
Approved by Chief Compliance Officer:	X	Yes		No
Is Agreement a Regulatory Requirement:	X	Yes		No
Budgeted Item:	X	Yes		No

Person responsible for oversight of agreement: Jeremy Raimo, Chief Operating Officer

Motion:
I move that the TCHD Board of Directors approve the renewal agreement with David Amory, M.D., James Andry, M.D., Andrew Hartman, M.D., Serge Kaska, M.D., Hannah Kirby, M.D., Grant Seiden, M.D., Morgan Silldorff, M.D., Erik Stark, M.D., Braden McKnight, M.D., James Layson, M.D., and Nicholas Kusnezov, M.D., to provide ED On-Call Coverage Panel for Orthopedics-General and Foot & Ankle, for a term of 24 months, beginning November 1, 2024 and ending October 31, 2026, for an annual cost of $746,725 and a total term cost of $1,493,450.

Tri-City Medical Center

TCHD BOARD OF DIRECTORS
DATE OF MEETING: November 14, 2024
PHYSICIAN AGREEMENT – Emergency Room and Inpatient Consultative Services

Type of Agreement		Medical Directors		Panel	X	Psychiatric Coverage
Status of Agreement		New Agreement	X	Renewal – New Rate (for unfunded/ underfunded patients)		Renewal – Same Rate

Physician's Name: Emad Tadros, M.D.

Area of Service: Emergency Room and Inpatient Units Unfunded, Underfunded and Denied Patients

Term of Agreement: 21 months, Beginning, October 1, 2024 – Ending, June 30, 2026

Maximum Totals: Within Hourly Fair Market Value.

	Hours per Month	Hours per Year (NTE)	Monthly Cost	Annual Cost (NTE)	Total Term Cost 21 Months (NTE)
Phone consults & availability for telehealth consults	On-Call Availability	384	$4,977	$59,724	**$104,517**
Unfunded, underfunded or denied patient initial evaluations	21 Average	250	$4,342	$52,104	**$91,182**
Unfunded, underfunded or denied patient follow up	8 Average	100	$762	$9,144	**$16,002**
	TOTALS:		$10,081	$120,972	**$211,701**

On-Call Duties:

- Provide psychiatric phone consults for emergency room and inpatient units within one hour of request
- Provide telehealth consultations within 12 hours of request.
- Provide clinical guidance to physicians and psychiatric liaisons for ED and IP patients.

Document Submitted to Legal for Review:	X	Yes		No
Approved by Chief Compliance Officer:	X			
Is Agreement a Regulatory Requirement:		Yes	X	No
Budgeted Item:		Yes	X	No

Person responsible for oversight of agreement: Sarah Jayyousi, Operations Manager-Outpatient Behavioral Health Services / Donald Dawkins, Chief Nurse Executive

Motion: I move that the TCHD Board of Directors approve the renewal of an agreement with Emad Tadros, M.D. for Emergency Room and Inpatient Units Unfunded, Underfunded and Denied Patients consultations services for a term of 21 months, beginning October 1, 2024 and ending June 30, 2026, for an annual cost of $120,972 and a total term cost of $211.701.

Tri-City Medical Center

TCHD BOARD OF DIRECTORS
DATE OF MEETING: November 14, 2024
CO-MEDICAL DIRECTOR AGREEMENT FOR UTILIZATION REVIEW/DRG PROGRAM

Type of Agreement	X	Co-Medical Directors		Panel		Other:
Status of Agreement		New Agreement		Renewal – New Rates	X	Renewal – Same Rates

Physician's Name: Quoc T. Tran, M.D. & Zhong Zhao, M.D.

Area of Service: Utilization Review / DRG Program

Term of Agreement: 12 months, Beginning, October, 1, 2024 – Ending, September, 30, 2025

Maximum Totals: Within Hourly and/or Annualized Fair Market Value: YES

Rate/Hour	Maximum Hours per Month, per Medical Director	Hours per Year, per Director, Not to Exceed	Total Monthly Cost Not to Exceed	Total Annual / Term Cost Not to Exceed
$170	25	300	$8,500	**$102,000**

Position Responsibilities:

- CMS "Conditions of Participation" and California Title XXII require the Utilization Review (UR) Committee Ensures DRG program compliance.
- Provide co-medical direction of the UR Committee
- Physician consultation for peer to peer reviews, denial reviews, and utilization review
- Works directly with the Director of Case Management/Social Services in overseeing multidisciplinary rounds, physician education and provider feedback.

Document Submitted to Legal for Review:	X	Yes		No
Approved by Chief Compliance Officer:	X	Yes		No
Is Agreement a Regulatory Requirement:	X	Yes		No
Budgeted Item:	X	Yes		No

Person responsible for oversight of agreement: Melissa Terah, Director of Nursing Strategy & Integration/Case Management / Donald Dawkins, Chief Nurse Executive

Motion:
I move that the TCHD Board of Directors approve the agreement with Quoc T. Tran, M.D. and Zhong Zhao, M.D. as Co-Medical Directors of the Utilization Review and DRG Oversight program, for a term of 12 months, beginning October 1, 2024 and ending September 30, 2025, for an annual and total term cost not to exceed $102,000.

Tri-City Medical Center

TCHD BOARD OF DIRECTORS
DATE OF MEETING: November 14, 2024
PHYSICIAN AGREEMENT for ED ON-CALL COVERAGE: SURGICAL HOSPITALIST PROGRAM

Type of Agreement		Medical Director	X	Panel		Other:
Status of Agreement		New Agreement		Renewal – New Rates	X	Renewal – Same Rates

Physician's Names: Coastal Surgeons

Area of Service: Surgical Hospitalist for all Acute Care Service Units

Term of Agreement: 24 months, Beginning, December 1, 2024 – Ending, November 30, 2026

Maximum Totals: Within Hourly and/or Annualized Fair Market Value: YES

Rate/Day	Annual Cost	Total Term Cost
$2,900	$1,058,500	$2,117,000

Position Responsibilities:

- Provide 24/7 patient coverage for a hospital-based, Surgical Hospitalist program otherwise referred to as a General Surgicalist to consult, manage, and treat all general surgical needs, including but not limited to primary management of soft tissue and deep space infections requiring surgical evaluation.
- Provide both inpatient and outpatient follow-up of all general surgical cases managed at Tri-City by the General Surgicalist Program.
- Coordinate surgical care across all specialties including emergency medicine, hospital medicine, and subspecialty care.
- Dedicate a medical director to oversee the success of the program, integration into hospital services, and to coordinate quality of care initiatives with the hospital quality department to achieve benchmarked quality outcomes.

Document Submitted to Legal for Review:	X	Yes		No
Approved by Chief Compliance Officer:	X	Yes		No
Is Agreement a Regulatory Requirement:	X	Yes		No
Budgeted Item:	X	Yes		No

Person responsible for oversight of agreement: Gene Ma, M.D., Chief Executive Officer / Jeremy Raimo, COO

Motion: I move that the TCHD Board of Directors approve the renewal of the agreement with Coastal Surgeons, a California Medical Corporation, to provide a comprehensive general surgicalist program for a term of 24 months, beginning December 1, 2024, and ending November 30, 2026, at a daily rate of $2,900, for an annual cost of $1,058,500 and a total term cost of $2,117,000.

Tri-City Medical Center

ADMINISTRATION CONSENT AGENDA
November 5th, 2024

CONTACT: Donald Dawkins, CNE

Policies and Procedures	Reason	Recommendations
Patient Care Services		
1. Duty to Warn Potential Victims Policy	3 year review	Forward to BOD for Approval
2. Infusion Pump-Infusion System with Guardrails Procedure	3 year review	Forward to BOD for Approval
3. Insulin, Use of Concentrated	3 year review	Forward to BOD for Approval
4. Obstetrical Hemorrhage	RETIRE	Forward to BOD for Approval
5. Outpatient Post Anesthesia Procedure Discharge Transportation Guidelines Policy	3 year review, practice change	Forward to BOD for Approval
6. Radiation Safety Policy	3 year review, practice change	Forward to BOD for Approval
7. Standards of Care Adult	Practice change	Forward to BOD for Approval
8. Stroke Code, In-House	Practice change	Forward to BOD for Approval
Administrative		
1. 340B Outpatient Drug Pricing 295	Practice change	Forward to BOD for Approval
~~2. Alcohol and Drug Testing for Employees Policy - 429~~	~~3 year review, practice change~~	~~Forward to BOD for Approval~~
3. Diversity - 471	RETIRE	Forward to BOD for Approval
4. Equal Employment Opportunity - 418	3 year review, practice change	Forward to BOD for Approval
Emergency Department		
1. Ketamine for Pain	3 year review	Forward to BOD for Approval
Employee Health & Wellness		
~~1. Alcohol and Drug Testing Guidelines~~	~~RETIRE~~	~~Forward to BOD for Approval~~
Laboratory General / Pathology		
1. Chain of Custody for Forensic Specimens or Foreign Objects Removed from Patients	2 year review, practice change	Forward to BOD for Approval
2. Individualized Quality Control Plan Policy	2 year review, practice change	Forward to BOD for Approval
3. Laboratory Infection Prevention and Control	2 year review, practice change	Forward to BOD for Approval
4. Pathology Staff Professional Competency Policy	2 year review	Forward to BOD for Approval

ADMINISTRATION CONSENT AGENDA
November 5th, 2024

CONTACT: Donald Dawkins, CNE

Policies and Procedures	Reason	Recommendations
Medical Staff		
1. Unintended Intraoperative Awareness During General Anesthesia 8710-546	3 year review	Forward to BOD for Approval
Outpatient Behavioral Health Services		
1. Psychotropic Medications Policy	NEW	Forward to BOD for Approval
Pharmacy		
1. Drug Supply Chain Security Act	3 year review	Forward to BOD for Approval
2. General and Concentrated Electrolytes Policy	3 year review, practice change	Forward to BOD for Approval
3. Licensure and Professional Standards	3 year review	Forward to BOD for Approval
4. Pharmaceutical Representatives Policy	3 year review, practice change	Forward to BOD for Approval
5. Unlabeled Uses of FDA-Approved Medications	3 year review	Forward to BOD for Approval
Pulmonary		
1. Respiratory Medication Administration	3 year review, practice change	Forward to BOD for Approval
Surgical Services		
1. Admission-Discharge Criteria Policy	3 year review	Forward to BOD for Approval
2. Discharge of Post Anesthesia and Post Sedation Patients to Inpatient Units Policy	3 year review	Forward to BOD for Approval
Telemetry		
1. Orientation of Registry Staff	3 year review, practice change	Forward to BOD for Approval

Tri-City Medical Center
Oceanside, California

PATIENT CARE SERVICES

ISSUE DATE: 02/18 **SUBJECT:** Duty to Warn Potential Victims

REVISION DATE~~(S)~~: 02/18, 12/21

Patient Care Services Content Expert Approval:	~~10/20~~07/24
Clinical Policies and Procedures Approval:	~~10/21~~08/24
Nursing Leadership:	~~11/21~~09/24
Division of Psychiatry:	n/a
Pharmacy and Therapeutics Approval:	n/a
Medical Executive Committee Approval:	~~11/21~~09/24
Administration Approval:	~~11/21~~11/24
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	12/21

A. **PURPOSE:**
1. To provide guidelines for the handling of threats of potential harm to an identified person.

B. **POLICY:**
1. A Psychiatric Liaison (PL)/Social Worker is responsible to warn, or take other appropriate action to protect, the foreseeable victim of a patient's violent tendencies, if a PL/Social Worker - patient relationship exists, the PL/Social Worker knows or should have known that the patient is dangerous, and there is a foreseeable victim of the patient's violent tendencies.
2. In carrying out this duty, the PL/Social Worker may need to release confidential patient information.
   a. The California Courts held that in such situations, the justification for protecting the confidentiality of the patient information (e.g. to encourage patients to seek treatment and fully disclose information to their psychotherapist) is outweighed by the need to warn potential victims so that they can protect themselves.
   b. In addition, legislation was enacted to provide for the release of confidential information when a therapist believes that a patient presents a serious danger of violence to a reasonably foreseeable victim or victims, or their property (property may be reported but it is not mandated).
3. The duty to warn arises not only when a patient expresses specific threats against an identifiable victim, but also when others report the threat to the treatment providers.
   a. If a family member or significant other reports such threats to the PL/Social Worker, the PL/Social Worker is obligated to follow reporting procedures.
4. A PL/Social Worker may be liable for injuries a third person suffers as a result of a patient's violent acts, if the PL/Social Worker fails to carry out his duty to appropriately evaluate the patient and identify his or her dangerous propensities.
5. In order to carry out the duty to warn, the PL/Social Worker must strike a careful balance between protecting the confidentiality of the patient's disclosures and protecting the potential victim.
   a. Initially, the PL/Social Worker should gather relevant information regarding the patient, including that pertaining to the patient's past treatment history.
   b. The PL/Social Worker's decision regarding whether it is likely that the patient will carry out his or her threats, or that the patient presents a danger to another person, should be documented along with the information that led to the decision. This will provide important protection against claims that the PL/Social Worker should not have released the information (if a warning is given) or that the PL/Social Worker did not carry out his

duty to warn the potential victim (if a warning was not given).

c. If a warning is given, the PL/Social Worker should disclose only that information which is necessary to enable the potential victim to recognize the seriousness of the threat and to take proper precautions to protect him or herself. A general indication to a person that perhaps the person should avoid the patient may not be sufficient warning.

d. Also, depending upon the patient's therapeutic condition and possible reaction, it is advisable to inform the patient that the warning will be given.

6. Situations in which a PL/Social Worker may have a duty to warn a potential victim usually involve difficult decisions. The treatment team, including the physician/Allied Health Professional (AHP), needs to be informed regarding any such reports. An ethical or legal consultation may also be obtained to guide the team with their decision.

C. **PROCEDURE:**

1. When a threat is made, the PL/Social Worker must notify the police department in the city in which the threat occurred. The following information is conveyed:
   a. Patient name
   b. Patient address
   c. Patient date of birth
   d. Patient gender and race
   e. Patient physical description
   f. Patient social security number and driver's license number (if available)
2. The police department in the city in which the intended victim resides must also be notified.
   a. Report must include information stated above, as well as, the name of the intended victim and address, if known.
3. The PL/Social Worker must make all reasonable attempts to notify the intended victim of the patient's threats (i.e. contacts or registered mail).
4. The Manager and physician/AHP are notified of any such occurrence and a Quality Review Report is filed.
5. Documentation of the threat and action taken is written in the medical record.

D. **RELATED DOCUMENT(S):**

1. Administrative Policy: Event Reporting396
2. Duty to Warn Letter – Sample

E. **REFERENCE(S):**

1. CA Civil Code, Section 43.92
2. CA Evidence Codes, 1010, 1024
3. CA Welfare & Institutions Code, Sections 5328, 8105 (c)
4. Ewing v Goldstein (2004) 120 Cal. App. 4th 807
5. Ewing v Northridge Hospital (2004) 120 Cal.App.4th 1289
6. HIPAA Privacy Regulations, 145 C.F.R. 164.512 (j)(l)(l)], Department Health & Human Services
7. Tarasoff v. Regents of the University of California (1976) 17 Cal. 3rd1425

Duty to Warn Letter – Sample

Tri-City Medical Center-Behavioral Health Unit
4002 Vista Way, Vista, CA 92056

To: Mr. Xxx
CC: Oceanside Police Dept.
3855 Mission Ave
Oceanside, CA 92054

CC: Oceanside Police Dept
3855 Mission Ave
Oceanside Ca 92054

April 13, 2010

Dear Mr. Xxx,

This letter is a written notice required by California law Civil Code 43.92 (commonly known as a "Tarasoff report") that mandates a psychotherapist has the "duty to protect" by making reasonable efforts to communicate with potential victims and to law enforcement, when in the course of performing work related functions a patient has communicated a "serious threat of physical violence against a reasonably identified victim or victims". This letter is to inform you that your student, (_____) has made threats towards you (_____) I recommend that you take the necessary precautions to protect yourself and anyone else that could be in possible danger due to this threat. In addition to notifying you, I have also notified Oceanside Police Department and spoke to (_____), (_____) and reported this incident and was given incident (_____). I have also contacted (add same info as above if you contacted another law enforcement agency here) to report the incident as you live in their jurisdiction. Please contact the respective police department if you have any questions regarding the police reports.

Respectfully,

Xxx xxx , LCSW, LCMFT

Tri-City Medical Center, BHU
760- 940-7396

Tri-City Medical Center	Patient Care Services
PROCEDURE:	**INFUSION PUMP – INFUSION SYSTEM WITH GUARDRAILS**
Purpose:	To regulate intravenous infusion using an electronic control device.
Supportive Data:	The Alaris Intravenous Infusion Pump with Guardrails System provides medication error prevention software to protect patients at the point of infusion delivery. The SmartSite System encourages needle-free compliance and provides needle-free safety for associates and patients. Staff must utilize the appropriate Profile™ and Guardrails™ features and the channel labels when programming the Alaris Medley Infusion System to enhance safe delivery of intravenous medications and solutions.
Equipment:	Alaris administration set Primary IV solution Filter Pump programmer point of care (POC) unit Pump module

A. **PROCEDURE:**

1. **Set-up of Primary Administration:**
   a. Remove blue sheath from the silastic-pumping segment.
   b. Close roller clamp and spike bag or glass container.
   c. Open vent between the spike and drip chamber if using a glass container. Keep vent closed when using a plastic bag.
   d. Squeeze drip chamber until 2/3 full.
   e. Slowly open roller clamp and prime administration set. Remove air from check valve and injection ports by inverting and tapping while fluid is passing each of these sites or pull out trapped air using a syringe.
   f. Close roller clamp when tubing is filled with fluid.
2. **Set-up of Pump (Module):**
   a. Attach pump (modules) to point of care unit (POC) by holding channel at a 45° angle and snapping it into place.
   b. Open large volume channel door by pulling up on the gray handle.
   c. Insert the administration set using a three step process:
      i. Drop the blue fitment of the administration set in place into the upper fitment recess (it will fit loosely).
      ii. Insert the "Free Flo-Stop" mechanism into the module (Blue to Blue).
      iii. Place the tubing section below the "Free Flo-Stop" mechanism snuggling into the air-in-line detector recess.
      iv. Failure to firmly place tubing below the "Free Flo-Stop" will result in air accumulating in the tubing.
      v. Close the door and secure by pressing inward at the top of the module door with one thumb while closing the door handle with the other hand.
3. **Programming the Guardrails IV Fluid Module:**
   a. Guardrails IV Fluid Library allows the programming of continuous intravenous fluids.
   b. Press the *SYSTEM ON* key (There will be a 10 second power on self-test POST).
   c. Press the *YES* or *NO* key to indicate a new patient.
      i. *YES* clears the previous patient data.
      ii. *NO* and then *"restore"* retains previous patient information and will lead to other profile information.

Patient Care Services Content Expert	Clinical Policies & Procedures	Nursing Leadership	Medical Staff Department or Division	Pharmacy & Therapeutics Committee	Medical Executive Committee	Administration	Professional Affairs Committee	Board of Directors
3/05, 4/07, 11/10, 01/19, 08/20, 04/24	12/10, 08/20, 08/24	12/10, 10/20, 09/24	n/a	05/21, 10/24	01/11, 07/21, 10/24	08/21, 11/24	02/11, n/a	02/11, 08/21

iii. The system has the capability to store previous information such as weight, drug calculations, and drug library entries indefinitely or up to 8 hours after the pump is turned off.

d. Selecting Unit Specific Profiles
   i. Press the *YES* key if the current profile is your unit's specific profile.
   ii. To change the current profile, press the *NO* key and select your unit specific profile. Press the *CONFIRM* key to verify your selection.
   iii. All modules shall be programmed using unit specific profiles.
   iv. Review the *TITLE BAR* every shift to confirm Unit Specific Profiles.

e. Pressing *CHANNEL SELECT* on the module turns on the module and makes it ready for programming.

f. Select *Guardrails IV Fluids*. Basic infusion shall only be selected when IV fluids are not listed in the Guardrails IV Fluids menu. Notify Nursing Leadership and/or Pharmacy to have medications added to the Guardrails Drug Library.

g. Select an *IV Fluid* by pressing selecting key beside name of the IV Fluid. For more selections, press the *PAGE DOWN* key or use the alphabet selection option.

h. If the IV fluid you are trying to program is not listed, then select the "Maintenance IV" entry. This is a "generic" IV fluid entry to be used for rarely used IV fluids/large volume parenterals that are not in the IV fluid library.

i. Press the *YES* key to confirm your selection or press the *NO* key to change your selection.

j. Enter the rate by pressing the *RATE* key followed by pressing the numerical keys of the ordered rate to be infused.

k. Enter the volume by pressing the *VTBI (Volume to be Infused)* key followed by pressing the numerical keys of the volume to be infused.

l. Begin the infusion by pressing the *START* key.

4. **Creating a Module Label for Guardrails Drugs not listed in the Guardrails Library:**
   a. Press the *CHANNEL SELECT* key on the desired module.
   b. Select Maintenance IV from the Infusion Menu.
   c. Enter the rate by pressing the *RATE* key followed by pressing the numerical keys of the ordered rate to be infused.
   d. Enter the volume by pressing the *VTBI* key followed by pressing the numerical keys of the volume to be infused.
   e. Press the *OPTIONS* key to label the module.
   f. Press the *CHANNEL LABELS* key followed by entering the desired infusion label. If the desired infusion label is not present, *PAGE DOWN* and use the alphabet selection option.
   g. Press the *START* key and the infusion will begin.

5. **Changing a Guardrail IV Fluid Label or Guardrail Drug Label**
   a. Select the appropriate module to be labeled.
   b. Press and hold the *CHANNEL OFF* key.
   c. Once the screen displays "Powering Down," press the *OPTIONS* key.
   d. Press the *CHANNEL SELECT* key on the module to be labeled.
   e. Press the *GUARDRAILS IV FLUIDS OR GUARDRAILS DRUGS* key.
   f. Select the new Guardrails IV Fluid or Drug by pressing the key beside the name of the IV Fluid or drug. For more selections, press the key below *PAGE DOWN* or use the alphabet selection option.
   g. Press the *YES* key to confirm your selection.
   h. Enter the rate by pressing the *RATE* key on the POC unit, followed by pressing the numerical keys of the ordered rate to be infused.
   i. Enter the volume by pressing the *VTBI* key followed by pressing the numerical keys of the volume to be infused.
   j. Begin the infusion by pressing the *START* key.

6. **Secondary Set-up and Programming Using the Guardrails Drug Library:**

a. Lower primary fluid on plastic suspension hanging device.
b. Prime, hang, and attach secondary line at injection site above pump.
c. Press *CHANNEL SELECT* on the module to be used for the secondary infusion.
d. Press the *SECONDARY* key.
e. Press the Secondary Guardrail Drug to be infused key.
f. Press the key next to the drug amount to be infused.
g. Press the *YES* key if the dosing unit (drug amount) selected is correct. Press the *NO* key if the dosing unit (drug amount) is incorrect and reselect the correct dosing unit (drug amount).
h. Press the *CONFIRM* key after secondary drug dose has been reviewed.
i. Press the *NEXT* key to confirm drug amount and diluent amount.
j. Enter the volume by pressing the *VTBI* key followed by pressing the numerical keys of the volume to be infused.
k. The rate and duration will automatically be entered. The rate and duration are programmed by pharmacy based on drug selected and total diluent.
    i. The duration of infusion of all medications within the Guardrails drug library shall be infused as programmed by pharmacy.
l. Begin the infusion by pressing *START* key.

7. **Changing a Guardrail Secondary Drug Label**
    a. Select the appropriate module to be labeled.
    b. Press and hold the *CHANNEL OFF* key.
    c. Once the screen displays "Powering Down," press the OPTIONS key.
    d. Press the *CHANNEL SELECT* key on the module to be used.
    e. Press the *RESTORE* key to resume the Guardrail IV fluid.
    f. Press the *SECONDARY* key.
    g. Press the Secondary Guardrail Drug to be infused key.
    h. Press the key next to the drug amount to be infused.
    i. Press the *YES* key if the dosing unit (drug amount) selected is correct. Press the *NO* key if the dosing unit (drug amount) is incorrect and reselect the correct dosing unit (drug amount).
    j. Press the *CONFIRM* key to verify the secondary drug dose has been reviewed.
    k. Press the *NEXT* key to confirm the drug amount and the diluent amount.
    l. Enter the volume by pressing the *VTBI* key followed by pressing the numerical keys of the volume to be infused.
    m. The rate and duration are automatically entered. The rate and duration are programmed by pharmacy based on the drug selected and the total diluent. The duration of infusion of all medications within the Guardrails Drug library shall be infused as programmed by pharmacy.
    n. Begin the infusion by pressing the *START* key.

8. **Guardrail Drugs: Programming Using the Guardrails Drug Library**
    a. The Guardrails Drug Library allows the programming of continuous intravenous medications.
    b. Select the appropriate Unit Specific Profiles.
    c. Press *CHANNEL SELECT* on the module.
    d. Select Guardrails Drug from Infusion menu:
        i. Select a Guardrail Drug by pressing the key beside the drug name to be infused. For more selections, press the soft key below *PAGE DOWN* or use the alphabet selection option.
        ii. Press the *YES* key to confirm your selection or press the *NO* key to change your selection.
    e. Enter the dose related questions associated with your drug selection by pressing the appropriate keys.
    f. If a *CLINICAL ADVISORY* message appears, confirm you have read the information by pressing the *CONFIRM* key.

i. Clinical Advisory/Message(s) are displayed to alert to nursing that the medication administration information does not match the data information entered into the Alaris Drug Profile by pharmacy. Nursing shall confirm they have read and implemented the advisory by pressing the *CONFIRM* key.
ii. Clinical advisory dose messages are displayed to alert nursing to one or more of the following:
    1) An entered medication dose exceeds Tri-City Medical Center's (TCMC) pharmacy safe administration limit.
    2) An entered medication dose is below TCMC's pharmacy safe administration limit.
    3) The rate of infusion exceeds TCMC's pharmacy identified infusion duration.
    4) The rate of infusion is below TCMC's pharmacy identified infusion duration.
    5) The total volume to be infused is above TCMC's pharmacy identified infusion drug volume.
    6) The total volume to be infused is below TCMC's pharmacy identified infusion drug volume.
iii. Clinical advisory/messages for non-dose related alerts include:
    1) Attach additional infusion devices such as filters
    2) Second RN to review the information programmed by the primary nurse.
iv. Drugs may be administered outside of the Pharmacy identified limits and durations with a physician's order.

g. Confirm the *Guardrails Drug Setup* by pressing the *NEXT* key.
h. For Antibiotics:
    i. Enter the volume, press the *VTBI* key followed by pressing the numerical keys of the volume to be infused.
    ii. The *RATE* and *DURATION* fields are automatically entered. Do not change the preset *DURATION* without consulting a pharmacist.
i. For Epidural Infusion:
    i. Enter the dose by pressing the *DOSE* key
    ii. Enter the *VTBI* by pressing the *VTBI* key
    iii. Enter the volume by pressing the numerical keys.
    iv. The *RATE* is automatically entered.
    v. Second RN to review the information programmed by the primary nurse.
j. Begin the infusion by pressing *START* key.

9. **For Cardiac Drug Infusions, Weight and Non-Weight Drug Infusions:**
    a. Select the appropriate drug and confirm the Guardrails Drug Setup
    b. For weight-based drug infusions:
        i. Press the *PATIENT'S WEIGHT* key to enter weight.
        ii. Press the *DOSE* key to enter dose.
        iii. Press the *VTBI* key to enter total volume.
        iv. The rate is automatically entered.
        v. Begin infusion by pressing the *START* key.
    c. For non-weight based drug infusions:
        i. Press the *DOSE* key to enter dose or you may enter the *RATE.*
        ii. Press the *VTBI* key to enter total volume
        iii. The rate is automatically entered when the *DOSE* is entered or the dose is automatically entered when the *RATE* is entered.
        iv. Begin infusion by pressing the *START* key.
10. **Drug Calculation for Drugs not Listed in the Guardrails Library**
    a. Press *CHANNEL SELECT* key on the desired module.
    b. Select *GUARDRAILS DRUG.*
    c. Press *DRUG CALC* key for the *DRUG CALCULATION SETUP* option.

d. Enter the *DRUG AMOUNT* and the appropriate *UNIT OF MEASURE* (mcg, mg, gram, unit, mEq).
e. Enter *DILUENT VOLUME.*
f. Press *PATIENT WEIGHT* key. Answer *YES* to enter weight, answer *NO* if medication is not weight-based.
g. Press *TIME UNITS* key and then select the appropriate measure (i.e., Min, Hour, Day).
h. Press *DOSING UNIT* key to enter the appropriate dosing unit (mcg/kg/min or mg/kg/min).
i. Press the *NEXT* key to confirm the correct dosing unit has been entered.
j. Press the *VTBI* key and enter the total volume to be infused then select *START.*
k. To edit a drug calculation, repeat steps 1 – 10 and enter the new drug information.

11. **Pause:**
    a. Press the *PAUSE* key on the module to be paused. (After 2 minutes, an audible alarm will sound and *PAUSE – RESTART CHANNEL* will scroll on the module display screen. The yellow alarm light will blink on the lighthouse of the module involved).
    b. Press *RESTART* to resume the infusion.
12. **Clearing Volume Infused Set:**
    a. Press the *VOLUME INFUSED* key on the screen of the POC. (NOTE: the screen displays time and date when each module was last cleared and soft key *PRI/SEC VOLUME* provides the ability to toggle between primary and secondary volumes infused.)
    b. Clear channel by pressing the key beside the desired module on the POC screen.
    c. Press the *CLEAR CHANNEL* key for one specific module *or CLEAR ALL* to clear volumes infused for entire system.
    d. Return to POC Main Menu by pressing the soft key below *MAIN SCREEN.*
13. **Removal of a Module Label that IS NOT a Guardrail**
    a. Press the *CHANNEL SELECT* key on the module to be labeled.
    b. Press the *OPTIONS* key on the POC unit.
    c. Press CHANNEL LABEL key.
    d. Press the *CLEAR LABEL* key or select a new label by pressing the key next to the label desired on the POC unit.
    e. Press the *START* key on the POC unit to resume the infusion.
14. **Silence an Alarm**
    a. Press the *SILENCE* key to temporarily silence an alarm.
        i. The RN must remain with the patient during the time the alarm is silenced.
        ii. The alarm will resume in two minutes if the cause of the alarm is not fixed.
15. **Increase/Decrease Alarm Sound**
    a. Press the *AUDIO ADJUST* key.
    b. Press *SOFTER* to decrease the volume of the alarms; press *LOUDER* to increase the volume of the alarms.
    c. Press the *TEST* key to hear the volume of the alarm programmed.
    d. Press *MAIN SCREEN* to return to the previous program.
16. **Adjusting Display Contrast**
    a. Press the key below *DISPLAY CONTRAST.*
    b. Press the *LIGHTER* or *DARKER* key to adjust the screen display.
    c. Press *MAIN SCREEN* to return to the previous program.
17. **Locking and Unlocking Tamper Resist Option**
    a. Initiate the desired module.
    b. Press and hold the *TAMPER RESIST SWITCH* located on the back of the POC unit for 3 to 4 seconds.
    c. An advisory Tone and a three-second *PANEL LOCKED* prompt will be displayed to confirm activation of the *TAMPER RESIST SWITCH.*
    d. Press *UNLOCK* the Tamper Resist, press and hold the TAMPER RESIST SWITCH for 3 to 4 seconds.

i. The MAIN DISPLAY will show a PANEL UNLOCKED prompt for three seconds and an advisory tone will sound when the panel is unlocked.

18. **Power Down of a Module (To Turn a Channel Off)**
    a. Press the *CHANNEL OFF* hard key on the desired module for approximately two seconds and then release the Channel will power off.
19. **Power Down of All Modules (To Turn Off All Channel Off)**
    a. Press the *OPTIONS* key.
    b. Press the *POWER DOWN ALL CHANNELS* key and then press *YES* to confirm. Powering Down will appear on the display screen.

B. **REFERENCES:**

1. Cardinal Health. (2003-2005). *Alaris system directions for use pc unit section*. Retrieved June 15, 2007, from http://www.cardinal.com/alaris/brochure/spodfuAlarisSystem8DFU.pdf

Tri-City Medical Center
Oceanside, California

PATIENT CARE SERVICES

ISSUE DATE: 05/17 **SUBJECT:** Insulin; Use of Concentrated

REVISION DATE~~(S)~~: 05/17

Patient Care Services Content Expert Approval:	~~09/19~~02/24
Clinical Policies and Procedures Approval:	~~10/19~~03/24
Nursinge Leadership~~Executive Committee~~ Approval:	~~10/19~~04/24
Division of Medicine Approval:	~~09/20~~06/24
Pharmacy and Therapeutics Approval:	~~05/21~~08/24
Medical Executive Committee Approval:	~~07/21~~10/24
Administration Approval:	~~08/21~~11/24
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	08/21

A. **PURPOSE:**
1. To address the inpatient management of insulin regimens for patients on a concentrated insulin product on an outpatient basis.
   a. Concentrated insulin products, particularly U-500 regular insulin pose a significant patient safety risk with regard to appropriate dose calculation, administration, and dose adjustments.
   b. Risk of inappropriate dosage adjustments is high due to lack of familiarity with concentrated insulin products by most non-specialized physician/Allied Health Professional (AHP) and the variable insulin needs of admitted patients.
      i. Many patients require significantly less insulin during admission as compared to their usual outpatient needs for various clinical reasons.

B. **DEFINITION(S):**
1. Concentrated insulin: Any insulin dosage form manufactured at concentrations greater than 100 units/mL, including but not limited to U-500 regular insulin, insulin degludec (Tresiba) U-200, insulin glargine (Toujeo) U-300, and Humalog U-200.

C. **POLICY:**
1. Concentrated insulins are not permitted for use at Tri-City Medical Center.
2. Patients on a concentrated insulin prior to admission who require continued insulin therapy during admission will be converted by a physician to a formulary based insulin regimen.
   a. A conversion to a basal/bolus regimen using insulin glargine and insulin lispro, respectively are recommended.
   b. A 20% to 50% reduction in total daily insulin units is recommended for the majority of patients when converting patients from a concentrated insulin regimen to a standard concentration basal/bolus regimen.

D. **REFERENCES:**

1. Paulus AO, Colburn JA, True MW, et al. Evaluation of total daily dose and glycemic control for patients taking U-500 regular insulin admitted to the hospital. Endocrine Practice. 2016;22:1187-1191
2. Samaan KH, Dahlke M, Stover J. Addressing safety concerns about U-500 insulin in a hospital setting. American Journal of Health Systems Pharmacy. 2011;68:63-68

3. Tripathy PR, Lansang MC. U-500 regular insulin use in hospitalized patients. Endocrine Practice. 2016;21:54-58

Tri-City Medical Center	Patient Care~~Women and Newborn~~ Services **RETIRE – Women and Newborn Services Suspended**
PROCEDURE:	**OBSTETRICAL HEMORRHAGE**
~~Purpose:~~	~~To provide guidelines for the optimal response of the multidisciplinary team in the event of obstetric hemorrhage and to assist all care providers in recognizing patients at risk for hemorrhage, identifying stages of hemorrhage, and primary treatment goals.~~
~~Supportive Data:~~	~~Maternal hemorrhage is defined as a cumulative blood loss greater than or equal to 1,000 mL or blood loss accompanied by signs or symptoms of hypovolemia within 24 hours after the birth process. Major causes of postpartum hemorrhage (PPH) include uterine atony, lacerations, hematomas, retained placental fragments, uterine inversion and blood coagulation disorders, (e.g., disseminated intravascular coagulation (DIC)).~~
~~Equipment:~~	~~1. Additional Intravenous (IV) fluid (e.g., normal saline, lactated ringers)~~ ~~2. Additional IV tubing~~ ~~3. Transfusion administration set~~ ~~4. Foley catheter~~ ~~5. Oxytocin 10 units per mL, uterotonic medications as ordered by provider~~ ~~6. Infusion pump~~ ~~7. Syringes for Intramuscular (IM) administration~~ ~~8. Oxygen delivery equipment (e.g. simple mask)~~ ~~9. OB Hemorrhage Cart & (Crash Cart, as needed)~~ ~~NOTE: Equipment for this procedure may vary, based on the clinical situation~~

~~A. **POLICY STATEMENTS:**~~

~~1. An optimal response to obstetrical (OB) hemorrhage should use a multidisciplinary and multifaceted approach that involves maintaining hemodynamic stability while simultaneously identifying and treating the cause of blood loss.~~

~~2. All births shall have active management and assessment practices in place to minimize OB hemorrhage.~~

~~3. The nursing unit, anesthesia, blood bank, operating room, and other appropriate services shall work together to mount an efficient and coordinated response to an OB hemorrhage.~~

~~4. The WNS department will maintain and have OB Hemorrhage Carts available for urgent hemorrhage management on Labor and Delivery (L&D), L&D Post Anesthesia Care Unit (PACU) and Post Partum (PP).~~

~~5. In the event of an OB hemorrhage, a CODE MATERNITY shall be initiated. Refer to Patient Care Services (PCS) Procedure; Code Maternity Team.~~

~~B. **DEFINITIONS:**~~

~~1. Postpartum hemorrhage is defined as a cumulative blood loss greater than or equal to 1,000 mL or blood loss accompanied by signs or symptoms of hypovolemia within 24 hours after the birth process regardless of route of delivery.~~

~~a. Vaginal birth:~~

~~i. Stage 1: >500 mL blood loss, with continued bleeding and/or Vital Sign (VS) instability~~

~~ii. Stage 2: <1500 mL cumulative blood loss with continued bleeding or VS instability~~

~~iii. Stage 3: >1500 mL cumulative blood loss, >2 units PRBCs given, VS unstable or suspicion for DIC.~~

~~b. Cesarean birth:~~

~~i. Stage 1: >1000 mL blood loss, with continued bleeding and/or VS instability.~~

Review/Revision Date	Clinical Policies and Procedures	Department of OB/GYN	Department of Pediatrics	Pharmacy & Therapeutics Committee	Medical Executive Committee	Administration	Professional Affairs Committee	Board of Directors
01/11, 05/15; 02/20, **11/23**	**05/30**	07/12, 06/15, 06/21	n/a	12/15, 07/21, **10/24**	05/13; 02/16, 11/21, **10/24**	11/21, **11/24**	06/13; 03/16, n/a	06/13; 03/16, 12/21

ii. Stage 2: <1500 mL cumulative blood loss with continued bleeding or VS instability
iii. Stage 3: >1500 mL cumulative blood loss, >2 units Red Blood Cells (RBC) given, VS unstable or suspicion for DIC.

3. Vital Sign (VS) instability:
   a. Heart rate >15% change or ≥ 110
   b. Blood pressure ≤ 85/45
   c. O2 saturation< 95%
4. Risk factor assessment for OB hemorrhage will be assessed on admission, within 30 minutes of delivery, 60 minutes post-delivery, admission to the postpartum unit and at each patient handoff/shift change for 24 hours after delivery. If high risk or hemorrhage after current delivery continue to assess every handoff/shift change until discharge.
   a. Risk factor interventions:
      i. Low Risk: Type and Rh upon admission
      ii. Medium Risk: Type and Screen
      iii. High Risk: Type and Crossmatch 2 units of PRBCs

C. PROCEDURE AND RESPONSIBILITIES:

1. The registered nurse (RN) will complete fundal and vaginal bleeding checks as indicated in WNS Standards of Care- Intrapartum and WNS Standards of Care- Postpartum.
2. If patient is having increased/continued bleeding or VS instability or greater than 500 mL blood loss, Notify Charge Nurse and call a Code Maternity for more assistance.
   a. See attached document: Obstetric Hemorrhage Emergency Management Plan to guide patient care during the OB Hemorrhage.
3. Notify provider, obtain and administer Intravenous (IV) Fluids as ordered.
   a. If patient's provider is a Certified Nurse Midwife (CNM), co-management with a physician is recommended for Stage 1 and required for Stage 2 and Stage 3.
4. Bring the OB Hemorrhage Cart into the patient room.
5. Monitor VS, level of consciousness (LOC) every 5 minutes.
6. Quantify blood loss (QBL) with scale. Calculate and record every 15 minutes.
7. Assure patients family/support person is updated regarding patient's status.
   a. If the WNS Social Worker is available, they can provide support to the family/support person.
8. Ensure an Operating Room (OR) is available for possible exam, repair, D&C or hysterectomy.
9. Consider transfusion on clinical criteria (not waiting for lab test results).
10. Prepare uterotonic medications. See Uterotonic Agents for Postpartum Hemorrhage.

D. BLOOD BANK CONSIDERATIONS:

1. Anticipate transfusion of blood products by having the patient Type and Crossmatched for 2 units of Packed Red Blood Cells (PRBC) during Stage 1 of an OB Hemorrhage.
   a. Infuse blood products per the Blood Products Administration Procedure.
      i. Suggested ratios may include
         1) 1:1 ratio of PRBC/FP during acute hemorrhage management
         2) 6:4:1 ratio of PRBC/FP/Platelets
         3) 4:4:1 ratio of PRBC/FP/Platelets
2. If continued bleeding after administration of the initial 2 PRBC then activate the Massive Transfusion Protocol (MTP) Procedure.
   a. The units will be prepared in multiples of five (5) RBC units and five (5) Thawed Frozen Plasma (FP) units at a 1:1 ratio followed by one (1) unit of Plateletpheresis (PLPH).
3. If the patient has unresponsive coagulopathy after 8-10 units of PRBC and coagulation factor replacement, Physician may consider risk/benefit of Factor VIIa, to be provided by pharmacy (ext. 3012).
   a. Provisional dosing range 60-90 units/kg

4. **If the physician determines the patient is stable for transport, the patient will be transported out to the accepting facility. If the patient is not stable for transport to another facility the patient will be transferred to the Intensive Care Unit**The Physician may consider transfer of the patient to the Intensive Care Unit (ICU) if the patient receives MTP.
5. Notify Blood Bank of patient stabilization and blood product adjustments/requirements per provider order.

E. SPECIAL CONSIDERATAIONS: JEHOVAH'S WITNESSES AND OTHERS WHO MAY DECLINE BLOOD PRODUCTS

1. There is a wide range of acceptable blood interventions within the Jehovah's Witness community and 50% will actually take some form of blood transfusions.
2. It is imperative that the provider and health care team review all possible options with the patient refusing to receive blood products.
   a. Labor and Delivery
      i. Anesthesia shall be consulted when the patient is admitted.
      ii. The OB provider shall review surgical options and other specific techniques for consideration to manage hemorrhage concerns to include but not limited to:
         1) Early Interventional Radiology involvement
         2) Use of Fibrin/ Thrombin glues
   b. Postpartum
      i. Maintain volume with crystalloids
      ii. Aggressively treat anemia

F. DOCUMENTATION:

1. Document assessment findings and interventions provided in patient medical record.
2. Document all medications, IV & blood products on eMAR and I/O forms in patient electronic medical record, as appropriate.
3. Complete documentation requirements for blood transfusion per Patient Care Services (PCS) procedure: Blood Products Administration.
4. May use Code MATERNITY report sheet to document events when Code MATERNITY is initiated, see PCS Procedure; Code Maternity Team Mobilization.

G. REFERENCES:

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2. Elmer, J, Wilcox, S. R. &Raja, A. S. (2013). Massive transfusion in traumatic shock. Journal of Emergency Medicine, 44(4): 829-838.
3. Sheilds, L., Chagolla, B., Fulton, J., Pelletreau, B. (2013). Comprehensive maternal hemorrhage protocols reduce utilization of blood products and improve patient safety. American Journal of Obstetrics and Gynecology. 208; S49-50.
4. Simpson, K. and Creehan, P. (2020). Perinatal Nursing 5th Edition. Philadelphia, PA
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Obstetric Hemorrhage Emergency Management Plan:

	Assessments	Meds/Procedures	Blood Bank
Stage 0	**Every woman in labor/giving birth**		
Stage 0 focuses on risk assessment and active management of the third stage.	• Assess every woman for **risk factors** for hemorrhage • Measure **cumulative quantitative blood loss** on every birth	**Active Management 3rd Stage:** • **Oxytocin** IV infusion or 10u IM • **Fundal Massage**- vigorous, 15 seconds min.	• **If Medium Risk:** T& Scr. • **If High Risk:** T&C 2 U • **If Positive Antibody Screen** (prenatal or current, exclude low level anti-D from RhoGam): T&C 2 U
Stage 1	**Blood loss: >500mL vaginal or >1000mL Cesarean, or VS changes (by >15% or HR ≥ 110, BP ≤ 85/45, O2 sat <95%**		
Stage 1 is short: activate hemorrhage protocol, initiate preparations and give Methergine IM.	• Activate OB Hemorrhage Protocol and Checklist • Notify Charge nurse, OB/CNM, Anesthesia • VS, O2 Sat q5' • Record **cumulative** blood loss q5-15' • **Weigh** bloody materials • Careful inspection with good exposure of vaginal walls, cervix, uterine cavity, placenta	• **IV Access:** at least 18gauge • Increase IV fluid (LR) and **Oxytocin** rate, and repeat **fundal massage** • **Methergine** 0.2mg IM (if not hypertensive) May repeat if good response to first dose, BUT otherwise **move on** to 2nd level uterotonic drug (see below) • Empty bladder: straight cath or place foley with urimeter	• **T&C 2 Units PRBCs** (if not already done)
Stage 2	**Continued bleeding with total blood loss under 1500mL**		
Stage 2 is focused on sequentially advancing through medications and procedures, mobilizing help and Blood Bank support, and keeping ahead with volume and blood products.	**OB back to bedside** (if not already there) • **Extra help:** 2nd OB, Rapid Response Team, assign roles • VS & **cumulative** blood loss q5-10 min • Weigh bloody materials • **Complete evaluation** of vaginal wall, cervix, placenta, uterine cavity • Send additional labs, including DIC panel • If in Postpartum: Move to L&D/OR • Evaluate for special cases: -Uterine Inversion -Amn. Fluid Embolism	**2nd Level Uterotonic Drugs:** • **Hemabate** 250 mcg IM or • **Misoprostol** 800 mcg SL **2nd IV Access** (at least 18gauge) Bimanual massage **Vaginal Birth:** (typical order) • Move to OR • Repair any tears • D&C: r/o retained placenta • Place intrauterine balloon • Selective Embolization (Interventional Radiology) **Cesarean Birth:** (still intra-op) (typical order) • Inspect broad lig, posterior uterus and retained placenta • B Lynch Suture • Place intrauterine balloon	• **Notify Blood Bank of OB Hemorrhage** • **Bring 2 Units PRBCs to bedside, transfuse per clinical signs – do not wait for lab values** • Use blood warmer for transfusion • Consider thawing 2 FFP (takes 35+min), use if transfusing >2u PRBCs • Determine availability of additional RBCs and other Coag products
Stage 3	**Total blood loss over 1500mL, or >2 units PRBCs given or VS unstable or suspicion of DIC**		
Stage 3 is focused on the Massive Transfusion protocol and invasive surgical approaches for control of bleeding.	• **Mobilize team** -Advanced GYN surgeon -2nd Anesthesia Provider -OR staff -Adult Intensivist • **Repeat labs** including coags and ABG's • Central line • Social Worker/ family support	• **Activate Massive Hemorrhage Protocol** • Laparotomy: -B-Lynch Suture -Uterine Artery Ligation -Hysterectomy • Patient support -Fluid warmer -Upper body warming device -Sequential compression stockings	**Transfuse Aggressively** Massive Hemorrhage Pack • Near 1:1 PRBCs: FFP • 1 PLT apheresis pack per 4-6 units PRBC's **Unresponsive Coagulopathy:** After 8-10 units PRBCs and full coagulation factor replacement: ma consult re rFactor VIIa risk/benefit

~~Uterotonic Agents for Postpartum Hemorrhage:~~

~~Drug~~	~~Dose~~	~~Route~~	~~Frequency~~	~~Side Effects~~	~~Contraindications~~	~~Storage~~
~~Pitocin (Oxytocin) 10 units/ml~~	~~10-40 units per 500-1000ml, rate titrated to uterine tone~~	~~IV infusion~~	~~Continuous~~	~~Usually none Nausea, vomiting, hyponatremia ("water intoxication") with prolonged IV admin. Decreased BP and increased HR with high doses, esp. IV push~~	~~Hypersensitivity to drug~~	~~Room temp~~
~~Methergine (Methylergonivine) 0.2 mg/ml~~	~~0.2 mg~~	~~IM (not to be given IV)~~	~~-Q 2-4 hours -If no response after first dose, it is unlikely that additional doses will be of benefit~~	~~Nausea, vomiting Severe hypertension, esp. if given IV, which is not recommended~~	~~Hypertension, Preeclampsia, Cardiovascular disease Hypersensitivity to drug Caution if multiple doses of ephedrine have been used, may exaggerate hypertensive response w/possible cerebral hemorrhage~~	~~Refrigerate~~
~~Hemabate (15 mthyl PG F2a) 250 mcg/ml~~	~~250 mcg~~	~~IM or intra-myometrial (not given IV)~~	~~-Q 15-90 min -Not to exceed 8 doses/24 hrs -If no response after several doses, it is unlikely that additional doses will be of benefit~~	~~Nausea, Vomiting, Diarrhea, Fever (transient), Headache, Chills, shivering, hypertension, bronchospasm~~	~~Caution in women with hepatic disease, asthma, hypertension, active cardiac or pulmonary disease Hypersensitivity to drug~~	~~Refrigerate~~
~~Cytotec (Misoprostol) 100 or 200 mcg tabs~~	~~600-1000 mcg~~	~~Sublingual, oral, or per rectum (PR)~~	~~One time~~	~~Nausea, vomiting, diarrhea, shivering, fever (transient), Headache~~	~~Rare Known allergy to prostaglandin Hypersensitivity to drug~~	~~Room temp~~

Tri-City Medical Center
Oceanside, California

PATIENT CARE SERVICES

ISSUE DATE: 10/13

SUBJECT: Outpatient Post Anesthesia/Procedure Discharge/ Transportation Guidelines

REVISION DATE~~(S)~~: 10/13, 11/18

Patient Care Services Content Expert Approval:	**~~05/18~~02/24**
Clinical Policies & Procedures Committee Approval:	**~~06/18~~03/24**
Nursinge Leadership~~Executive Committee~~ Approval:	**~~07/18~~04/24**
Department of Anesthesiology Approval:	**~~09/18~~09/24**
Pharmacy & Therapeutics Committee Approval:	**n/a**
Medical Executive Committee:	**~~09/18~~10/24**
Administration Approval:	**~~10/18~~11/24**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	**11/18**

A. **PURPOSE:**

1. To establish guidelines for discharge of outpatients undergoing procedures at Tri-City Healthcare District (TCHD).

B. **POLICY:**

1. Procedures with no sedation/anesthesia:
   a. Patients who have procedures without anesthesia or sedation are discharged upon the order of the treating physician.
   b. Patients may use transportation of their choice (privately owned vehicle [POV], taxi, public transportation).
   c. A responsible person to accompany the patient is recommended, but not required.
2. Procedures with sedation/anesthesia:
   a. Patients undergoing procedures with sedation or anesthesia are discharged upon the order of the treating physician and have met discharge criteria.
   b. Patients undergoing procedures with sedation or anesthesia are required to be discharged in the company of a responsible person and have a pre-arranged ride home.
3. -Pre Procedure:
   a. Patients scheduled for procedures with planned sedation/anesthesia will be notified prior to the day of their procedure that they must arrange a ride and a responsible person to take them to their destination post procedure or their procedure may be cancelled.
      i. Patients will be offered a list of transportation resources for their information.
   b. ~~The patient will sign a form stating they were notified of this policy, if seen in a Preoperative Education appointment. Patients not seen in the~~ Preoperative Education ~~center prior to their procedure~~ will ~~be~~ advise~~d~~ **patients** of the above requirement, and the person making the call will document the discussion.
   c. The day of the procedure~~, the responsible person must accompany the patient to the procedural admission area and~~ confirm availability, ~~and~~ contact information and document in patient chart.
4. Post Procedure:
   a. If the responsible person cannot be contacted at the time of discharge, the department ~~manager~~**Nurse Leader** is contacted to assist with resolution.
      i. ~~Manager~~**Nurse Leader** resolution includes documented consultation and agreement with the surgeon/procedural physician and anesthesiologist.

5. Urgent case/unanticipated use of sedation/anesthesia:
   a. If the procedure is of an urgent nature, and the patient is unable to arrange for a responsible person to accompany them home, contact the department ~~manager~~**Nurse Leader** to assist with resolution.

C. **RELATED DOCUMENT(S):**
1. Transportation Resources

Tri-City Medical Center
Oceanside, California

PATIENT CARE SERVICES
~~**POLICY**~~

ISSUE DATE: **06/13** **SUBJECT: Radiation Safety**

REVISION DATE(S): 06/13

Patient Care Services Content Expert Approval:	**~~11/17~~10/22**
Clinical Policies & Procedures Committee Approval:	**~~03/20~~02/24**
Nursing Leadership Approval:	**~~04/20~~03/24**
Department of Radiology Approval:	**~~09/20~~08/24**
Pharmacy &Therapeutics Committee Approval:	**n/a**
Medical Executive Committee Approval:	**~~10/20~~09/24**
Administration Approval:	**~~12/20~~11/24**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	**12/20**

A. **PATIENT SAFETY:**

1. A radiation warning sign will be placed outside the doors of any patients receiving radiation therapy or where there is a radiation exposure risk.
2. Only a RN may provide routine care for patients receiving radioactive therapy.
3. Admitted patients receiving radioactive therapy will be assigned a room on the 2 Pavilion or Progressive Care Unit (PCU), unless the patient requires cardiac monitoring.
4. The Radiation Safety Officer (RSO) must be contacted for any radiation therapy patient movement throughout the facility including an expired patient.
5. ~~Gonadal protection will be used especially on children and adults of childbearing and producing ages during radiographic examinations whenever possible.~~
6. **~~6.~~5.** All radiographic and fluoroscopic systems will be maintained in accordance with the recommendations contained in the California Department of Public Health (CDPH) Title 22 and Title 17 regulations.
7. **~~7.~~6.** Patients receiving Y-90- Radioembolization see Patient Care Services Procedure: Y-90 Micropsphere Brachytherapy Patient Management.
8. **~~8.~~7.** Patients receiving Iodine$_{131}$ see Patient Care Services Procedure: Therapeutic Use of Radiopharmaceuticals for Inpatients.

B. **VISITOR SAFETY:**

1. **All Radiation rooms have been equipped with coded lock doors.**
1. ~~Visitors will not spend more than thirty (30) minutes in any twenty-four (24) hour period in a radiation implant patient room.~~
2. Pregnant women **and children** will be restricted from radiation ~~therapy~~ rooms.
3. ~~Persons under eighteen (18) years of age will be restricted from radiation therapy rooms.~~
4. **~~4.~~3.** All doors will be closed during radiographic and fluoroscopic examinations.

C. **PERSONNEL SAFETY:**

1. A radiation warning sign will be placed outside the doors of any patients receiving radiation therapy or where there is a radiation exposure risk.
2. No more than two (2) radioactive therapy patients will be assigned to any one (1) Registered Nurse (RN) per shift.
3. All designated radiation workers that engage in fluoroscopic or radiographic work will wear exposure-monitoring badges.

a. Badges are to be worn outside the lead apron at collar level and should be put on upon arrival for duty.
b. Badges are not to leave the facility.

4. Occupationally exposed personnel engaged in fluoroscopic or radiographic work should notify either their director or the RSO of a suspected or confirmed pregnancy in writing.
5. Department of Human Services (DHS) regulations do not allow technologists to hold patients during radiation exposures except during rare or emergent type situations. If a technologist is in a room during an exposure, lead aprons will be worn.
6. All personnel will stand behind lead barriers during exposures when appropriate. If personnel must be in the room during radiation exposures, lead aprons shall be worn.
7. All doors will be closed during radiographic and fluoroscopic examinations.
8. Personnel will not enter a radiographic or fluoroscopic room when the door is closed.
9. All lead aprons and gloves will be checked annually for leakage and replaced when needed.
10. All personnel involved in the care of patients receiving radioactive therapy or are involved with handling or exposure to radiation will receive yearly education on radiation safety.

D. **AS LOW AS REASONABLY ACHIEVABLE (ALARA) GUIDELINES:**

1. Purpose:
   a. The functional control of occupational radiation exposure for personnel employed in situations of exposure to ionizing radiation from radioactive materials under the authorization of the radioactive materials license will be the responsibility of the RSO and the Radiation Safety Committee (RSC). The goal will be to maintain personnel radiation dose ALARA and, in keeping with that goal, the following Action Levels (below the Maximum Permissible Dose [MPD] for occupational radiation have been established).

Dose Category	Action - Level I	Action - Level II
Whole Body	125~~675~~ mrem/qtr	375~~1275~~ mrem/qtr
Skin	300~~750~~ mrem/qtr	1125~~2250~~ mrem/qtr
Extremities	1250~~1875~~ mrem/qtr	3750~~5625~~ mrem/qtr

2. Process:
   a. When the monthly occupational dose reports are received, the RSO will review them. The Medical and Administrative Director of Diagnostic Imaging will review the report during the quarterly Radiation Safety Committee meetings.
3. The RSO will make an annual written report to management on the Radiation Safety Program.
4. In the event an occupationally exposed person exceeds Level I doses, the RSO shall review the circumstances of the exposure in an informal manner and if determined advisable, will discuss the situation with accepted persons and, if necessary, counsel the individual exposed. Since the average monthly acceptable dose of Level I is only 40 mrem per month/ minor variations above this average acceptable dose are not to be considered alarming (since this is the allowable limit for the non-occupationally exposed general public as well as persons in the status of Declared Pregnancy), but rather the object is to monitor trends to prevent personnel doses from reaching or exceeding Level II or the MPD.
5. It must be remembered that when an occupationally exposed person becomes pregnant and it is known by responsible persons (a Declared Pregnancy), their maximum permissible dose is reduced to 10% of the MPD for adults. In essence, when an individual is known to be pregnant, the Level I dose is the MPD.
6. In the event an occupationally exposed person exceeds the maximum occupational dose specified in the California Control of Radiation Hazard Regulations the Office of Radiation Control will be contacted immediately.
7. If a full year of dosimetry records indicate no exposure for an individual, that person will no longer need to wear personal dosimetry and will no longer be issued a badge.
8. These guidelines apply to those persons occupationally exposed as a result of activities related to this radioactive materials license.

E. **RELATED DOCUMENT(S):**

1. Patient Care Services Procedure: Therapeutic Use of Radiopharmaceuticals for Inpatients
2. Patient Care Services Procedure: Y-90 Micropsphere Brachytherapy Patient Management Procedure
3. Principles of Radiation Safety

F. **REFERENCE(S):**

1. California Code of Regulations, Titles 17 and 22 California Department of Public Health

Tri-City Medical Center
Oceanside, California

PATIENT CARE SERVICES

STANDARDS OF CARE ADULT

I. **PREAMBLE:**

A. Health care providers at Tri-City Medical Center (TCMC) shall ensure that each adult patient and their family are treated equally, with dignity, and respect. Cultural, racial, language, life-style customs, and ethnic diversity of each patient shall be considered when providing care. Adult patients shall receive care based on disease, injury prevention, health promotion, health restoration and/or health maintenance. The nursing process shall be used to implement all patient care. Health care providers shall use TCMC Administrative Policy Manual, Patient Care Services Policies (PCS), PCS Procedures, Online Skills, and unit specific Standards of Care, policies and procedures to provide patient care.

II. **DEFINITION(S):**

A. Scope and Standards of Practice: "Describe what nursing is, what a nurse does, responsibilities for which a nurse is accountable, and the outcomes of that practice (American Nurses Association (ANA))".

B. Standards of Care: "Authoritative statements by which the nursing profession describes the responsibilities for which its practitioners are accountable (ANA, p.77)". "Standards of care describe a competent level of nursing care as demonstrated by the nursing process (ANA, p. 78) and are examples of the nursing professional expected roles and responsibilities for providing patient care.

C. Nursing Process: "The essential core of practice for the Registered Nurse (RN) to deliver holistic, patient-focused care. The nursing process as outlined by the ANA (2016) includes the following:

1. Assessment: "A systematic, dynamic way to collect and analyze data about a patient i.e., patient. Assessment includes not only physiological data, but also psychological, sociocultural, spiritual, economic and life-style factors".
    a. An assessment includes subjective and objective data
        i. Subjective – what the patient says
        ii. Objective – observation based on assessment findings
2. Diagnosis: A nurses' clinical judgment about the patient's response to actual or potential health conditions or needs.
3. Outcomes/Planning: "Based on the assessment and diagnosis. Outcomes are measurable and achievable short – and long-range goals".
    a. Planning: Care Plan i.e., Plan of Care: A comprehensive outline of care to be delivered to attain expected outcomes
4. Implementation: "Nursing care is implemented to the care plan. This is "continuity of care ~~for~~from the patient during hospitalization and in preparation for discharge needs".
5. Evaluation: The process of determining both the "patient's status and the effectiveness of nursing care. It is a process that involves continuous evaluation of the patient and the modifications to the Plan of Care".

D. Patient: Recipient of nursing care.

E. Health Care Providers: Individuals with special expertise who provide health care services or assistance to patients

F. Significant Others: Family members and/or those significant to the patient

Patient Care Services Content Expert Review	Clinical Policies & Procedures Committee	Nursing Leadership	Medical Staff Department or Division	Pharmacy & Therapeutics Committee	Medical Executive Committee	Admini stration	Professional Affairs Committee	Board of Directors
02/16, 03/19, 07/22	11/16, 05/19, 04/23, **05/24**	01/17, 05/19, 05/23,**09/24**	n/a	n/a	03/17, 06/19, 05/23, **09/24**	07/19, 06/23, **11/24**	10/17, n/a	03/13, 10/17, 08/19, 06/23

G. Reasonable and a timely manner: Defined as within 4 hours after completion of assessments or care provided.

III. POLICY:

A. "Registered nurses use the nursing process to plan and provide individualized care to their patients. Nurses use the theoretical and evidence-based knowledge of human experiences and responses to collaborate with patients to assess, diagnose, identify outcomes, plan, implement, and evaluate care. Nursing interventions are intended to produce beneficial effects, contribute to quality outcomes, and above all, do no harm. Nurses evaluate the effectiveness of their care in relation to identified outcomes and use evidence-based practice to improve care (ANA, 2010)".

IV. GENERAL NURSING ASSESSMENT:

A. Standards of Care: Vital Signs:
   1. Vital signs shall include:
      a. Temperature, documented in Celsius
      b. Blood Pressure (BP)
      c. Heart Rate (HR)
      d. Respiratory Rate (RR)
      e. Oxygen Saturation (SpO2)
   2. Vitals signs shall be obtained on admission, transfer to a unit, at discharge, per physician's orders and as follows:
      a. Intensive Care Unit (ICU): every 1 hour until stable then every 2 hours and as needed (PRN)
         i. For patients on vasopressors, every 15 minutes until stable
      b. Telemetry: every 4 hours while patient is awake and PRN
      c. Acute Care Services (ACS): every 8 hours and PRN
      d. Emergency Department: every 2 hours or more frequently for Emergency Severity Index (ESI) of 1 and 2
      e. Progressive Care Unit (PCU): Obtain vital signs based on the ordered Patient Admission Status i.e., ACS, Telemetry, Postpartum, and Rehabilitation
      f. Obstetrical patient not in Labor and Delivery (L&D): Obtain vital signs based on the ordered medical service and level of service.
      g. Postpartum patient not in Postpartum: Obtain vital signs based on the ordered medical service and level of service.
   3. Document values in the medical record

B. Standards of Care: Pain Assessment:
   1. Assessment: Pain - A general pain assessment shall be performed as outlined in the Pain Management Policy

C. Standards of Care: Intake and Output:
   1. Intake and output shall be monitored as ordered and as follows:
      a. ICU: at least every hour and PRN
      b. Telemetry: at least every four hours and PRN
      c. ACS: at least every 8 hours and PRN
         i. Oncology: at least every 6 hours and PRN
      d. PCU: Obtain intake and output based on the ordered Patient Admission Status i.e., ACS, Telemetry, Postpartum, and Rehabilitation
      e. Obstetrical patient not in L&D: document I&O based on the ordered medical service and level of service
      f. Postpartum patient not in Postpartum: document I&O based on the ordered medical service and level of service
   2. Intake and output shall be documented in the medical record after collecting and as follows:
      a. Prior to transfer to another level of care
      b. Prior to the end of the shift
      c. As ordered by a physician

d. Zero/clear infusion pumps every shift and prior to transferring to another level of care

3. Review patient's intake and output for baseline urine output
   a. Patients 14 years and older assess a minimum of 0.5 mL per kilogram per hour (example if the patient weighs 70 kg multiply 70 x (times) 0.5 equals 35 mL per hour or per physician order. Notify physician of abnormal findings.

D. Standards of Care: Height and Weight
1. All patients shall be weighed on admission if not contraindicated and every seven days thereafter until discharge. Exceptions are as follows.
   a. All ICU patients shall be weighed daily in the AM
   b. Patients with the following diagnoses shall be weighed daily in the AM at or prior to 0600 after voiding, if indicated
      i. Acute and chronic kidney failure e.g., renal failure, renal insufficiency, acute renal injury
      ii. Heart Failure this includes patients with cardiomyopathy receiving diuretics
      iii. Post cardiovascular surgery patients
   c. Patients receiving nutrition support - i.e., enteral or parenteral feedings shall be weighed every 3 days after admission.
   d. Medications shall be calculated using the patient's admission weight unless ordered otherwise by a physician.
   e. Patient's weight shall be documented in the medical record in kilograms.
   f. Patient's height shall be documented in the medical record in centimeters.
      i. Height shall be obtained on admission; stated, estimated or measured.

E. Standards of Care: Aspiration Assessment:
1. Assess on admission, initial shift assessment, and PRN per Online Skills: Aspiration Precautions Procedure
   a. Perform a swallow screening PRN based on assessment findings as outlined in the Swallow Screening in the Adult Patient Procedure
   b. Maintain head of bed (HOB) at 30 to 45 degrees and as ordered, unless contraindicated
   c. Ensure suction equipment is readily available at the bedside at all times.

F. Standards of Care: Patient Safety:
1. The health care team shall provide measures to ensure patient safety.
2. Patient safety shall be assessed per the following:
   a. The RN shall observe the patient's physical condition on admission and/or transfer to their unit, prior to and after transport to procedures and as needed.
   b. Patients shall be identified per Patient Care Services (PCS): Identification, Patient Policy.
   c. Orders shall be obtained, reviewed, and implemented per PCS: Physician Orders Policy.
   d. Critical test values shall be reported per PCS Procedure: Critical Results and Critical Test/Diagnostic Procedures.
   e. Patient's specimens shall be handled per PCS: Specimen Handling Procedure or by selecting the appropriate Online Skills Specimen Collection Procedure.
   f. Electronic or medical equipment brought to TCMC shall be evaluated, used, and stored per PCS: Medical Equipment Brought into the Facility Policy.
      i. Respiratory Care Practitioner shall be responsible for setting up home CPAP equipment.
   g. Patients shall be assessed for falls per PCS: Falls Risk Procedure.
   h. Hand-off Communication shall be provided per PCS: Hand-off Communication Policy and unit specific hand-off policies.
   i. Medication shall be reconciled per PCS: Medication Reconciliation Policy.
   j. Line connectors for IVs, epidurals, or enteral feedings cannot be used for a type other than the type intended.

k. All alarms shall be reviewed for appropriateness as outlined in the Clinical Alarm Management policy.

V. **SYSTEM REVIEW:**

A. All adult patients will have a general system review in all systems completed and documented. Detailed system assessments shall be completed and documented as indicated by the patient's condition as outlined in this document.

B. Standards of Care I: Assessment:

1. All patients admitted to inpatient nursing areas shall be assessed by a RN as outlined in this document.
2. Admission and/or Transfer Assessment
   a. All patients admitted or transferred to a higher level of care shall have a brief assessment to identify patients' safety considerations, general well-being and immediate needs initiated within the following time frames
      i. ICU Patients: approximately 15 minutes upon arrival to unit
      ii. Telemetry Patients: approximately 30 minutes upon arrival to unit
      iii. ACS Patients: approximately 1 hour upon arrival to unit
      iv. Emergency department per unit specific policy
      v. PCU Patients: Based on the ordered level of care (i.e., Medical Surgical, Telemetry, Postpartum, and Rehabilitation)
      vi. Obstetrical patient not in Labor and Delivery (L&D): based on the ordered medical service and level of service
      vii. Postpartum patient not in Postpartum: based on the ordered medical service and level of service
3. Admission Head to Toe Assessment:
   a. The RN shall perform a head to toe assessment as follows:
      i. ICU Patients: approximately 1 hour after the patient's arrival to the unit
      ii. Telemetry Patients: approximately 2 hours after the patient's arrival to the unit
      iii. ACS Patients: approximately 3 hours after the patient's arrival to the unit
      iv. PCU Patients: Based on the ordered level of care (i.e., Medical Surgical, Telemetry, Postpartum, and Rehabilitation)
      v. Obstetrical patient not in Labor and Delivery (L&D): based on the ordered medical service and level of service
      vi. Postpartum patient not in Postpartum: based on the ordered medical service and level of service
4. Admission Assessment- Patient History
   a. All inpatients shall have the Admission Assessment-Patient History completed and documented within 24 hours of admission to the unit.
5. Medication Patient History
   a. All patients shall have a Medication Patient History completed as soon as possible upon arrival to the unit per the Medication Reconciliation Policy.
6. Initial Shift Assessment (including upon Transfer to the unit)
   a. The RN shall perform a head to toe assessment as follows:
      i. ICU Patients: approximately 1 hour of the start of the shift
      ii. Telemetry Patients: approximately 2 hours of the start of the shift
      iii. ACS Patients: approximately 3 hours of the start of the shift
      iv. PCU Patients: Based on the ordered level of care (i.e., Medical Surgical, Telemetry, Postpartum, and Rehabilitation)
      v. Obstetrical patient not in Labor and Delivery (L&D): based on the ordered medical service and level of service
      vi. Postpartum patient not in Postpartum: based on the ordered medical service and level of service
7. Reassessment:

a. After completion and documentation of an admission, initial shift or transfer head to toe assessment, all patients will be reassessed as follows. Document only the reassessment changes in the electronic health record
   i. ICU: approximately 4 hours after completion of the initial assessment and every 4 hours thereafter
   ii. Telemetry: approximately 6 hours after completing the initial shift assessment
   iii. ACS: approximately 8 hours after completing the initial shift assessment
   iv. PCU Patients: Based on the ordered level of care (i.e., Medical Surgical, Telemetry, Postpartum, and Rehabilitation)
   v. Obstetrical patient not in Labor and Delivery (L&D): based on the ordered medical service and level of service.
   vi. Postpartum patient not in Postpartum: based on the ordered medical service and level of service.

8. Night Shift Reassessments
   a. During the night shift, the reassessment shall be performed during the shift and no later than with the AM vital signs.
   b. If the patient refuses a reassessment, document their refusal in the medical record.
9. PRN Focus assessment (i.e., system specific assessment) shall be completed as follows:
   a. Change in patient's condition from the initial shift assessment or reassessment
   b. Response to treatment provided to a patient

C. Standards of Care I.1: Assessment Neurological System Review
1. Neurological: System Review
   a. Assess the following:
      i. Orientation Assessment
      ii. Level of consciousness
      iii. Affect/Behavior
      iv. Characteristics of Speech
      v. Characteristics of Communication
      vi. Extremity movement and strength right and left upper and lower
      vii. Facial symmetry
      viii. Hearing
      ix. Pupil checks (pupil description, size, reaction to light, and accommodation)
         1) Pupil Checks
         2) Pupil checks shall be performed as follows to establish a baseline:
            a) On admission, initial shift assessments, and PRN
            b) As ordered by physician
2. Neurological: Detailed System Review
   a. The National Institute of Health Stroke Scale (NIHSS) will be performed by RNs who have met TCMC's criteria.
   b. A NIHSS assessment is required for:
      i. Patients admitted with signs and symptoms of a Cerebral Vascular Accident (CVA) or Transient Ischemic Attack (TIA)
      ii. Inpatients admitted or inpatient presenting with new signs and symptoms of a CVA or TIA
   c. A complete NIHSS assessment will be performed in the Emergency Department (ED), ICU, Telemetry, ACS as follows:
      i. Upon arrival to the ED
      ii. Admission
      iii. Transfer
      iv. Every shift
   d. A complete NIHSS assessment will be performed in ICU:

i. Every four (4) hours for the first seventy-two (72) after diagnosis
   1) Recommended times 0400, 0800, 1200, 1600, 2000, and midnight

e. A modified NIHSS assessment will be performed in Telemetry and ACS as follows:
   i. 0400, 1200, 1600 and midnight for the first 72 hours (72) after diagnosis

f. Modified Rankin Assessment:
   i. A Modified Rankin Assessment shall be completed on admission and discharge.

g. Neurological: Assessment: Spinal Cord Injury
   i. All patients with a spinal cord injury shall have the following assessed every four (4) hours:
      1) Neurological: System Assessment
      2) Neurological: Detailed Assessment
      3) Assess motor and sensory function from level of spinal cord injury using dermatomes.

h. Neurological: Spinal Cord Injury Nursing Interventions
   i. To decrease worsening of neurological deficits, the following interventions shall remain in place unless otherwise ordered by a Physician:
      1) Immobilization (stabilization) of the injury
      2) Reposition patient as follows:
         a) Changing position in bed: full log roll with three (3) healthcare providers, including one (1) nurse, to stabilize the patient's neck
      3) Assist patient out of bed as ordered or as follows:
         a) Full log roll with assistance
         b) Dangle patient's legs
         c) Ask patient to use arms to push up to a sitting position
         d) Assist patient to chair or with ambulation as ordered
      4) Mattress to remain flat at all times (reverse Trendelenburg with physician order); do not place a pillow, rolled blanket or towel under the patient's head
      5) Bed rest only (transport off unit in bed or stretcher, do not use a wheelchair)
      6) Use slide board when transferring and stabilize neck with three (3) healthcare providers, including one (1) nurse
      7) Observe autonomic dysreflexia precautions
      8) Avoid bowel and bladder distention
      9) Apply supportive devices as ordered prior to getting patient out of bed

i. Neurological: Intracranial Pressure (ICP) Monitoring: ICU
   i. Neurological assessment per physician order or every hour and PRN

j. Neurological: ICP Nursing Interventions
   i. Post an intracranial pressure tracing every shift and PRN with changes in patient status in the patient's chart.
   ii. Shut device off to drain when recording ICP value and obtaining tracing
   iii. Document ICP and Cerebral Perfusion Pressure (CPP) every hour and PRN
   iv. Fluid may be removed but never instilled
   v. All fluid filled ICP monitoring devices shall have the transducer air/fluid interface leveled at the Foramen of Monroe (2 fingers breadths above the ear)
   vi. Do not attach flush devices to the ICP monitoring system
   vii. All ICP monitoring devices shall have sterile, occlusive dressing at insertion site

k. Neurological: Comatose Patients in the ICU

i. Comatose and pharmaceutically paralyzed patients shall have their eyes taped shut with non-allergic tape to prevent corneal abrasion or injury unless otherwise ordered. Obtain an order to administer lubricating eye ointment to both eyes.

l. Neurological: Neuromuscular Blockade (NMB): ICU
   i. Assess patient per Online Skills Peripheral Nerve Stimulator.

D. Standards of Care I.2: Assessment Cardiovascular System Review:
   1. Cardiovascular System Review
      a. Cardiovascular symptoms
      b. Assess the following:
         i. heart sounds in all auscultatory areas; note regular or irregular
         ii. Nail Bed color
         iii. Check capillary refill
         iv. Check edema location and grade
         v. Palpate bilateral peripheral pulses: radial and dorsalis pedis
         vi. skin temperature
         vii. A presence of cardiovascular implantable electronic devices i.e., permanent pacemaker or defibrillator
   2. Cardiovascular: Detailed System Review
      a. All patients admitted to ED, ICU, and Telemetry shall have the following assessed on admission initial shift, and reassessment.
         i. Heart sounds note S1,S2 or presence of abnormal sounds
         ii. Cardiac rhythm
         iii. Jugular venous distension
      b. Pacemaker Temporary
         i. Check temporary transvenous/epicardial pacer stimulation and sensitivity thresholds every shift. Check thresholds with physician for patients with underlying complete heart block or extreme bradyarrhythmias. Assess the following:
            1) Type
            2) Function
            3) Percent paced
            4) Connection status i.e., on or off
            5) Presence of atrial, ventricular or both wires
            6) Mode
            7) Rate
            8) Output settings
            9) Site, dressing
            10) Side effects i.e., coughing of hiccups, or muscle twitching
            11) Distal pulses for transvenous femoral site
      c. Lead Placement and Rhythm interpretation for ED, ICU, and Telemetry; this includes PCU patients with Telemetry orders
         i. Standard lead selection shall be leads II and V1. V1 shall be used to assess Supraventricular Tachycardia's, Bundle Branch Blocks, and wide QRS complexes
         ii. Cardiac rhythm ECG shall be monitored continuously unless otherwise ordered.
         iii. A six (6) second ECG strip shall be recorded, interpreted and posted in the patient's chart on:
            1) Admission
            2) Transfer
            3) At the beginning of the shift and per unit specific policies and procedures
            4) As needed with rhythm and rate changes
            5) Alarms shall be set per the Clinical Alarm Management policy

6) Heart rate alarms shall be set 10-20 beats above or below the patient's baseline heart rate.
7) The following shall be documented in the electronic health record (EHR), if present:
   a) Ventricular heart rate
   b) Lead interpreted
   c) Wave form measurements of the following:
      i) PR Interval
      ii) QRS Interval
      iii) QT Interval
   d) Presence of ectopic beats
   e) Documentation of the following is recommended but not required:
      i) ST segment elevation or depression
      ii) Morphology of P waves and T waves
      iii) presence of U waves

iv. ED: Cardiac Monitoring
1) All patients requiring cardiac monitoring shall be placed on a cardiac monitor on arrival to the unit
2) All patient requiring cardiac monitoring shall be transported with an ECG monitor and RN

v. ICU: Cardiac Monitoring
1) All patients shall be placed on a cardiac monitor on arrival to the unit
2) All patients shall be transported with an ECG monitor and RN

vi. Telemetry: Cardiac Monitoring
1) All patients shall be placed on a cardiac monitor as outlined in the Management of Telemetry Patients unit specific policy.
2) PCU patients with Telemetry admission orders shall follow the requirements outlined in Telemetry unit specific policy.
3) All patients shall be transported with an ECG monitor and RN unless otherwise ordered. Review the following unit specific policies:
   a) Management of Telemetry Patients
   b) Admission and Discharge Criteria

vii. Medically Monitored Lead Placement and Rate Monitoring
1) Standard lead selection shall be leads II and V1
2) The monitor technician (MT) shall record and analyze a six (6) second strip on:
   a) Admission, At the beginning of the shift
   b) As needed with rate changes or new ectopic beats
3) The MT shall communicate the analyzed strip to the primary RN or designee
4) The Unit Secretary or designee identified by the Nurse Manager or relief charge RN will post the strips in the appropriate patient chart.

d. Invasive Pressure Monitoring Lines (Arterial, Pulmonary Artery, and Central Venous Pressure (CVP).)

i. Alarms
1) All invasive pressure lines must be monitored with alarms on.
2) All arterial line alarms shall be set according to the parameters and limits specified in the physician orders. If the physician orders do not address limits, alarms shall be set based on systolic pressure.

3) Pulmonary artery lines shall be set according to the diastolic parameter and shall be set 10 mm/Hg above and below the diastolic pressure.
4) CVP/RA alarms shall be set at "Mean" with limit set per physician order or 50% above and below baseline when port is not being used for infusions.

ii. Invasive Pressure Line Maintenance
1) Transducers shall be leveled to and maintained at the phlebostatic axis (supine or prone position), 4th intercostal space, ½ anterior-posterior diameter of the chest for all pressure measurements.
2) All pressurized transduced indwelling catheters shall be maintained with a flush bag pressurized at 300 mm/Hg with normal saline.
a) 2 unit per mL concentration heparin flush bag if ordered by physician
3) The flush bag shall be assessed for adequate volume every shift and PRN. Change bag every 4 days and when empty.
4) Needleless system shall be used for drawing blood from all invasive lines.
5) A safety transfer device shall be used when filling blood tubes.
6) All arterial and pulmonary artery catheters shall be attached to a transducer.
7) All transduced lines shall have pressure waveforms continuously displayed on the bedside monitor.
8) All transduced lines shall have accuracy of the system checked by performing a square waveform test at the beginning of each shift and any time the system is disturbed (e.g. blood draw).
9) Patient shall be positioned supine, head of bed (HOB) between 0-60 degrees, lateral position 20, 30 or 90 degrees or supine for all pulmonary artery pressure (PAP), pulmonary artery occlusion pressure (PAOP) and central venous pressure (CVP) measurements. Patient shall be stabilized 5-15 minutes after a position change before readings are obtained.
10) Obtain PAP/PAOP/CVP measurements from a graphic tracing at end-expiration Q shift and PRN using a simultaneous ECG tracing to assist with proper waveform identification.

e. Pulmonary Artery Catheter Monitoring
i. Cardiac Output (CO) shall be measured at least every 4 hours and PRN

E. Standards of Care I.3: Assessment Pulmonary System Review
1. Pulmonary: System Review
a. Assess the following:
i. Oxygen delivery devices
ii. Oxygen flow/FiO2
iii. Respiratory Symptoms
iv. Respirations
v. Respiratory Pattern
vi. Chest Motion
b. Auscultate breath sounds, all lobes
c. Assess the following if present:
i. Sputum amount, color, and consistency
ii. Cough
iii. Artificial airway, tubes, and drains
2. Pulmonary: Detailed System Review
a. Pulmonary: Chest Tubes
i. Assess the following:

1) Insertion location
    a) Palpate insertion site for crepitus, document if present
2) Dressing condition
3) Color and consistency of drainage
4) Amount of suction or gravity drain i.e., water seal
5) Suction chamber fluid level
6) Water seal chamber fluid level, presence of air leak, tidling
7) Complications i.e., air leaks, indications of bleeding etc.

b. Pulmonary: Chest Tube Nursing Interventions as outlined in the following:
    i. Chest Tube Management Procedure
    ii. Online Skills Chest Tube: Closed Drainage Systems
c. Pulmonary: Bi-Level Positive Airway Pressure (BiPAP) Assessment
    i. Patients receiving BIPAP shall have skin assessed as follows:
        1) Area under headgear
        2) Bridge of nose, around perimeter of mask and along course of headgear straps
            a) Ensure mask has a tight seal
    ii. Place patient in a room near the nurse's station when possible
    iii. Elevate head of bed 30 degrees unless contraindicated
    iv. Remove BIPAP mask when patient is eating or drinking to prevent aspiration as tolerated
    v. Readjust mask as appropriate to maintain oxygenation parameters as ordered and for patient comfort
    vi. Provide communication equipment, i.e. picture boards
    vii. Monitor continuous pulse oximetry and respiratory rate per physician's order
        1) Ensure continuous pulse oximetry is ordered for patients on Telemetry
d. Pulmonary: Artificial Airway
    i. The RN is primarily responsible for ensuring the tracheostomy tube is secured.
    ii. Patients with tracheostomy tubes shall have a tracheal change set and an extra tracheostomy tube of the same size readily available at their bedside.
    iii. Manual self-inflating resuscitation bags shall be used in the adult patients with endotracheal tubes (ETT) or tracheostomy patients for temporary ventilation whenever patient cannot be effectively ventilated by his/her own efforts.
    iv. Two licensed health care providers are required when taping, manipulating, or cutting an endotracheal tube.
    v. Trach care shall be done every shift and PRN by a licensed nurse or Respiratory Care Practitioner (RCP).
        1) Trach care shall include evaluation and cleaning of the site
            a) Trach holders shall be changed PRN by a licensed nurse or RCP with the assistance of a second healthcare provider
        2) Disposable inner cannula shall be changed every shift and PRN by the RN or RCP
    vi. The head of the bed will be elevated 30 degrees unless contraindicated
    vii. Oral care will be provided every 2-4 hours
e. Artificial Airway Nursing/Mechanical Ventilation Interventions
    i. Ensure ICU and Telemetry patients with mechanical ventilation have continuous pulse oximetry.
    ii. Ensure continuous pulse oximetry is ordered and monitored on patients with tracheotomies on Telemetry.

iii. Verify mechanical ventilation settings every shift and PRN with changes
1) Assess tidal volume with routine ~~vitals~~ assessments in ICU and PRN with changes in condition
iv. Ensure ICU patients with mechanical ventilation have continuous end tidal carbon dioxide ($EtCO_2$) monitoring (preferred).
v. Collaborate with respiratory therapy to assess patient's readiness for extubation daily except for patients receiving paralytic agents, ICP monitoring, pressure control inverse ratio ventilation, and/or immediate post-op open heart surgery
1) Stop all sedation prior to 0800 between 0800 and 1000
2) Assess readiness to extubate
a) Patient is awake and calm with a Richmond Agitation Sedation Scale (RASS) of 3 to 4
b) Obtain rapid shallow breathing index (RSBI) as appropriate for RCP
c) Initiate spontaneous breathing trials as appropriate
i) Monitor patient for signs of fatigue
ii) Continue for up to 2 hours or as ordered
vi. Collaborate with physician regarding patient's readiness to extubate
vii. Monitor patient for signs of weaning failure during all weaning trials
1) Notify the physician if patient is unable to reach or maintain physician set goals.
viii. Ensure ETT placement is confirmed with a chest x-ray.
ix. Documentation of oral endotracheal tube placement shall be in cm at the lip line. Make every adjustment to an ETT with the aid of an RCP or additional RN.
x. Perform oropharyngeal suctioning prior to making adjustments to the ETT.
xi. Standard oral endotracheal tube position shall be changed (from side to side) every 24 hours.
xii. Auscultate and document after any ETT repositioning or manipulation.
1) Never re-tape, move, or adjust an ETT without assistance.
xiii. Suction patient only when necessary and do NOT instill normal saline while suctioning unless necessary.

f. Pulmonary: Passy Muir Speaking Valve
i. Requires a physician order for application
ii. Initial application and evaluation shall be completed by Speech Therapy
iii. Tracheostomy cuff must be deflated prior to the application of the Passy Muir

g. Pulmonary: Respiratory Procedures
i. Nasotracheal/Orotracheal suctioning requires a physician order except in the ICU
ii. Nasal airway (trumpet) may be used per RN/RCP discretion for patient comfort or airway protection

F. Standards of Care1.4: Assessment Gastrointestinal (GI) System Review
1. GI: System Review
a. Assess contour of abdomen
b. Assess for nausea and/or vomiting
c. Auscultate for presence of bowel sounds in all four quadrants
d. Assess bowel function including passing flatus or last stool
e. Assess for the presence of tubes and drains. If present, assess type and location
i. Confirmation of placement, and drainage description
ii. Check tube placement for drainage and insertion site integrity
iii. Assess type of formula, rate, residual amounts

iv. Assess condition of nares and mucosa (check for inflammation and excoriation)

f. Assess for the presence of ostomies. If present, assess condition of stoma and surrounding skin.

i. Document nursing ostomy interventions in the medical record

G. Standards of Care 1.5: Assessment Genitourinary (GU) System Review

1. GU: System Review

a. Assess urine color and clarity, frequency, and voiding difficulties

b. Assess for bladder distension

c. Assess external anatomy/perineum as applicable

d. Dialysis vascular access, if present

i. Type

ii. Location

iii. Patency i.e., presence of thrill and bruit

iv. Site

v. Dressing

e. Assess for presence of tubes/drains/ostomies, if present

i. Document nursing ostomy interventions in the medical record

2. GU: Nursing Interventions

a. Use bladder scanner to assess for urinary retention

b. Urinary catheter, indwelling

i. Insertion

1) Pericare shall be performed prior to urinary catheter insertion

2) Urinary catheters should be inserted only when necessary and left in place only for as long as necessary.

3) If urine analysis or urine culture is ordered, obtain the urine specimen at the time of catheter insertion

ii. Preexisting urinary catheters

1) If patient is admitted with a preexisting urinary catheter it should be removed and a new urinary catheter should be inserted.

iii. Maintenance

1) Assess and consult with a physician for the need, indwelling catheter daily.

a) Other methods of urinary drainage such as condom catheter drainage, suprapubic catheterization, external catheters and intermittent urethral catheterization should be considered as alternatives to indwelling urethral catheterization.

2) Urinary catheter care should be performed every shift and PRN (i.e., after bowel movement)

a) Document care provided in the EHR

3) Ensure drainage tube is secured with hospital approved securement device, i.e. Statlock

4) Ensure the tamper evident seal is intact

5) Ensure the drainage system does not touch the floor and is without dependent loops

6) Ensure the drainage bag is not overfilled

7) Urinary catheters should be changed every 28 days.

c. Discontinuation

i. Review the patient's medical record for an order to discontinue the urinary catheter.

1) If a patient has discharge orders and there is no order to discontinue the urinary catheter, contact the discharging physician.

ii. Discontinue the urinary catheter per the Urinary Catheter: Indwelling Catheter Removal Procedure
iii. If patient is unable to void 2 hours after the urinary catheter is removed:
1) Verify the bladder volume using a bladder scanner, document the volume in the medical record
2) If patient has discharge orders, notify the discharging physician (do not discharge the patient)
a) Time urinary catheter removed
b) Bladder volume
iv. Document the following in the medical record after removing the urinary catheter:
1) Amount of urine in urinary drainage bag
2) Time catheter removed
3) Condition of the catheter
4) Patient's response to the procedure
5) Unexpected outcomes related to the removal of the urinary catheter
v. Document the time the patient voids after the removal of the urinary catheter, color and amount of urine and unexpected outcomes in the medical record.

3. Dialysis In-Patients Nursing interventions
a. Weigh all patients receiving peritoneal or hemodialysis daily prior to 0600
b. Only dialysis staff shall access dialysis catheters except with a physician order, See TCMC Central Venous Access Devices Procedures.
c. Do not use the extremity in which a fistula or graft is placed for peripheral IV, blood pressure measurements, invasive monitoring or blood draws without a physician order.
i. Place an information sign above the head of the patient's bed to communicate the extremity with the dialysis access to other members of the health care team.
ii. Maintain bed rest for all patients with femoral dialysis access catheters. The head of the bed may be elevated per the patient's request or comfort.

H. Standards of Care 1.6: Assessment Musculoskeletal System Review
1. Musculoskeletal System Review
a. Assess the following:
i. Extremity movement
ii. Extremity strength
iii. Gait/ mobility appropriate for age
iv. Presence of joint or musculoskeletal abnormalities, if applicable
v. Full range of motion against gravity, some to full resistance of all extremities, if applicable
b. Musculoskeletal System Abnormality Review
i. Presence of assistive devices

I. Standards of Care 1.7: Assessment Integumentary System Review
1. Integumentary System Review shall be performed as outlined in the Skin and Wound Care Policy

J. Standards of Care 1.8: Assessment Psychological/Social
1. Psychosocial assessment shall consist of the following:
a. Coping
b. Affect/Behavior
c. Social Service (SS) Referral Reason
d. Distress
e. Stressors
f. Support/Coping Interventions
2. Psychological/Social: Nursing Interventions

a. In ordered to promote family centered care, the nurse shall:
   i. Introduce bedside health care providers to the patient/family.
   ii. Review visitation and unit policies with patient/family on admission and as needed.
   iii. Assess and then verify with patient/family age appropriate needs.
   iv. Assess and then verify patient/family ability to understand and participate in the plan of care.
b. Promote patient/family centered care
   i. Discuss expectations and collaborate with patient/family
   ii. Encourage patient/family to ask questions
   iii. Encourage patient and/or their family to participate in their plan of care.
   iv. Request the assistance of Case Managers and Social Services
c. Promote patient independence in Activities of Daily Living (ADL)
d. Promote comfort measures by:
   e. Pharmacological and nonpharmacological
f. Patients shall be informed of their responsibilities upon admission and as necessary thereafter. These responsibilities include: providing information, asking questions, following instructions, accepting consequences, following rules and regulations, showing respect and consideration, and meeting financial commitments.

K. Standards of Care: Infusion Therapy
1. Central venous lines shall be assessed as outlined in the PCS Central Venous Access Devices Procedure
2. Peripheral IV site shall be assessed:
   a. On admission
   b. Initial shift assessment
   c. The following shall be assessed:
      i. IV insertion date and time
      ii. IV access type
      iii. IV site and condition
      iv. Patency
      v. Dressing type and condition
      vi. Document drainage if present
      vii. Infiltration score
      viii. Phlebitis score
3. Maintenance or continuous infusion shall be monitored every 2 hours, PRN and prior to transfer to another nursing unit/department
4. Infusion Therapy: Nursing Interventions
   a. Peripheral IV's are removed upon unresolved complications such as phlebitis, pain or malfunction.
   b. Peripheral IV dressings are changed every 7 days and PRN.
   c. Document initials and date IV started directly on the dressing.
   d. Pre-hospital IV starts shall be discontinued and restarted within 24 hours of admission.
   e. Rotate IV insertion sites
   f. IV site shall be discontinued immediately and restarted with patient's complaint of persistent discomfort or signs and symptoms of the following:
      i. Infiltration
         1) Skin at site blanched, cool to touch with or without pain
      ii. Inflammation
      iii. Pallor
      iv. Phlebitis
         1) Erythema at site with or without pain
         2) Pain at site with erythema and/or edema
         3) Streak formation, palpable, cord of any size

v. Bleeding at insertion site
vi. Leaking of IV solution at insertion site
vii. Pain

g. IV solutions and tubing shall be changed as follows:
i. Change every 4 days
1) All IV tubing
2) Add-on devices (neutral displacement connector (MicroClave), anti-reflux, extension set, etc.) and with tubing change
3) Commercially prepared solutions, if the bag is spiked once with initial start
4) Piggyback tubing (back flush with a minimum of 10 mL before and after each piggyback

h. Change every 24 hours
i. All IV solutions mixed by pharmacy or nursing, unless manufacturer's
1) Expiration recommends less than 24 hours (examples: Lipids or lipid containing products, neutral displacement connector, anti-reflux, extension set, etc. and with tubing change).

5. Label IV tubing change date sticker indicating date tubing is to be changed using numerical day and month.
6. Label IV solutions with date and time IV solution hung.
7. Dressings shall be changed when damp, loose, soiled, or whenever dressing prevents direct visualization of the site.
8. Infusion pumps shall be used per TCMC Infusion Pump-Infusion System with Guardrails.
9. A separate site shall be used for research study drugs per TCMC Investigational Drugs Policy.
10. Needleless components added to IV administration sets shall be changed every 4 days unless contaminated or a catheter-related infection is suspected or documented.
11. Port Protector
a. Place a port protector on all unused central venous and peripheral line injection port(s) and at the lowest port of the IV tubing if used frequently for intravenous pushes (IVP) or intermittent infusions
b. Port protector shall be used on IV tubing ports for patients with central and peripheral lines receiving mainline infusion.
c. Apply a new port protector
i. Every time a port protector is removed
ii. Every 8 hours with routine IV flushing
iii. PRN IV flushing

VI. NURSING PROCESS:

A. Standard of Care: Assessment
1. The RN shall ensure all adult patients have a general system review in all systems completed. Detailed system assessments shall be completed as indicated by the patient's condition.

B. Standard of Care: Diagnosis
1. The RN shall review the data obtained from the patient's assessment, history, and information documented by the interdisciplinary team to identify outcomes to develop the patient's plan of care (POC) on admission, every shift, on transfer to another nursing unit, and PRN.
2. RNs shall review the data collected by Advanced Care Technician (ACT)'s and Licensed Vocational Nurse (LVN)s to develop the patient's POC.

C. Standard of Care: Outcome Identification
1. The RN shall use the information obtained from Standard of Care: Assessment and Standard of Care: Diagnosis to identify appropriate patient outcomes every shift and PRN.

D. Standard of Care: Planning

1. The RN shall use the outcomes identified in Standard of Care: Outcome Identification and the physician orders to develop an individualized patient POC. The POC shall prescribe interventions that which may be implemented to attain expected outcomes.

E. Standard of Care: Implementation
   1. A RN shall implement the interventions identified in the POC and ensure task delegated to unlicensed assistant personnel are assigned appropriately and completed.

F. Standard of Care: Evaluation
   1. A RN shall evaluate the patient's progress toward obtaining their outcomes in the POC every shift and PRN.
   2. Emergent and urgent changes in the patient's assessment shall be communicated to physicians as soon as possible per TCMC policy.
   3. Non-emergent and/or not urgent changes in patient's assessment shall be communicated during physician rounds or as soon as possible within the shift the changes were identified.

G. Standard of Care: Documentation
   1. All shift assessments, focus reassessments, PRN assessments and/or care provided will be documented after completion of the care in a timely manner.
   2. When it is not possible to document shift assessments, focus reassessments, PRN assessments and/or care provided due to unforeseen circumstances such as urgent or emergent situations, changes in assignment or increased patient acuity, document the nursing care and assessment as soon as reasonably able to do so.
   3. Reasonable and a timely manner may be defined as within 4 hours after completion of assessments or care provided.

VII. ADDENDUM:

A. Obstetrical Patients Receiving Care on Non-Obstetric Nursing Units

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Addendum A
For Obstetric Patients Receiving Care on Non-Obstetric Nursing Units

I. **GENERAL NURSING ASSESSMENT**

A. Antepartum patients are assessed for vaginal bleeding, leaking of amniotic fluid, presence of fetal movement pelvic pain/pressure and uterine contractions/cramping/tightening as part of the initial shift assessment and reassessment throughout the antepartum period.
   1. Notify the obstetrician for any positive symptom or decline in status

B. Fetal heart monitoring:
   1. L&D nurse will perform fetal monitoring as ordered by the obstetrician

C. Postpartum assessment is performed with the initial shift assessment and reassessment throughout the postpartum period
   1. Postpartum Assessment:
      a. Fundal height in relation to the umbilicus (-3, -2, -1, at umbilicus, +1, +2, +3)
      b. Fundal position in relation to the umbilicus (left, midline, right)
      c. Fundal Tone (firm, boggy, firm after massage)
      d. Bladder Distention (absent or present)
      e. Lochia Color (rubra, alba or serosa)
      f. Lochia Amount (none, scant, light, moderate, heavy or excessive)
      g. Lochia Description (clots, foul odor or other)
      h. Perineal Description (edema, episiotomy/laceration gaping, episiotomy/laceration well approximated, perineum intact, hematoma, hemorrhoids, varicosity or other)
      i. Perineal Interventions
      j. Cesarean Section Incision Description
      k. Cesarean Section Dressing
      l. Breasts Postpartum (engorged, filling, full, painful, reddened, soft, or tender)
      m. Nipples Postpartum (bleeding, blisters, cracked, everted, flat, intact, inverted, painful, or reddened)
      n. Treatment to Breasts/Nipples
      o. Patient Affect Postpartum (anxious, cheerful, cooperative, hostile, passive, sad, withdrawn or other)
      p. Amount of time breast pumping on the right and left side

D. For antepartum and postpartum patients with hypertension assess the following:
   1. Gestational hypertension symptoms (blurred vision, double vision, epigastric pain, headache, loss of vision, seizure activity, spots before eyes/flashing, tinnitus, vertigo or visual disturbances)
   2. Edema
   3. Left and right knee reflex
   4. Left and right arm reflex
   5. Clonus
   6. Clonus number of beats

E. In the event of an obstetrical hemorrhage, dial 66 from an in-house phone and call a Code Maternity and Rapid Response.

F. Patients with Magnesium Sulfate infusion see: Magnesium Sulfate, Administration in Obstetric Patients.

G. Notify the Obstetrical provider if:
   1. Temperature is greater than 38°C
   2. HR is greater than 110 beats per minute
   3. Systolic BP is greater than 140mmHg and/or Diastolic BP is greater than 90mmHg
      a. If known hypertension diagnosis, Systolic BP greater than or equal to 160mmHg and/or Diastolic BP greater than or equal to 110mmHg
   4. RR is greater than 25 breaths per minute or less than 12 breaths per minute
   5. Headache not relieved with medication with or without vision changes

H. Lactation Service Consult order for lactating patient's

Tri-City Medical Center	Patient Care Services
PROCEDURE:	**STROKE CODE, IN-HOUSE**
Purpose:	To outline the procedure for prompt recognition and interventions for a patient with signs and symptoms of stroke or worsening stroke
Supportive Data:	Rapid response is critical for a prompt diagnosis and appropriate intervention.
Equipment:	Stroke Admission Packet

A. POLICY:

1. The primary Registered Nurse (RN) shall call the Rapid Response Team (RRT) if a patient is experiencing new or worsening "stroke-like" symptoms and will obtain a blood glucose level via point of care blood glucose meter prior to RRT arrival.
2. The RRT will do a patient assessment with the National Institute of Health Stroke Scale (NIHSS) detailed stroke scale assessment on the patient when they arrive on the unit.
3. The RRT will initiate the in-house stroke code by dialing 66 from the patient's room and inform the Public Branch Exchange (PBX) operator that there is an in-house stroke code on the unit and will give the patient's room number.
4. The RRT or designee will order the In House Stroke Code power plan
5. **RRT will page Neurologist on call at (760)~~940~~ 631-3002**
    - ~~4.~~**i. RRT to give the on call Neurologist the patient's NIHSS score and patient assessment details so the neurologist can verify the stroke code is appropriate and any further orders.**

~~5.~~**6.** PBX Operator:

a. The operator shall call a stroke code overhead and will page the Stroke Team which consists of the following staff members:
    - i. Computed Tomography technologist
    - ii. Lab phlebotomist
    - iii. Stroke coordinator
    - iv. Radiology technologist

~~6.~~**7.** The primary nurse or designee will contact the on call hospitalist at (760) 966-2499 and inform the hospitalist of the in-house stroke code.

~~7. The hospitalist will come assess the patient and if the hospitalist agrees with the stroke code, the hospitalist will contact the neurologist on call at (760)940-3002~~

~~a. The Stroke Code will continue unless cancelled by the hospitalist on call.~~

~~b. If the hospitalist does not arrive to assess the patient in a timely manner, the RRT will page the neurologist and continue on with the stroke code.~~

~~i. RRT to give the on call Neurologist the patient's NIHSS score and patient assessment details so the neurologist can verify the stroke code is appropriate and any further orders.~~

8. The RRT**/Intensive Care Unit (ICU) RN** and/or Stroke Coordinator serve as the team leader:
    a. Evaluates timeline (time from symptom onset to intravenous thrombolytic administration should be less than 4.5 hours). Determines eligibility for thrombolytics in collaboration with Neurologist
    b. Performs patient NIHSS and patient assessment
    c. Orders necessary tests/labs –
        - i. In House stroke code order set which includes:
            1) STAT (Computed Tomography) CT Brain/Head Stroke Alert and CT Angio Brain and Neck.
                a) No need to wait for creatinine level or **glomerular filtration rate** (GFR) prior to scans

Department Review	Clinical Policies & Procedures Committee	Nursing Leadership	Division of Neurology	Pharmacy & Therapeutics Committee	Medical Executive Committee	Administration	Professional Affairs Committee	Board of Directors
8/15, 02/21, **0724**	05/14, 9/15, 05/17, 08/21, **08/24**	05/14, 09/15, 05/17, 10/21, **09/24**	11/14, 04/18, 11/21, **09/24**	09/21, **10/24**	11/14, 05/18, 01/22, **10/24**	02/22, **11/24**	01/15, 06/18, n/a	01/15, 06/18, 02/22

2) Prothrombin Time (PT), Partial Thromboplastin Time (PTT), International Normalized Ratio (INR), **Comprehensive Metabolic** ~~Chemical~~ Panel (**CMP**~~Chem 12~~) and Complete Blood Count (CBC) **with Auto Diff**

d. Discusses possible treatment options that may be ordered by physician with patient/family
e. Accompanies monitored patient to CT scanner as indicated by acuity
f. Administers thrombolytic agent if ordered
g. Monitors for signs/symptoms of bleeding, neurologic deterioration, changes in vital signs

9. The Neurologist shall collaborate with RRT and the attending physician when available during the stroke code.
10. Primary nursing:
    a. Administers supplemental oxygen as ordered
    b. Assesses vital signs
    c. Monitors cardiac rhythm (in monitored areas) and pulse oximetry
    d. Ensures intravenous (IV) access (prefer 18-20 g in antecubital or forearm)
    e. Considers/secures second IV as indicated for thrombolytic administration
    f. Administer thrombolytics as ordered **(ICU RN only)**
11. Lab Phlebotomist:
    a. Draws stat blood tests as ordered, draws PT/INR, PTT, **CMP**~~Chem 12~~ and CBC **with Auto Diff**
    b. Immediately delivers to lab and hands off to technologist
12. Laboratory technologist:
    a. Performs testing
        i. If specimen hemolyzes, immediately initiate redraw. Notify RRT 760-802-3727 or physician of delay.
    b. Call results directly to the RRT (760)802-3727, and document the communication in Cerner.
        i. Time from order to communication of results should be less than 45 minutes
13. Pharmacist:
    a. RRT or designee will notify pharmacy at extension 3012 possible ~~tPA~~ **thrombolytic** candidate, Pharmacy then contacts ICU/ED Pharmacist based on their shift and availability.
    b. Pharmacy will verify inclusion/exclusion criteria and weight while awaiting ~~tPA~~**thrombolytic** orders from the Neurologist.
    c. Pharmacist to contact the provider as soon as possible to clarify any exclusions.
    ~~d. When tPA **thrombolytic** is ordered, pharmacy will prepare and send tPA **throymbolytic** to RRT RN~~
    ~~e.~~**d.** ~~In case of emergency, t~~The stroke team will override ~~tPA~~ **thrombolytic** from **the ICU**~~Emergency Department~~'s **Automatic Dispensing Cabinet** and mix it based on Tri-City Medical Center (TCMC) policy and procedure.
14. Assigned radiology transporter:
    a. Transports patient to CT scanner
15. Radiology technologist:
    a. Verifies with RN that Stroke Code notification was received.
    b. Prepares the CT scanner for emergent head CT as per imaging protocol
    c. Performs the CT.
        i. Time from order to completion of test should be less than 25 minutes for patients eligible for thrombolysis.
    d. CT alerts Radiologist to stroke code
16. Radiologist:
    ~~17.~~**a.** ~~a.~~ Reads CT immediately and contacts the on-call neurologist with results: (Time from completion of test to communication with Neurologist should be less than 20 minutes for patients eligible for thrombolysis.)

~~18.~~**17.** Care of the patients eligible for thrombolytics per physician orders:
- a. Continuous cardiac monitoring
- ~~b. Place second peripheral IV.~~
- ~~c.~~**b.** Monitor blood pressure every 15 minutes.
  - i. Acceptable blood pressure obtained prior to administration of ~~tPA~~ **thrombolytic** is a systolic blood pressure less than (<) 185 **mmHg** and diastolic blood pressure of less than (<) 110 **mmHg**.
- ~~d.~~**c.** If patient is eligible for ~~tPA~~ **thrombolytic** treatment informed consent will be obtained by the Neurologist.
  - i. Signed consent is not required for administration of ~~tPA~~**thrombolytic**.

~~19.~~**18.** Administer ~~tPA~~ **thrombolytic** per physician order~~:~~**, see Thrombolytic Administration Guidelines.**
- ~~a. Recommended TOTAL dose of tPA is 0.9 mg/kg, not to exceed 90 mg.~~
- ~~b. Reconstitute and administer tPA as follows:~~
  - ~~i. Reconstitute tPA with 100 mL of sterile water for injection utilizing the transfer device to create a solution with a concentration of 1 mg/mL.~~
  - ~~ii. With a second Registered Nurse, verify the weight based dose of tPA.~~
  - ~~iii. Remove from the vial any quantity drug in excess of that specified for patient treatment~~
  - ~~iv. Withdraw the bolus amount (bolus dose is 10% of total dose) and administer IVP over 1 minute.~~
  - ~~v. Program the infusion pump to deliver the remaining dose over 60 minutes.~~
  - ~~i. Once the chamber is near empty, hang 50 ml normal saline and infuse at the same rate to ensure the patient receives the complete dose.~~

~~20.~~**19.** Monitoring During and Post Thrombolytic Administration:
- a. Continuous cardiac monitoring.
- b. Monitor blood pressure:
  - i. Every 15 minutes for 2 hours
  - ii. Then every 30 minutes for 6 hours
  - iii. Then every 1 hour for 16 hours.
  - iv. Notify Physician immediately for systolic blood pressure greater than (>) 180 and/or diastolic blood pressure greater than (>) 105.
- c. Monitor neurological status every:
  - i. 15 minutes for 2 hours
  - ii. Then every 30 minutes for 6 hours
  - iii. Then every 1 hour for 16 hours.
  - iv. Neurological assessment should include: level of consciousness, orientation, response to commands, motor scoring of upper and lower extremities, language, dysarthria.
  - v. If the patient develops a severe headache, acute hypertension, nausea, vomiting or has worsening neurological examination notify, ~~P~~physician immediately.
  - vi. Monitor temperature and maintain normothermia.
  - vii. Monitor blood sugar and maintain euglycemia.

~~21.~~**20.** The Nursing Leader/designee shall assist RRT to assure patient is placed on the appropriate nursing unit.
- a. Patients receiving ~~tPA~~ **thrombolytic** shall be assigned to a bed in the Intensive Care Unit (ICU)
- b. All other patients~~,~~ are assigned based on acuity or physicians order~~, to 4P or Telemetry~~
- ~~c. Whenever possible patients must be in the monitored/camera beds on 4P~~

~~22.~~**21.** Post-Stroke Code Care; per Stroke Care Set (unless superseded by physician orders):
- a. Continuous cardio respiratory monitoring
- b. Blood pressure recording
- c. Monitor temperature

d. Monitor neurological status~~:~~ **including** NIH Stroke Scale~~ and neuro checks~~
e. Monitor peripheral circulation and end-organ perfusion (skin temperature, capillary refill, peripheral pulses, and urinary output).
f. Monitor for signs of bleeding or other complications if ~~tPA~~ **thrombolytic** administered.
~~g. Maintain two (2) intravenous lines (if tPA administered).~~
~~h.~~**g.** Monitor blood studies.
~~i.~~**h.** Measure intake and output

~~23.~~**22.** Documentation:
a. RRT shall document events in the patient's medical record. (NOTE: Obtaining CT scan ~~and labs have~~**has the** highest priority and should not be delayed unless absolutely necessary for patient safety.)

~~C. RELATED DOCUMENT(S):~~
~~1. Stroke Code; In-House Algorithm~~

~~D.~~C. **REFERENCES:**
1. ~~Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke A~~**Early Management of Acute Ischemic Stroke: A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association 10.2019**~~ssociation Powers, WJ, Rabinstein AA, Ackerson, T, Adeoye, OM et al. Originally published30 Oct 2019Stroke. 2019;50:e344–e418~~
2. Scientific Rationale for the Inclusion and Exclusion Criteria for Intravenous Alteplase in Acute Ischemic Stroke. Stroke 2016;47:581-641

Tri-City Medical Center
Oceanside, California

ADMINISTRATIVE
DISTRICT OPERATIONS

ISSUE DATE: 12/14 **SUBJECT:** 340B Outpatient Drug Pricing Program

REVISION DATE: 05/19, 12/22 **POLICY NUMBER:** 8610-295

Administrative Content Expert Approval:	~~11/2110/2309~~/24
Administrative Policies & Procedures Committee Approval:	~~12/2104/2409~~/24
Pharmacy & Therapeutics Committee Approval:	~~03/2206/24~~10/24
Organizational Compliance Committee Approval:	~~10/22~~ n/a
Medical Executive Committee Approval:	n/a
Administration Approval:	~~12/22~~11/24
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	12/22

A. **PURPOSE:**~~–~~

1. ~~To define the processes that allows~~ **This document contains descriptions of the policies and procedures used at** Tri-City Medical Center (TCMC) to ~~purchase pharmaceuticals at discounted prices for its qualified outpatients that is consistent~~**maintain compliance** with the ~~Human Resources Services Administration (HRSA)~~ 340B ~~Drug Discount Purchasing~~ Program ~~as defined by~~. **If any modifications are made to** the ~~enactment Section~~ 340B ~~of the Public Health Service Act.~~**Program by any governing body, this document shall be updated, and all Tri-City departments impacted by the updates shall be notified.**

B. **BACKGROUND:**

1. Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign an agreement with the Secretary of Health and Human Services. This agreement limits the price manufacturers may charge certain covered entities for covered outpatient drugs. The resulting program is called the 340B Program. The program is administered by the Office of Pharmacy Affairs (OPA), a part of the federal Health Resources and Services Administration **(HRSA)**/Department of Health and Human Services **(DHHS)**.-
2. Upon registration on the OPA database as a participant in the 340B Program, entities agree to abide by specific statutory requirements and prohibitions.-

~~C. DEFINITIONS:~~

~~1. 340B Eligible Covered Entity: The statutory name for facilities and programs eligible to purchase discounted drugs through the Public Health Service's 340B Drug Pricing Program~~
~~2. Covered Outpatient Drugs: The category of drugs for which manufacturers must pay rebates to state Medicaid agencies under the Medicaid rebate program and give 340B discounts to covered entities under the 340B program. The 340B statute defines "covered outpatient drug" by referencing the definition found in the Medicaid rebate statute at 42 USC §1396r-8(k) (2). As of November 2012, OPA explained on its website that the 340B program generally covers the following outpatient drugs:~~
~~a. Prescription drugs approved by the Food and Drug Administration (FDA)~~
~~b. Over-the-counter (OTC) drugs dispensed pursuant to a prescription~~
~~c. Biological products that can be dispensed only by prescription (other than vaccines)~~
~~d. FDA-approved insulin~~

3. Non-covered outpatient drugs: These include vaccines, plain large volume parenterals, anesthetic gases, saline flushes, contrast agents, compounding supplies, bundled items, floor stock and outsourced sterile products.
4. Inpatient status: TCMC determines that patients have an inpatient status according to Admission Discharge and Transfer (ADT) data.
5. Outpatient status: TCMC determines that patients have an outpatient status according to ADT data.

D.C. 340B POLICY STATEMENTS:

1. As a 340B Covered Entity, Tri-City Medical Center's**TCMC's** policy, as a system of 340B Covered Entity, is to comply with all applicable rules and regulations governing its participation in the 340B Drug Pricing Program.
2. Due to the complex nature of the 340B program, Tri-City TCMC has adopted specific policies and procedures governing program monitoring, testing, and maintenance.
3. These written policies and procedures will be updated and approved by TCMC Tri-City Medical Center staff through relevant /committees whenever there is a clarification or change to the 340B Program. Otherwise, the policy will be reviewed and approved annually.
4. This policy manual applies to the following Tri-City Covered Entity: Medical Center**TCMC (DSH050128), its**Tri-City Medical Center Covered Entity (DSH050128) and child sites, and contract pharmacy(ies).
5. TCMC will keep records for six (6) years.

D. DEFINITIONS:

1. Definitions of terms may be found on Apexus 340B Glossary of Terms.
   a. https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-glossary-of-terms.pdf

340B Drug Pricing Program (340B Program or 340B): The federal program codified at 42 U.S.C. § 256b that requires drug manufacturers participating in the Medicaid Drug Rebate Program to limit the price manufacturers may charge certain Covered Entity for Covered Outpatient Drugs.

Actual Acquisition Cost (AAC): Amount paid by Tri-City for drugs, less any discounts, rebates, and price or trade concessions.

Annual 340B Recertification Period (Recertification Period): Annual window in which 340B Covered Entity must recertify to OPA their eligibility to remain in the 340B Drug Pricing Program and continue purchasing Covered Outpatient Drugs at discounted 340B prices. Each Tri-City Authorizing Official is responsible for submitting the recertification.

Authorizing Official: An individual who represents a Tri-City Covered Entity and is fully authorized to legally bind that Covered Entity to a relationship with the federal government. This individual has knowledge of the practices and eligible programs and is also the person whom the OPA will comply with all applicable contact in the event of compliance requests, integrity evaluations, and audits. Each Tri-City Authorizing Official must be at least CEO/CFO/COO/President/Vice President level.

1. Child Site: A outpatient clinic/department of a Covered Entity eligible to participate in the 340B Program that appears or will appear on that Covered Entity's most recently filed Medicare cost report as a reimbursable facility (i.e., meets the provider-based rules and requirements of the 340B drug discount program as set forth in these policies and procedures.as promulgated by CMS).

1. TCMC meets all Contract Pharmacy: A retail pharmacy under an arrangement to fill retail prescriptions for Eligible Patients on behalf of a Tri-City Covered Entity using that Covered Entity's 340B drugs.

2. Covered Entity: Facilities and programs eligible to purchase discounted drugs through the 340B Program eligibility requirements.TCMC's as defined by 42 U.S.C. §

256b(a)(4) and appear on the OPA Database covered entity listing is complete, accurate, and correct. .

a. TCMC is a public non-profit corporation which is formally granted governmental powers by a unit of State or local government

- **Covered Outpatient Drugs (340B drugs)**: A covered outpatient drug, as defined by Section 1927(k) of the Social Security Act and summarized as an FDA-approved prescription drug, an over-the-counter (OTC) drug that is written on a prescription, a biological product that can be dispensed only by a prescription (other than a vaccine), or FDA-approved insulin. A Covered Entity should have documentation demonstrating how the Covered Entity interprets and applies the definition of Covered Outpatient Drug with respect to GPO use.
- **Director of Pharmacy**: Managing pharmacist in charge of the pharmacy department at Tri-City's Covered Entity with responsibility for all pharmacy activities, including the performance of duties by pharmacy department employees.
- **Diversion**: Covered Entity are required to prevent the resale or transfer of drugs purchased at 340B prices to non-eligible patients/facilities. Failure to ensure that medications are used by the appropriate patients constitutes Diversion.
- **Eligible Patient**: An individual who is a 340B-Eligible Patient of a Covered Entity as described by 61 Fed. Reg. 55156 (Oct. 24, 1996).
- **Group Purchasing Organization (GPO)**: An organization that represents and organizes a group of hospitals to evaluate and select pharmaceutical products. Using the purchasing power of the entire group, the GPO negotiates contracts that are more favorable than a single organization could achieve.
- **Health Resources Services Administration (HRSA)**: The agency of the United States Department of Health and Human Services that is primarily responsible for overseeing the 340B Drug Pricing Program.
- **NDC**: A National Drug Code as described by Section 510 of the Federal Food, Drug, and Cosmetic Act.
- **Office of Pharmacy Affairs (OPA)**: The division of HRSA that is responsible for overseeing the day-to-day activity of the 340B Drug Pricing Program.
- **Office of Pharmacy Affairs Information System (OPAIS) Database**: Online database used to perform 340B enrollment management tasks. The OPA Database also lists all eligible Covered Entity approved for participation in 340B. The OPA Database can be accessed at https://340bopais.hrsa.gov/home.
- **Orphan Drug Exclusion**: The HRSA interpretive rule dictating that a drug designated by the FDA as "a drug for a rare disease or condition" pursuant to Section 526 of the Federal Food, Drug, and Cosmetic Act may not be purchased at 340B prices unless the manufacturer approves 340B-like pricing for that drug.
- **Patient Status**: For purposes of the 340B Program, a patient is determined to be either inpatient or outpatient based on the most recent cost reporting period that ended before the calendarorder to admit.
- **Third Party Administrator**: Entity that assists Covered Entity in establishing and operating 340B Contract Pharmacy arrangements.
- **Pharmacy Services Agreement**: Agreement between a Tri-City Covered Entity and either a Third Party Administrator or Contract Pharmacy detailing the pharmacy services provided and duties in administering Covered Entity's Contract Pharmacy program.
- **Prime Vendor Program**: A federal program that allows participating Covered Entity to obtain drug prices below the 340B ceiling price as negotiated by OPA's designee.
- **Provider Panel**: A list of eligible prescribers that are either employed by the Covered Entity or under contractual or other arrangements with the Cover Entity
- **Purchaser**: Tri-City staff member at each Covered Entity responsible for monitoring the accumulations of prescription drugs in the Split-Billing Software and placing 340B drug orders with the Wholesaler.

~~Quarterly Enrollment Period: Four 15-day periods (Jan. 1-15, Apr. 1-15, July 1-15, Oct. 1-15) where safety net hospitals and other healthcare providers can enroll themselves, their outpatient facilities, or their contract pharmacies in the 340B Program. Providers are eligible to obtain 340B pricing the quarter involved, TCMC had a disproportionate share adjustmentafter they enroll (e.g., enroll Jan. 1-15 for an effective start date of Apr. 1).~~

~~Third Party Administrator (TPA)/ Split Billing Software: Software program designed to track Covered Outpatient Drug utilization and convert Wholesaler drug purchase orders into separate 340B, GPO, and WAC drug orders.~~

~~Wholesale Acquisition Cost (WAC): The price paid by a wholesaler (or direct purchasers) for drugs purchased from the drug's manufacturer or supplier.~~

~~Wholesaler: A drug wholesaler is an organization that provides drugs to Entity, serving as the distributor between the drug manufacturer and the Entity.~~

~~B. PROCESS OR PROCEDURES~~

E. 340B ELIGIBILITY

1. ~~Tri-City Medical Center~~TCMC will meet the requirements of 42 USC §256b(a)(4)(L) to be eligible for enrollment in, and the purchase of drugs through, the 340B Program.

~~The 340B Program is administered by the Office of Pharmacy Affairs (OPA), a part of the federal Health Resources and Services Administration (HRSA)/Department of Health and Human Services. Participate ration on the OPA Database as a participant in the 340B Program, Tri-City agrees to abide by specific requirements and prohibitions.~~

~~Covered Entity Eligibility~~

~~a.~~2. ~~Each Tri-City Covered Entity shall periodically review and confirm its 340B eligibility. The Tri-City Covered Entity are~~~~Medical Center~~ TCMC is eligible to participate in the 340B Program because ~~each~~ it meets the following ~~four(three?)~~ eligibility criteria as established by Section 602 of the Veterans Health Care Act of 1992:

   ~~i.~~a. ~~Tri-City Covered Entity~~~~Medical Center~~ TCMC is a California Health Care District – (Tri-City Health District) that maintains a contract(s) with a State or local government to provide healthcare services to low-income individuals who are not entitled to Medicare or Medicaid benefits~~;~~

   ~~ii.~~b. ~~Tri-City Covered Entity~~~~Medical Center~~TCMC is a Disproportionate Share Hospital (DSH)~~)~~ with a DSH percentage greater than 11.75~~ percent~~%~~,~~

   c. ~~TCMC~~~~Tri-City Covered Entity that is a DSH~~~~Medical Center~~TCMC does not obtain ~~covered outpatient drugs~~c~~C~~overed o~~O~~utpatient d~~D~~rugs through a group purchasing organization (~~group purchasing organization~~GPO) or other group purchasing arrangement~~, except~~, except in accordance with GPO Policy Release.

3. ~~Tri-City Medical Center~~TCMC will maintain ~~auditable~~ records for audits (6-year time frame minimum), policies, and procedures related to the definition of a covered outpatient drug and the use of a GPO that is consistent with the 340B statute and Social Security Act.
4. ~~Tri-City Medical Center~~TCMC will define covered outpatient drugs based on section 1927(k) of the Social Security Act ~~and~~, summarized as an FDA-approved prescription drug, an over-the-counter (OTC) drug that is prescribed~~written on a prescription~~, a biological product that can be dispensed only by a prescription (other than a vaccine), or FDA-approved insulin.
5. ~~Tri-City Medical Center~~TCMC ensures that 340B OPAIS Database is complete, accurate, and correct for all 340B eligible locations including the parent entity, off-site locations, and contract pharmacy(ies). Each eligible location will be registered with and approved by OPA and appear on the OPA Information System (OPAIS) 340B Database. ~~Tri-City Medical Center~~TCMC shall ~~periodically~~ review and confirm its 340B eligibility periodically.
   a. ~~Tri-City Medical Center~~TCMC will inform HRSA immediately of any changes ~~as follows~~ to the following:
      - 340B Medicaid Information

- Medicare Disproportionate percentage less than 11.75%
  - TCMC will stop the purchase of 340B drugs in this event.
- 340B OPAIS Database Information

b. ~~Tri-City Medical Center~~TCMC's Authorizing Official will complete the online change request as soon as a change in eligibility is identified.

c. If for any reason, ~~Tri-City Medical Center~~TCMC determines that it no longer meets the eligibility requirements for participation in the 340B Program, it shall cease purchasing drugs at 340B rates and inform HRSA of its ineligibility. ~~Tri-City Medical Center~~TCMC shall also notify any party who purchases 340B drugs on ~~Tri-City Medical Center~~TCMC's behalf to cease purchasing drugs at 340B rates.

d. ~~Tri-City Medical Center~~TCMC will work with the contract pharmacy's Third-Party Administrator (TPA) to submit any changes regarding the c~~C~~ontract ~~P~~pharmacy information to the OPAIS Database.

F. 340B ENROLLMENT

1. Enrollment Period is as follows: Four 15-day periods (Jan. 1-15, Apr. 1-15, July 1-15, Oct. 1-15) where safety-net hospitals and other healthcare providers can enroll themselves, their outpatient facilities, or their contract pharmacies in the 340B Program. Providers are eligible to obtain 340B pricing the quarter after they enroll (e.g., enroll Jan. 1-15 for an effective start date of Apr. 1).

~~iii.~~ ~~.~~

~~Additionally, in order to participate in the 340B Program, each Covered Entity must be registered with and approved by the OPA and appear on the OPA Database.~~

~~Procedure:~~

~~iv.~~2. Annually, during the relevant Recertification Period established by the OPA, ~~each Tri-City Covered Entity~~Medical Center TCMC shall recertify its enrollment data listed on the OPAIS Database in accordance with ~~group purchasing organization (GPO) Policy Release~~the Patient Protection and Affordable Care Act and the OPA's recertification guidelines.

3. On a quarterly basis, ~~each Tri-City Covered Entity's~~Tri-City Medical Center~~TCMC~~'s Authorizing Official shall meet with pertinent 340B personnel to review the Covered Entity's OPA Database registration and evaluate whether any changes or updates should be made. At a minimum, the following information will be verified:
   a. Covered Entity name and address~~.~~
   b. Medicaid provider number(s)
   c. National Provider Identifier(s) (NPI)~~(s)~~
   d. Authorizing Official Information
   e. Primary Contact Person Information
   f. Covered Entity meets the minimum DSH percentage~~.~~
   g. Local/State government contract is in place~~.~~
4. Authorizing Official must be at the level of CEO/CFO/President/Vice President.

G. CHILD SITE ELIGIBILITY

~~Child Site Eligibility~~

1. ~~Tri-City Medical Center~~TCMC may only use 340B drugs in provider-based locations. ~~P~~Provider-based status is governed by 42 C.F.R. § 413.65. In order for a provider-based department to be eligible to use ~~Tri-City Medical Center~~TCMC's 340B-priced drugs, it:
   a. ~~, it (1) m~~Must appear or will appear under a reimbursable cost center on ~~Tri-City Medical Center~~TCMC's ~~the Covered Entity's~~ most recently filed Medicare Cost Report~~; and (2)~~
   b. ~~m~~Must administer or prescribe outpatient drugs to Eligible Patients.
2. In the event that a provider-based location meets the eligibility requirements but does not yet appear on the most recently filed Medicare Cost Report, ~~Tri-City Medical Center~~TCMC shall utilize 340B Drugs at that location in concordance with its Eligible

Patient definition and enroll the location in the next available Enrollment Period after the location does appear on the Medicare Cost Report. When enrolling on the OPAIS Database, each department ~~utilizing 340B drugs~~ located outside ~~the four walls~~ of the Covered Entity's main hospital building that is utilizing 340B drugs must enroll as a unique Child Site with a unique 340B ID, even if two or more such departments share the same mailing address.

~~b. Procedure:TCMC uses 340B only in outpatient clinics that are registered on the OPA database (or within the four walls of the parent), fully integrated into the Disproportionate Share Hospital (DSH), and reimbursable on the most recently filed cost report.~~

~~a. TCMC complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity.~~

~~b. TCMC maintains auditable records demonstrating compliance with the 340B requirement described in the preceding bullet.~~

~~c. Prescriber is on the hospital's eligible prescriber list as employed by the entity, or under contractual or other arrangements with the entity, and the individual receives a health care service from this professional such that the responsibility for care remains with the entity.~~

~~d. 340B drugs are used in outpatient facilities that appear as reimbursable on the most recently filed Centers for Medicare and Medicaid Services (CMS) cost report and are registered on the OPA database (or within the four walls of the parent).~~

3. ~~TCMC~~**Annually, within 30 days of submission of the filed Medicare Cost Report, relevant ~~key~~ 340B key stakeholders for that Covered Entity, including but not limited to the Authorizing Official, Director of Pharmacy, Purchaser, and a Mmedical Rrecords representative, shall evaluate the Cost Report to identify any new departments of the Covered Entity that may be eligible to participate in the 340B Program and determine whether those departments should be registered.**
4. **Criteria considered when identifying new departments shall include:**
    a. **Does the department administer outpatient drugs onsite or generate discharge prescriptions?**
    b. **Does the department have patients that meet the 340B Eligible Ppatient definition ~~discussed in Section II.C.? an~~?d**
    c. **Does the department appear as a reimbursable cost center on the most recently filed Medicare Cost Report?**
5. **If a new department meets the criteria for enrollment as a 340B Child Site of ~~a~~ Tri-City ~~Covered Entity~~Medical Center, the ~~Covered Entity's~~ Authorizing Official, or a competent ~~party acting on behalf~~representative of the Authorizing Official, shall complete the 340B online registration process during the next 340B quarterly enrollment period in accordance with the procedures established by the OPA for Child Site enrollment. ~~After enrollment, the Covered Entity must notify the Tri-City Director of Contracting and Resource Utilization.~~**
6. **In the event that ~~a Tri-City Medical Center~~TCMC~~Covered Entity~~ intends to close or relocate a Child Site, or if it intends to change the way a Child Site's costs appear on Covered Entity's CMS cost report, the Covered Entity's Authorizing Official and Director of Pharmacy shall evaluate whether changes should be made to the ~~Covered Entity's~~ OPA Database registration. All such changes shall be submitted in accordance with OPA policy~~, as discussed in Section d~~. The OPA Database can be accessed at the following web address: https://340bopais.hrsa.gov/home.**

H. CONTRACT PHARMACY(IES)

1. ~~Tri-City Medical Center~~**TCMC carves out Medicaid Fee-for-Service (MFFS) for all contract pharmacy(ies).**
2. ~~Tri-City Medical Center~~**TCMC will have a signed contract pharmacy services agreement between ~~Tri-City Medical Center~~TCMC and the contract pharmacy prior to registration on**

340B OPAIS.

3. ~~Tri-City Medical Center~~TCMC's legal counsel has reviewed the contract and verified that all federal, state, and local requirements have been met.
4. ~~Tri-City Medical Center~~TCMC has contract pharmacy oversight, monitoring procedure developed, approved, and implemented.
5. ~~Tri-City Medical Center~~TCMC's Authorizing Official or designee completes the online registration during one of four registration windows.

I. PATIENT ELIGIBILITY

~~Patient Eligibility~~

1. 340B drugs shall be distributed only to Eligible Patients of ~~Tri-City Medical Center~~TCMC. According to 61 Fed. Reg. 55156, 55157 (Oct. 24, 1996), an individual is an Eligible Patient of ~~Tri-City Medical Center~~TCMC only if:
    a. ~~Tri-City Medical Center~~TCMC has established a relationship with the individual, such that ~~Tri-City Medical Center~~TCMC maintains records of the individual's health care.~~ ; and~~
    ~~e. Patient is an outpatient at the time medication is administered/dispensed.~~
    ~~f. TCMC does not purchase covered outpatient drugs using a GPO (as described above)~~
    a. ~~TCMC has elected to carve in Medicaid. TCMC bills Medicaid per The~~
    b. ~~i~~The ~~i~~individual receives health-care services from a health-care professional who is either employed by ~~Tri-City Medical Center~~TCMC or provides health-care under a contractual or alternate arrangement (e.g., referral for consultation) such that responsibility for the care provided remains with ~~Tri-City Medical Center~~TCMC.
2. An individual will not be an Eligible Patient of ~~Tri-City Medical Center~~TCMC if the only health-care service provided by ~~Tri-City Medical Center~~TCMC to the individual ~~i~~was the dispensation of a drug for subsequent self-administration or administration in a home setting. Evidence of a ~~Tri-City Medical Center~~TCMC employment relationship alone is insufficient to determine 340B patient eligibility. ~~Tri-City Medical Center~~TCMC employees ~~that~~who receive drugs from ~~a~~ ~~Tri-City Medical Center~~TCMC must meet the same Eligible Patient criteria to qualify for 340B pricing.
3. All 340B drugs can ~~only~~ be provided only to eligible outpatients. Patient Status is either inpatient or outpatient based on the most recent order to admit. The individual must be considered an outpatient in ~~Tri-City Medical Center~~TCMC's electronic health record (EHR) information system at the time medication is administered/dispensed. Medications administered to inpatients are not eligible for 340B pricing. In the event that an Eligible Patient's admission status at the time of the administration/dispensation is retroactively changed from outpatient to inpatient, ~~Tri-City Medical Center~~TCMC still considers this administration 340B-eligible. ~~Tri-City Medical Center~~TCMC will maintain auditable records demonstrating compliance with the outpatient status requirement.

~~Procedure:~~

4. When applicable, ~~Tri-City Medical Center~~TCMC utilizes Split-Billing software to determine Patient Eligibility. The Split-Billing software:
    a. Verifies the prescriber is listed on the Covered Entity's Provider Panel
    b. Verifies the drug administration/dispensation location ~~was~~is a 340B-eligible location~~;~~
    c. Determines if the individual is a Medicaid patient; and
    d. Determines Patient Status based on a live feed of ~~electronic~~ EHR Admission Discharge Transfer (ADT) orders ~~feed~~ and a daily transmission of EHR and billing transaction files~~.~~
5. At least quarterly, ~~Tri-City Medical Center~~TCMC 340B Personnel shall meet to discuss any updates, changes, or clarifications to the 340B patient eligibility rules and their

applicability to ~~Tri-City Medical Center~~TCMC. To the extent that changes or clarifications are necessary, ~~Tri-City Medical Center~~TCMC shall take appropriate action to update its software systems, as well as its policies and ~~policies~~procedures, to reflect those changes or clarifications. These discussions shall encompass software systems for in-house pharmacies, contract pharmacies, and ~~entity-owned~~ retail pharmacies owned by the Covered Entity.

~~OPA Database Profile~~

~~It is Tri-City' ongoing responsibility to notify the OPA of any changes with any Covered Entity's 340B Program that necessitate updates to its profile on the OPAIS Database. If for any reason the Covered Entity determines that it no longer meets the eligibility requirements for participation in the 340B Program, it shall cease purchasing drugs at 340B rates and inform the OPA of its ineligibility. The Covered Entity shall also notify any party who purchases 340B drugs on the Covered Entity's behalf to cease purchasing drugs at 340B rates.~~

~~Procedure~~

~~On a quarterly basis, each Tri-City Covered Entity's Authorizing Official shall meet with pertinent 340B Personnel to review the Covered Entity's OPA Database record to identify and report any necessary updates to the OPA. Tri-City Covered Entity will review existing enrollments and terminate any enrollments for facilities or pharmacies that have been closed.~~

~~The Covered Entity shall update its OPA Database information in accordance with the following two processes:~~

~~In the event the Covered Entity becomes aware that its OPA Database information is incorrect at a time outside the Annual 340B Recertification Period, the Authorizing Official, or other 340B Personnel acting on behalf of the Authorizing Official, shall submit an online change request to the OPA updating the relevant information. The Covered Entity shall also work with the contract pharmacy's Third-Party Administrator (TPA) to submit any changes regarding the Covered Entity's Contract Pharmacy information to the OPA~~

J. ~~In the event the Covered Entity becomes aware that its OPA Database information is incorrect during the Annual 340B Recertification Period, the Authorizing Official, or 340B Personnel acting on behalf of the Authorizing Official, shall update the relevant information during recertification. The Covered Entity shall also work with the Third Party Administrator to submit any updates to the Covered Entity's Contract Pharmacy enrollments to the OPA at that time.~~PREVENTION OF DUPLICATE DISCOUNTS

1. ~~42~~ USC §256b(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. ~~Tri-City Medical Center~~TCMC does have mechanisms in place to prevent duplicate discounts.
2. ~~Tri-City Medical Center~~TCMC has answered "yes" to the question, "Will the covered entity dispense 340B purchased drugs to Medicaid patients?" on 340B OPAIS.
3. ~~Tri-City Medical Center~~TCMC elected to carve in for California state.
4. ~~Tri-City Medical Center~~TCMC has chosen to elect both carve in and carve out status for selected child site locations shown on OPAIS 340B Database.
5. ~~Tri-City Medical Center~~TCMC's contract pharmacy(ies) carve out Medicaid fee-for-service (FFS).

~~C.~~K. INVENTORY MANAGEMENT

~~Procurement~~

1. As a participant in the 340B Program, drugs purchased must be limited to outpatient use and provided only to eligible patients. ~~Tri-City Medical Center~~TCMC utilizes a replenishment model with a virtual inventory in hospital mixed-use~~d~~ and separate physical 340B inventory for ~~Oncology Infusion Center~~clean use.~~-~~
2. ~~TCMCthroughbased onTCM2. Tri-City Medical Center~~TCMC purchases mixed-use inventory (according to eligible accumulations).~~-~~
3. ~~3. Tri-City Medical Center~~TCMC replenishment drug order(s) are placed according to eligible accumulations.
4. ~~4. Tri-City Medical Center~~TCMC's 340B drugs shall be replaced on an 11~~-~~digit NDC-to-NDC basis. NDC~~-~~to~~-~~NDC replacement also requires ~~Tri-City Medical Center~~TCMC to purchase from the same manufacturer; therefore, ~~Tri-City Medical Center~~TCMC shall not alternate between manufacturers when replenishing 340B drugs unless required to do so due to drug availability issues.
5. ~~5.~~ In the event of a drug shortage, ~~Tri-City Medical Center~~TCMC may purchase through a separate w~~W~~holesaler or manufacturer. ~~Tri-City Medical Center~~TCMC shall use a Split-Billing software vendor to track the accumulation of 340B-eligible drugs and determine when replacement 340B drugs should be purchased. ~~. Oncology Infusion Center uses a separate physical inventory since it is 100% clean 340B outpatient location. 6.~~ In exceptional circumstances, when 11-digit NDC replenishment is not possible, ~~Tri-City Medical Center~~TCMC will replenish at the 9-digit NDC level and maintain auditable records demonstrating that the appropriate amounts are replenished from the same manufacturer, regardless of the package size. In addition, accumulations will not be transferred over from 11-digit NDC to 9-digit NDC that is ordered for the shortage.~~-~~
~~10.~~6. ~~Procedure:~~On a nightly basis, ~~Tri-City Medical Center~~TCMC's EHR and billing transaction software shall send patient encounter data to the Split-Billing software vendor containing sufficient information to confirm that the patient and the drug provided satisfy 340B eligibility requirements. Patient encounter data may include, but is not limited to:
   ~~a. Information regarding the patient receiving the drug.~~
   ~~b. Name and NDC of the drug administered/prescribed.~~
   ~~c. Patient status at the time of administration/dispensation~~
   ~~d. Quantity administered/prescribed.~~
   ~~e. Name of the prescribing provider~~
   ~~f. Date and time the drug was administered/prescribed.~~
   a. ~~Location of where the drug was administered/prescribed.~~Information regarding the patient receiving the drug
   b. Name and NDC of the drug administered/prescribed
   c. Patient status at the time of administration/dispensation
   d. Quantity administered/prescribed
   e. Name of the prescribing provider
   f. Date and time the drug was administered/prescribed
   g. Location of where the drug was administered/prescribed
~~6.~~7. The Split-Billing software vendor shall electronically assign each individual drug dispensed to a 340B, wholesale acquisition cost (WAC), GPO, or other applicable account, based on NDC, using a CDM to NDC match, and according to applicable rules and regulations, including the GPO Prohibition.
~~7.~~8. The Purchaser shall rely upon these accumulations to generate purchase orders through the Wholesaler. Drugs will only be ordered under the 340B account when the NDC being ordered has accumulated a full package size. If a drug accumulation has not reached a full package size for 340B, the drug should be purchased from the respective ~~Covered Entity's~~~~Tri-City Medical Center~~TCMC WAC account as DSH. Inpatient drugs shall be ordered under ~~that Tri-City Medical Center~~TCMC~~Covered Entity~~'s GPO account.
~~8.~~9. The Purchaser shall review all 340B deliveries and compare the 340B order to the

Wholesaler invoice for both drug quantity and NDC discrepancies. In the event discrepancies exist, the Purchaser shall notify the Wholesaler. Any drugs purchased on the 340B account without proper supporting data should be returned to the Wholesaler, reversed in the Split-Billing software system, and repurchased from the WAC account.

~~9.~~10. ~~Tri-City Medical Center~~TCMC shall maintain auditable records of 340B-related transactions for a period of not less than six~~three~~ (63) years to demonstrate 340B compliance.

~~10.~~11. Direct Purchases

a. TCMC shall only purchase drugs directly from a manufacturer when the drug needed is not available through the Wholesaler. For any drugs purchased through a vendor other than the Wholesaler, TCMC's buyer shall contact the vendor to inquire about opening a 340B account to purchase 340B-priced drugs directly from that vendor.
b. In the event that a TCMC Outpatient Drug is not made available at 340B pricing by a manufacturer, TCMC shall notify the OPA in writing identifying the Covered Outpatient Drug(s) at issue, the manufacturer of the drugs, and the manner by which the affected TCMC was notified that 340B-pricing is not being offered.
c. When 340B pricing is not available for a Covered Outpatient Drug, TCMC shall purchase the affected drugs using a non-340B account (e.g. GPO or Prime Vendor account). At the Director of Pharmacy's professional discretion, TCMC may choose to purchase only quantities of drugs that are critical to patient care while TCMC awaits OPA action concerning its written notification; however, patient health and safety shall never be jeopardized in the interest of waiting for 340B-priced drugs to become available.
d. In any instance where a Tri-City Medical Center has to go outside of its typical procurement process to obtain a drug, TCMC should carefully document relevant patient encounter information and correspondence with vendors to provide support for 340B compliance in the event of an OPA audit. TCMC shall retain purchase orders for those transactions for at least six (6) years to demonstrate 340B compliance.
e. The Orphan Drug Exclusion does not apply to DSHs or Children's Hospital (PED) Covered Entity; therefore, DSH and PED may purchase drugs at 340B pricing for use on eligible patients regardless of the drug's Orphan status.

~~Tri-City Medical Center shall only purchase drugs directly from a manufacturer when the drug needed is not available through the Wholesaler. For any drugs purchased through a vendor other than the Wholesaler, Tri-City Medical Center's buyerthe affected Covered Entity's Purchaser shall contact the vendor to inquire about opening a 340B account to purchase 340B-priced drugs directly from that vendor.~~

~~In the event that a Tri-City Medical CenterCovered Outpatient Drug is not made available at 340B pricing by a manufacturer, Tri-City Medical Center shall notify the OPA in writing identifying the Covered Outpatient Drug(s) at issue, the manufacturer of the drugs, and the manner by which the affected Tri-City Medical Center was notified that 340B-pricing is not being offered.~~

~~When 340B pricing is not available for a Covered Outpatient Drug, the Covered EntityTri-city Medical Center shall purchase the affected drugs using a non-340B account (e.g. GPO or Prime Vendor account). At the Director of Pharmacy's professional discretion, the Covered EntityTri-City Medical Center may choose to purchase only quantities of drugs that are critical to patient care while the Covered EntityTri-City Medical Center awaits OPA action concerning its written notification; however, patient health and safety shall never be jeopardized in the interest of waiting for 340B-priced drugs to become available.~~

~~In any instance where a Tri-City Covered EntityMedical Center has to go outside of its typical procurement process to obtain a drug, the Covered EntityTri-City Medical Center should carefully document relevant patient encounter information and correspondence with vendors to provide support for 340B compliance in the event of an OPA audit. Tri-City Medical Center shall retain purchase orders for those transactions for at least sixthree (63) years to demonstrate 340B compliance.~~

~~The Orphan Drug Exclusion does not apply to Disproportionate Share Hospital (DSH) or Children's Hospital (PED) Covered Entity; therefore, DSH and PED may purchase drugs at 340B pricing for use on eligible patients regardless of the drug's Orphan status.~~

~~11.~~12. Non-340B Items and Bundled Drugs

a. TCMC does not interpret the following to meet the definition of Covered Outpatient Drugs:
   i. Vaccines
   ii. An OTC that is not written on a prescription
   iii. Bundled drugs/charges (such as anesthesia gases)
b. If a drug does not meet the definition of a Covered Outpatient Drug (e.g., bundled drugs, vaccines), TCMC will follow the GPO Prohibition guidelines.

~~Tri-City Medical Center does not interprets the following to meet the definition of Covered Outpatient Drugs:~~

~~Vaccines~~

~~An OTC that is not written on a prescription~~

~~Bundled drugs/charges (such as anesthesia gases)~~

~~If a drug does not meet the definition of a Covered Outpatient Drug (e.g., bundled drugs, vaccines), Tri-City Medical Center will follow the GPO Prohibition guidelines.~~

~~to not include bundled drugs. If a drug does not meet the definition of a Covered Outpatient Drug (e.g., bundled drugs, vaccines, insulin,), Tri-City is not bound by the GPO Prohibition rules and may use a GPO account to purchase the drug.~~

~~12.~~13. Loaned/Borrowed Drugs

a. TCMC's 340B drugs are for use on Eligible Patients only; however, in limited circumstances (e.g., emergent medical condition), drugs may be transferred from a TCMC's physical 340B inventory to a non-340B inventory.
b. TCMC shall transfer the affected medication and record the transfer in a borrowed drug transaction log identifying the date, time, and destination of the medication at issue. A replacement medication shall be transferred back to the TCMC's 340B inventory through a purchase on a non-340B and non-GPO account (e.g., Prime Vendor account, WAC account of the same NDC and quantity that was borrowed. The medication shall be returned as soon as possible.

~~Tri-City Medical CenterCovered Entity's 340B drugs are for use on Covered Entity's Eligible Patients only; however, in limited circumstances (e.g., emergent medical condition), drugs may be transferred from a Covered Entity'sTri-City Medical Center's physical 340B inventory to a non-340B inventory. and between Tri-City Covered Entity.~~

~~The Covered EntityTri-City Medical Center shall transfer the affected medication and record the transfer in a borrowed drug transaction log identifying the date, time, and destination of the medication at issue. A replacement medication shall be transferred back to the Covered Entity'sTri-City Medical Center's 340B inventory through a purchase on a non-340B and non-GPO account (e.g., Prime Vendor account, WAC (account) of the same NDC and quantity that was borrowed. The medication shall be returned as soon as possible.~~

~~13.~~14. Expired 340B Drugs

a. TCMC shall ensure that expired medications are not administered to TCMC patients. Consistent with TCMC's general pharmacy policy regarding inventory management, TCMC shall assess its medication inventory periodically and identify the extent to which any of its purchased 340B-priced drugs have expired. Expired 340B medications shall be returned to the Wholesaler and credited back to the 340B account from which the medication was purchased originally.
b. If the Wholesaler will not receive a return of expired medications and is issued a credit, the 340B medication shall be returned or destroyed through Inmar—a pharmaceutical reverse distributor. TCMC shall not purchase a replacement at 340B rates unless accumulation in the Split-Billing software is sufficient to justify that purchase.

~~Tri-City Medical Center shall ensure that expired medications are not administered to Tri-City Medical Center patients. Consistent with Tri-City Medical Center's general pharmacy policy regarding inventory managementreview, Tri-City Medical Center shall periodically assess its medication inventory and identify the extent to which any of its purchased 340B-priced drugs have expired. Expired 340B medications shall be returned to the Wholesaler and credited back to the 340B account from which the medication was originally purchased.~~

~~If the Wholesaler will not receive a return of expired medications and is issued a credit, the 340B medication shall be returned or destroyed through INMAR. Tri-City Medical Center shall not purchase a replacement at 340B rates unless accumulation in the Split-Billing software is sufficient to justify that purchase. pursuant to Section III above.~~

15. Procurement When Split-Billing System is Unavailable
    a. If the Split-Billing software system is unavailable to identify a TCMC's accumulation of 340B drugs, TCMC shall avoid purchasing drugs off of its 340B accounts until the system becomes available. To the extent that drug orders must be made during this period of time to ensure continued patient health, TCMC will limit its order to essential items until the system is available. When TCMC is unable to determine patient eligibility, these items will be placed on a non-340B and non-GPO account.
    b. However, in locations where only 340B patients are treated, drugs may be purchased using its 340B account during a time when the Split-Billing software is unavailable and when necessary to ensure patient health and safety. Similarly, locations where only inpatients are treated, drugs may be purchased using its GPO account during a time when the Split-Billing software is unavailable and when necessary to ensure patient health and safety.

~~If the Split-Billing software system is unavailable to identify a Tri-City Medical CenterCovered Entity's accumulation of 340B drugs, Covered EntityTri-City Medical Center shall avoid purchasing drugs off of its 340B accounts until the system becomes available. To the extent that drug orders must be made during this period of time to ensure continued patient health, Tri-City Medical Center will limit its order to essential items until the system is available. When Tri-City Medical Center is unable to determine patient eligibility, these items will be placed on a non-340B and non-GPO account. However, in locations where only 340B patients are treated, drugs may be purchased using its 340B account during a time when the Split-Billing software is unavailable and when necessary to ensure patient health and safety. Similarly, locations where only inpatients are treated, drugs may be purchased using its GPO account during a time when the Split-Billing software is unavailable and when necessary to ensure patient health and safety.~~

L. 340B COMPLIANCE

~~340B Compliance~~

1. Tri-City shall maintain compliance with the 340B Program at all times and take corrective actions ~~as may be~~if necessary as findings or issues arise.
2. To maintain compliance, ~~Tri-City Medical Center~~TCMC conducts a rigorous review of its 340B operations, including but not limited to:
    a. Annual review of all of the OPAIS Database information.
    b. Annual review of CMS Medicare Cost Report to validate a disproportionate share percentage in excess of 11.75%, if a DSH Covered Entity
    c. Annual review of California rules related to the 340B Program
    d. Monthly review of patient eligibility for TCMC, child sites and contract pharmacies to identify and prevent diversion to ineligible patients

    ~~Review of patient eligibility for all Covered Entity, child sites, and contract pharmacies~~
    e. Quarterly review of 340B Program performance to include program savings/revenue and benefits to uninsured/underinsured patients.
    f. Quarterly~~Monthly~~ review and update of Provider Panel files with Split-Billing software vendor.
    g. Split-Billing software maintenance (e.g., CDM-NDC mapping, location eligibility mapping, updates) as indicated.~~; and~~
3. Internal Audits
    a. It is ~~Tri-City Medical Center~~TCMC's policy to maintain a compliant and transparent system-wide 340B Program. In order to ensure ongoing compliance with relevant rules and regulations, ~~the Covered Entity~~~~Tri-City Medical Center~~TCMC shall monitor its 340B Program's compliance by conducting internal reviews and audits.

    ~~Procedure:~~
    b. On a monthly basis, ~~Tri-City Medical Center~~TCMC and/or a third party acting on its behalf shall conduct an internal audit~~testing~~ of patient eligibility compliance.
    c. ~~Utilizing Split-Billing software reports, EHR software, and any other relevant documentation, maintained by Covered Entity, Tri-City Medical Center~~TCMC shall review 340B drug utilization by NDC at the patient level using Split-Billing software reports, EHR software, and any other relevant documentation. ~~Tri-City Medical Center~~TCMC or a third party acting on its behalf shall review a minimum of thirty (30) patient samples from every month in which 340B utilization occurs. During each review, ~~Tri-City Medical Center~~TCMC shall confirm, at minimum:
        i. That the 340B drug in question was administered to a patient who has a medical record on file at ~~the Covered Entity~~~~Tri-City Medical Center~~TCMC;
        ii. That 340B drug in question was administered in an OPA-registered department of ~~Covered Entity~~~~Tri-City Medical Center~~TCMC;
        iii. The patient receiving 340B drugs was in outpatient status at the time the drug was dispensed.
        iv. That the practitioner who ordered the 340B drug is on the ~~Covered Entity's~~ active medical staff or under contractual agreement with ~~Tri-City Medical Center~~TCMC.

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        v. To the extent that the ~~Tri-City Medical Center~~TCMC determines that 340B drugs were administered to ineligible patients, ~~Tri-City Medical Center~~TCMC shall work to correct the accumulation.
        vi. ~~Tri-City Medical Center~~TCMC shall maintain written records of its

audit activity for a period of not less than six~~three~~ (63) years and shall make it available to OPA auditors upon the auditors' request.

4. **External Audits**
   a. **~~Tri-City Medical Center~~TCMC~~, at minimum on a bi-annual basis,~~ will conduct an independent external 340B audit at least biannually.~~.~~**
   ~~**The OPA recommends Covered Entity that utilizes Contract Pharmacies to conduct independent 340B audits on an annual basis.**~~
   ~~**Procedure:**~~
   b. **Independent audits shall, at a minimum, cover the following tasks:**
      i. **Patient eligibility verification, including GPO prohibition review~~.~~**
      ii. **Prescriber/ordering provider eligibility verification~~.~~**
      iii. **Verification of OPA Database record accuracy~~.~~**
      iv. **Review of ~~Tri-City Medical Center~~TCMC~~Covered Entity~~'s internal audits~~.~~**
      v. **Verification of compliance with this Manual's procedures; and**
      vi. **Interview staff on 340B Program requirements~~.~~**
   c. **~~Tri-City Medical Center~~TCMC shall ensure that it obtains written documentation of the methodology, findings, and recommendations of any independent audit of that Covered Entity's 340B Program.**
   d. **~~Tri-City Medical Center~~TCMC ~~The Covered Entity~~ will retain this documentation for no less than ~~three~~six (63) years.**
5. Medicaid ~~reimbursement requirements, and as TCMC has reflected its information~~ **Program Requirement**
   a. **~~Tri-City Medical Center~~TCMC shall carve-in their Medicaid patients from the 340B Program.**
   b. **~~Tri-City Medical Center~~TCMC will inform HRSA and provide a Medicaid provider number and/or NPI. ~~Tri-City Medical Center~~TCMC will not administer 340B drugs to eligible Medicaid patients until ~~the Covered Entity is~~ listed on the HRSA Medicaid Exclusion file.**
   c. **All claims for drugs purchased through the 340B drug program must have a UD modifier listed along with the HCPCS code and other required data elements billed via paper or electronically using CMS-1500 or UB-04 form related format.**
   ~~a.~~**d. ~~Tri-City Medical Center~~TCMC shall inform OPA immediately of any changes to its carve-in status and will make the appropriate changes** on the OPA website/Medicaid Exclusion File
      ~~a. TCMC informs OPA immediately of any changes to its information on the OPA website/Medicaid Exclusion File~~
   ~~i.~~**e.** Medicaid reimburses for 340B drugs per state policy and does not collect rebates on claims ~~from TCMC.~~ **for 340B-covered outpatient drugs.**
   f. ~~TCMC has systems/mechanisms~~**Annually, ~~Tri-City Medical Center~~TCMC shall verify all carved-in ~~Covered Entity~~ and internal controls in place ~~Child Sites~~ locations are listed appropriately in the OPA Database and are listed on the OPA Medicaid exclusion file.**
6. **GPO Prohibition**
   a. **Tri-City ~~Covered Entity~~Medical Center shall not administer Covered Outpatient Drugs purchased from a GPO account** to ~~reasonably~~**outpatients within the four walls of a ~~Tri-City Medical Center~~TCMC or a Child Site registered on the OPA Database, regardless of the service department.**
   b. **~~Tri-City Medical Center~~TCMC may administer drugs purchased from a GPO account to outpatients treated in a department outside the four walls of the ~~Covered Entity~~Tri-City Medical Center~~TCMC that is not registered on the OPA Database as a Child Site. ~~However, the GPO account used must be distinct from the account(s) used for inpatient GPO purchases at that Covered Entity.~~**

~~The GPO prohibition only applies to Tri-City 340B enrolled DSHs.~~

7. **Medical Staff**
    a. **As a component of meeting its obligation to** ensure ~~ongoing~~ compliance with ~~all 340B~~**the Eligible Patient definition, ~~Tri-City Medical Center~~TCMC shall maintain an accurate and up-to-date medical staff list of all ~~Tri-City Medical Center~~TCMC professionals who are eligible to administer and/or prescribe 340B drugs.**
    b. **On a quarterly~~monthly~~ basis, ~~Tri-City Medical Center~~TCMC will update Split-Billing Software provider list.**

M. CONTRACT PHARMACY PROGRAM

~~Contract pharmacy program~~

1. **~~Tri-City Medical Center~~TCMC has contracted with a ~~Third Party Administrator~~TPA to assist Tri-City in administering, establishing, and operating its 340B Contract Pharmacy program when applicable.~~ On behalf of TCMC, ~~T~~the ~~Third Party Administrator~~TPA may contract with retail pharmacies ~~on Tri-City Medical Center's behalf~~ that treat ~~Tri-City Medical Center~~TCMC patients such that those retail pharmacies may dispense 340B drugs ~~on Tri-City Medical Center's behalf~~ to ~~Tri-City Medical Center~~TCMC's Eligible Patients in accordance with HHS rules and regulations, including 75 Fed. Reg. 10272 (Mar. 5, 2010).**

~~Procedure:~~

~~b.~~2. **Eligible Contract Pharmacies are enrolled with the OPA pursuant to the following** requirements~~.~~**:**
    ~~b. TCMC has an internal audit plan adapted by the Internal Chief Compliance Officer and conducted annually.~~
    a. ~~TCMC~~~~Tri-City Medical Center~~**TCMC~~Covered Entity~~'s Authorizing Official or designee shall ensure that a signed Pharmacy Services Agreement is in place ~~between~~with the Contract Pharmacy ~~and the Covered Entity~~ and that ~~Tri-City Medical Center~~TCMC's legal counsel has reviewed and approved the Pharmacy Services Agreement prior to enrolling the Contract Pharmacy on the OPA Database. ~~Tri-City Covered Entity will ensure that the Pharmacy Services Agreement explicitly includes all of the Covered Entity locations that are contracted with the contract pharmacy.~~**
    b. **~~Tri-City Medical Center~~TCMC's~~The Covered Entity's~~ Authorizing Official, or 340B staff member acting on behalf of the Authorizing Official, shall enroll the Contract Pharmacy(ies) during the quarterly enrollment period following the execution of a Pharmacy Services Agreement. Enrollment shall be conducted through the online portal found at: https://340opais.hrsa.gov.home**
    c. **~~The~~~~Tri-City Medical Center~~TCMC's ~~Covered Entity's~~ Authorizing Official ~~and Third Party Administrator~~ shall ensure that the Contract Pharmacy registration request is certified online within 15 days of completing the online registration.**
    d. **~~Tri-City Medical Center~~TCMC's ~~The Covered Entity's~~ Director of Pharmacy or designee ~~and Third Party Administrator~~ shall ensure that any newly enrolled Contract Pharmacy does not begin dispensing ~~Tri-City Medical Center~~TCMC's 340B drugs prior to the Contract Pharmacy's effective date of enrollment on the OPA Database.**
3. **On an annual basis, ~~Tri-City Medical Center~~TCMC shall assess each Contract Pharmacy to ensure that they are meeting the 340B eligibility requirements, dispensing sufficient 340B drugs, and confirm that the OPA Database record is accurate.**

~~Contract Pharmacy Procurement~~

4. **~~Tri-City Medical Center~~TCMC has contracted with a ~~Third Party Administrator~~TPA when**

applicable to facilitate both the design and implementation of ~~each Covered Entity's~~ 340B Contract Pharmacy program.

a. ~~Each Covered Entity~~~~Tri-City Medical Center~~TCMC is responsible for 340B compliance at its Contract Pharmacies.
b. ~~-~~The ~~Third Party Administrator~~TPA uses a virtual inventory replenishment model for tracking Contract Pharmacy prescription accumulations.
c. The ~~Third Party Administrator~~TPA shall procure 340B drugs in accordance with the Pharmacy Services Agreement, executed between ~~Tri-City Medical Center~~TCMC and the ~~Third Party Administrator~~TPA.

~~Medicaid Requirement for Contract Pharmacy~~
~~Tri-City Covered Entity carve-out their Medicaid patients from the 340B contract pharmacy program.~~
~~Contract Pharmacy Audit~~

5. ~~Tri-City Medical Center~~TCMC shall review 340B drug utilization, by NDC, to the patient level. ~~Tri-City Medical Center~~TCMC or a third party acting on its behalf shall review a representative sample of each contract pharmacy of at least five (5) per pharmacy for every month in which 340B utilization occurs at a registered and invoicing Contract Pharmacy. In each review, ~~Covered Entity~~~~Tri-City Medical Center~~TCMC shall confirm, at minimum:
   a. That the retail prescription in question was filled for a patient who has a medical record on file at ~~the Tri-City Medical Center~~TCMC~~Covered Entity~~;
   b. That retail prescription in question was generated in an eligible department of ~~Tri-City Medical Center~~TCMC ~~the Covered Entity~~ that is registered on the OPA Database, or that the retail prescription in question was generated as the result of a written referral – documented in the patient's medical record – resulting from care received at an eligible department of ~~Tri-City Medical Center~~TCMC~~the Covered Entity~~.
   c. That the practitioner who wrote the prescription in question was an eligible provider ~~by~~for ~~Tri-City Medical Center~~TCMC ~~the Covered Entity~~
   d. To the extent that ~~the Tri-City Medical Center~~TCMC determines that 340B drugs were dispensed to ineligible patients, ~~Tri-City Medical Center~~TCMC shall notify the TPA~~Third Party Administrator~~ to reverse the ineligible claims.~~-~~
   e. ~~Tri-City Medical Center~~TCMC shall maintain written records of its audit activity for a period of not less than six~~three~~ (~~6~~3) years.

N. SELF-DISCLOSURES:

1. ~~This addendum contains Tri-City Medical Center~~TCMC's 340B policy regarding self-disclosure of a material breach of any 340B Program requirement. It is the policy of ~~Tri-City Medical Center~~TCMC to comply with all applicable rules and regulations governing its participation in the 340B Drug Pricing Program, including 340B diversion, GPO prohibition, and Medicaid duplicate discount requirements.
2. ~~c.~~ During annual recertification, ~~each Tri-City Medical Center~~TCMC~~Covered Entity~~ attests that it acknowledges its responsibility to contact ~~OPA~~HRSA as soon as reasonably possible if there is any ~~change in 340B eligibility or material breach greater than 5% by the hospital of any of the foregoing policies.TCMC acknowledges that if there is a~~ material breach of ~~the 340B requirements, TCMC may be liable to the manufacturer of the covered outpatient drug that is the subject of the~~ 340B requirement. ~~Tri-City Medical Center~~TCMC defines a material breach as a systematic violation~~, and depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.~~ and not as any one instance of non-compliance with a 340B Program requirement. A Covered Entity that discovers a 340B violation that constitutes a material breach must notify HRSA as soon

as reasonably possible while they move to correct the issue and should not limit its disclosure to the annual recertification period.

3. ~~**Tri-City Medical Center**~~**TCMC defines a material breach of compliance that would require self-disclosure as a violation(s) that exceeds 5% of total 340B purchases annually.**
4. **The** ~~The 340B~~ **program team**~~committee~~ will assess the violation, determine the actions, and communicate the information to the appropriate parties. **Violations identified through internal self- audits, independent external audits, or** ~~**otherwise**~~ **that otherwise meet or exceed this threshold, will be** ~~**immediately**~~ **reported immediately to HRSA and applicable manufacturers using the following self–disclosure report template: https://docs.340bpvp.com/documents/public/resourcecenter/ALL_Entities_Self_Reporting_340B_NonCompliance.pdf**
5. The 340B committee will maintain records of materiality assessments and of violations that led to manufacturer resolutions, correspondence and or formal self-disclosure process through HRSA.

~~a. Address the types of non compliance that warrant a report to OPA/manufacturer, records kept, documentation, and plan for corrective action~~

~~c. TCMC elects to receive information about the 340B Program from trusted sources.~~

~~E.~~O. RESPONSIBLE STAFF, COMPETENCY:

1. **The** TCMC 340B Compliance **Program**~~Committee~~ is tasked with oversight for 340B program integrity in alignment with HRSA/OPA (Health Resources and Services Administration/Office of Pharmacy Affairs) policy for the covered entity.
2. **Responsible** Members of the 340B ~~Committee~~**Program** include:
    a. Chief Financial Officer (CFO)
        i. Responsible as the principal officer and authorizing official in charge for compliance and administration of the program
        ii. Responsible for attesting to the compliance of the program in form of recertification
        iii. Responsible for communication of all changes to the Medicare Cost report regarding clinics or revenue centers of the cost report
    b. Director of Pharmacy
        i. Accountable agent for 340B compliance
        ii. Agent of the CFO and primary contact responsible to administer the 340B program to fully implement and optimize appropriate savings and ensure current policy statements and procedures are in place to maintain program compliance
        iii. Must maintain knowledge of the policy changes that impact the 340B program which includes, but not limited to, HRSA/OPA rules and Medicaid changes
        iv. Must coordinate constant knowledge of any change in clinic eligibility/information
        v. Responsible for documentation of policy and procedures
        vi. Assure compliance with 340B program requirements of qualified patients, drugs, providers, vendors, payors and locations
    c. Pharmacy 340B Coordinator/Pharmacy Buyer
        i. -Day--to--day manager of the program
        ii. Maintain system databases to reflect changes in the drug formulary or product specifications
        iii. Manage purchasing, receiving and inventory control processes
        iv. Continuously monitor product min/max levels to effectively balance product availability and cost-efficient inventory control
        v. Assure appropriate safeguards and system integrity

vi. Monitor ordering processes, integrating most current pricing from wholesaler, analyze invoices, shipping, and inventory processes
vii. Responsible for establishing three distribution accounts and maintaining those accounts; i.e., non-GPO account, 340B account, and GPO account
viii. Responsible for establishing and maintaining direct accounts for GPO ("own use") class of trade as well as direct 340B accounts
ix. Responsible for ordering all drugs from the specific accounts as specified by the process employed

~~d. Director of Revenue Cycle Operations~~
~~x.a. Responsible for communication of all changes to the Medicare Cost report regarding clinics or revenue centers of the cost report~~
~~a. Responsible for communication of all changes to Medicaid reimbursement for pharmacy services/products that impact 340B status~~
~~b. Responsible for modeling all managed care contracts (with/without 340B)~~
~~c. Pharmacy Informaticist/Analyst~~
~~xi.~~**x.** Define process and access to data for compliant identification of outpatient utilization for eligible patients
~~xii.~~**xi.** Archive the data so as to be available to auditors when audited.
xii. Review charges from billing software to **S**split-**B**billing software to help identify and -resolve data exchange issues
~~xiii.~~

P. 340B PROGRAM EDUCATION & COMPENTENCY

1. ~~Tri-City Medical Center~~**TCMC will establish 340B education and competency requirements for the 340B key stakeholders based on their roles and responsibilities in the 340B Program.**

~~f.~~**2. ~~Tri-City Medical Center~~TCMC determines the knowledge and educational requirements for each 340B Program role on an as needed basis through various educational systems to meet program competency.** ~~Clinical Pharmacy Manager~~

~~a. Be aware of products covered by 340B and Prime Vendor Program pricing~~
~~b. Work with the Medical Staff to use effective therapeutic classes that optimize savings with good clinical outcomes~~

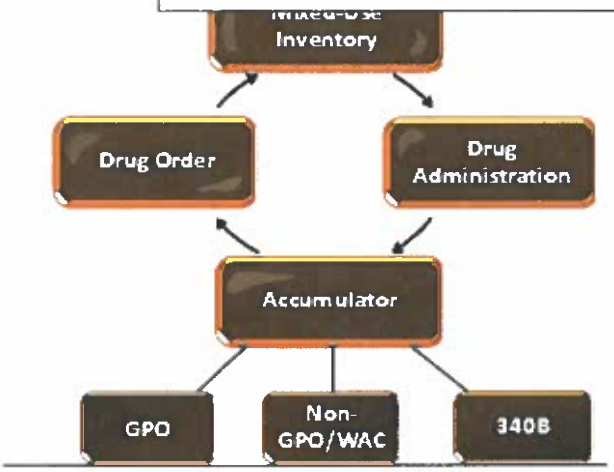
~~D. 340B ENROLLMENT, RECERTIFICATION, CHANGE REQUESTS:~~
~~1. Recertification Procedure~~
~~a. OPA requires entities to recertify their information as listed in the OPA database annually. TCMC Authorizing Official (AO) and Primary Contact (PC) annually recertifies TCMC's information by following the directions in the recertification email sent from the OPA to TCMC's AO by the requested deadline. Specific recertification questions should be sent to: 340b.recertification@hrsa.gov~~
~~2. Enrollment Procedure: New Clinic Sites~~
~~a. The 340B Committee evaluates a new service area or facility to determine if the location is eligible for participation in the 340B Program. The criteria used include:~~
~~a. Service area must be fully integrated into DSH~~
~~b. Appear as a reimbursable clinic on the most recently filed cost report~~
~~c. Have outpatient drug use~~
~~d. Have patients that meet the 340B patient definition.~~
~~b. If a new clinic meets these criteria, the TCMC AO completes the online registration process during the registration window (January 1–January 15 for an effective start date of April 1; April 1– April 15 for an effective start date of July 1; July 1–July 15 for an effective start date of October 1; and October 1– October 15 for an effective start date of January 1). This includes submitting cost report information, as required by OPA. http://www.hrsa.gov/opa/eligibilityandregistration/index.html~~
~~3. Changes to TCMC Information in OPA Database Procedure~~

a. It is TCMC's ongoing responsibility to immediately inform OPA of any changes to its information or eligibility. As soon as TCMC is aware that it loses eligibility, it will notify OPA immediately and stop purchasing (or may be required to repay manufacturers).
b. An online change request will be submitted to OPA by the AO for changes to TCMC's information outside of the annual recertification timeframe. Change form will be submitted to OPA as soon as the entity is aware of the need to make a change to its database entry. The entity will expect changes to be reflected within about 2 weeks of submission of the changes/requests.

E. **340B PROCUREMENT, INVENTORY MANAGEMENT, DISPENSING:**

1. 340B inventory is procured and managed in the following settings:
a. Hospital, Mixed-use
b. Oceanside Infusion Center
2. TCMC will participate in the 340B prime vendor program; providing price protection in the Wholesale Acquisition Cost (WAC) account, and sub-ceiling prices.
3. Oceanside Infusion Center Separate Physical Inventory
a. TCMC uses physically separate 340B inventory as well as non-GPO/WAC inventory. Pharmacists and technicians only dispense 340B drugs to eligible patients.
b. TCMC Staff places 340B orders from Cardinal through daily inventory reviews
c. TCMC Staff checks in 340B inventory by examining the wholesaler invoice against the order, and reports inaccuracies to the wholesaler.
d. TCMC Staff maintains records of 340B related transactions for a period of 6 years in a readily retrievable and auditable format located in the main pharmacy
e. 340B inventory is stored in the outpatient pharmacy maintained with a security system. Only pharmacy employees have access to the pharmacy
4. Hospital

DELETE



1. Purchase mixed-use inventory (according to eligible accumulations).
2. Administer/dispense drugs to patients.
3. Accumulator accumulates drug on an 11-digit NDC match until unit of use is met, prepares patient/clinic/prescriber information to determine the appropriate contract for ordering.

GPO	Non-GPO/WAC	340B
GPO/Inpatient class of trade: Inpatient status determined by hospital at the date/time of administration GPO/Outpatient class of trade: Offsite/unregistered outpatient clinics	Products that do not have an 11 digit NDC match on the 340B contract but are otherwise eligible for 340B purchase Non-340B eligible outpatients, i.e.: • Administration or dispensing occurred at a clinic within 4 walls of parent, but not 340B eligible • In-house pharmacy open to public	Patients met 3 definition and r services on an basis in a 340E registered/part hospital clinic

4. Replenishment drug order(s) are placed according to eligible accumulations.

5. Transfer Processes
a. From non-340B to 340B
a. Transfers between non-340B and 340B inventory are only in rare circumstances, and according to the following procedure:
i. TCMC Staff records the transaction on a borrow/loan transaction log.
ii. TCMC Staff reconciles the process by transfer back to the separated non-340B inventory area through a purchase on the borrowing area's 340B account of the same National Drug Code (NDC) and quantity that was borrowed.
b. From 340B to non-340B
a. Only in the case of an emergency medical situation will drugs be transferred from a 340B inventory to a non-340B inventory. In the case this happens, the following procedures will be used:
i. TCMC Staff records the transaction on a borrow/loan transaction log.
ii. TCMC Staff reconciles the process by transfer back to the separated 340B inventory area through a purchase on the borrowing area's non-340B account (non-GPO/WAC account) of the same NDC and quantity that was borrowed. Reconciliation is completed within [interval] of the original loan date.

F. **MONITORING AND REPORTING:**
1. Reporting 340B Non-Compliance
a. TCMC defines a material breach of compliance that would require self-disclosure as a violation(s) that exceeds 5% of total 340B purchases or impact to any one manufacturer
b. The 340B committee will assess the violation, determine the actions and communicate the information to the appropriate parties. Violations identified through internal self-audits, independent external audits, or otherwise that meet or exceed this threshold will be immediately reported to HRSA and applicable manufacturers using the following self-disclosure report template: https://docs.340bpvp.com/documents/public/resourcecenter/ALL_Entities_Self_Reporting_340B_NonCompliance.pdf
d. The 340B committee will maintain records of materiality assessments and of violations that led to manufacturer resolutions, correspondence and or formal self-disclosure process through HRSA
e. Address the types of non-compliance that warrant a report to OPA/manufacturer, records kept, documentation, and plan for corrective action

Tri-City Medical Center
Oceanside, California
ADMINISTRATIVE POLICY
HUMAN RESOURCES

RETIRE – until such time as an actionable framework can be established to represent Diversity, Equity and Inclusion

ISSUE DATE: 12/02

SUBJECT: Diversity

REVISION DATE(S): 06/12, 04/15

POLICY NUMBER: 8610-471

Human Resources Department Approval:	**~~04/15~~09/24**
Administrative Policies & Procedures Committee Approval:	**~~03/20~~09/24**
Medical Executive Committee Approval:	**n/a**
Administration Approval:	**~~08/20~~11/24**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	**08/20**

A. **DEFINITION:**

1. Multicultural Diversity: refers to the unique characteristics that distinguish people as individuals and identify them as belonging to a group or groups. Diversity transcends concepts of race, spiritual and religious belief, religious creed (including religious dress and grooming practices), color, national origin, ancestry, ethnicity, socio-economic status, education, social customs, physical disability, mental disability, medical condition (including AIDS and/or HIV status), genetic information, marital status, military and veteran status, sex, gender, gender identity, gender expression, age, sexual orientation, pregnancy, childbirth, breastfeeding and/or related medical conditions or any other status protected by State or Federal Law
2. Workforce Member: Employees, Medical Staff and Allied Health Professionals (AHP), volunteers, trainees, Business Visitors and other persons whose conduct, in the performance of work for Tri-City Healthcare District (TCHD), is under the direct control of TCHD whether or not they are paid by TCHD.

B. **PURPOSE:**

1. To create an environment where differences among people are valued and appreciated and are treated with dignity and respect; thus comprising a workforce consisting of individuals with diverse competencies, values, backgrounds, ethnicity and experiences who realize their maximum potential within a multicultural organization.
2. To further facilitate Tri-City Health District (TCHD) Workforce Members in working together respectfully, to foster appreciation for their unique and diverse talents, and perspectives, and how together TCHD's Workforce Members contributes to the mission, vision and effective achievement of the business goals of TCHD

C. **POLICY:**

1. Diversity at all levels among TCHD's Workforce Members requires to display sensitivity and respect for the needs of others including visitors, customers, employees, volunteers, and patients and their families, friends, support persons, and surrogate decision makers.
2. TCHD values diversity among staff and will recruit, retain, and promote at all levels of the organization in order to meet the needs of our unique population. TCHD's culture and practices contribute to a workplace which values diversity and encourages Workforce Members to provide service excellence in carrying out their responsibilities. .
3. TCHD expects Workforce Members to treat each other with dignity, fairness, and respect regardless of their differences. This includes how they treat physicians, visitors, patients and their families, friends, support persons, and surrogate decision makers and those who provide on-site vendor services.
   a. TCHD's Workforce Members will support diversity through TCHD's mission statement,

values, ethics statement

b. Commitment to workplace values is measured and documented in employee performance evaluations.

4. Administrative policies and procedures support respect and diversity including Administrative Policies: Coaching and Counseling for work Performance 424, and Discrimination, Harassment and Retaliation Prevention Policy 403..
5. TTCHD will offer diversity education and training to support and facilitate diversity awareness and positive recognition of the unique talents among TCHD diverse Workforce Members.
6. TCHD places a high value on diversity and inclusion. We believe that diversity and inclusion are essential to organizational effectiveness and excellence, and that services are enhanced when organizations are a reflection of the communities they serve. The objectives are:
   a. To create a diverse and inclusive workplace environment that promotes mutual respect, acceptance and cooperation among TCHD's Workforce Members.
   b. To support an environment where all TCHD's Workforce Members are valued, supported and empowered.
   c. To plan and coordinate activities which deepen the appreciation and celebration of differences, including but not limited to race, ethnicity, age, gender, sexual orientation, geographic diversity color, national origin, ancestry, marital status, socio-economic status, sex, gender identity, gender expression, spiritual and religious beliefs, education, physical disability, mental disability, medical condition, genetic information, military and veteran status, social customs, or any other status protected by State or federal law.
   d. To facilitate high quality, high standard initiatives providing opportunities for capacity building through diversity and inclusion.
   e. To provide a communication link to TCHD's Workforce Members at all levels of the organization.
   f. To promote excellence in healthcare, and patient safety and satisfaction by recognizing the diversity of the TCHD patient population, and the diversity of patients' families, friends, support persons, and surrogate decision makers, and by promoting cultural diversity, awareness, and sensitivity among TCHD's Workforce Members.
7. To the extent that any applicable that any applicable collective bargaining agreement that is consistent with applicable law conflicts with certain provisions of this policy, the collective bargaining agreement for employees covered under that agreement prevails.

D. **RELATED DOCUMENT(S)**:

1. Administrative Policy: Coaching and Counseling 424
2. 1. Administrative Policy: Discrimination, Harassment and Retaliation Prevention 403

Tri-City Medical Center
Oceanside, California

ADMINISTRATIVE
HUMAN RESOURCES

ISSUE DATE: 08/80

SUBJECT: Equal Employment Opportunity

REVISION DATE~~(S)~~: 01/09; 04/12; 03/13, 12/13, 02/16, 3/20

POLICY NUMBER: 8610-418

Administrative Content Expert~~Human Resources Department~~ Approval:	**~~03/20~~09/24**
Administrative Policies & Procedures Committee Approval:	**~~04/20~~09/24**
Pharmacy & Therapeutics Committee	**n/a**
Medical Executive Committee ~~Approval~~:	**n/a**
Administration Approval:	**~~08/20~~11/24**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	**~~08/20~~**

A. **PURPOSE:**

1. ~~To comply with EEOC and DFEH guidelines and mandates.~~**Our Equal Employment Opportunity (EEO) policy statement outlines Tri-City Healthcare District's commitment to providing a workplace that is free from discrimination and harassment. Our goal is to ensure that all employees, applicants, patients, and visitors are treated with dignity, respect, and fairness, in accordance with federal, state, and local laws, including the guidelines set forth by the Equal Employment Opportunity Commission (EEOC).**

B. **POLICY:**

1. Tri-City Healthcare District (TCHD) is **committed to creating an inclusive environment where equal employment opportunities are available to all individuals without regard to race, color, religion, sex (including pregnancy, childbirth, or related medical conditions), sexual orientation, gender identity or expression, national origin, age, disability, genetic information, marital status, military or veteran status, or any other characteristic protected by federal, state, or local law.**~~an equal opportunity employer. It is TCHD's policy to provide equal employment opportunity for all applicants and employees, in all areas of employment including recruitment, hiring, training, promotion, compensation, benefits, transfer, and general treatment during employment.~~

2. **This policy applies to all aspects of employment, including, but not limited to:**
   - **a. Recruitment, hiring, and promotion**
   - **b. Compensation and benefits**
   - **c. Training and development**
   - **d. Transfers, layoffs, and terminations**
   - **e. Work conditions and environment**
   - ~~a.~~**f. Disciplinary actions**~~TCHD does not unlawfully discriminate on the basis of race, spiritual and religious belief, religious creed (including religious dress and grooming practices), color, national origin, ancestry, ethnicity, socio-economic status, education, social customs, physical disability, mental disability, medical condition (including AIDS and/or HIV status), genetic information, marital status, military and veteran status, sex, gender, gender identity, gender expression, age, sexual orientation, pregnancy, childbirth, breastfeeding and/or related medical conditions or any other status protected by State or Federal Law ; these characteristics are defined as "protected classes." TCHD will accommodate nursing employees' lactation needs in accordance with state and federal law. TCHD will make reasonable accommodations for religious belief or observance~~

~~(including religious dress and grooming practices), for pregnant employees, and for the known physical or mental disabilities of an otherwise qualified applicant/employee, unless undue hardship would result. Requests for accommodation should be made to Human Resources, who will determine whether a reasonable accommodation can be made for a qualified individual. Requests for accommodation of religious belief or observance should also be directed to Human Resources.~~

~~2.~~3. **Non-Discrimination and Anti-Harassment – TCHD prohibits any form of discrimination or harassment in the workplace. All employees are expected to conduct themselves in a manner that fosters a professional and respectful work environment. Harassment, whether verbal, physical, or visual, that is based on any protected characteristic, will not be tolerated.**~~It is the responsibility of every manager and employee to conscientiously follow this policy. Any employee with questions or concerns about any type of discrimination or harassment on any of these bases in the workplace is encouraged to bring these issues to the attention of their immediate supervisor or to a Human Resources representative. Employees can raise concerns and make reports without fear of retaliation (refer to Administrative Policy: Discrimination, Harassment and Retaliation Prevention Policy 403).~~ Anyone found to be engaging in any type of unlawful discrimination will be subject to disciplinary action up to and including termination of employment with TCHD.

~~3.~~4. **Reasonable Accommodations – TCHD will provide reasonable accommodations to qualified individuals with disabilities and to employees with sincerely held religious beliefs, unless doing so would result in undue hardship to the organization.**~~In carrying out this responsibility TCHD will:~~

~~Conduct recruitment practices and base hiring decisions for all job classifications upon the position requirements and an individual's qualifications for the position.~~

~~Make transfer and promotional decisions based on the individual's qualifications as related to the position for which they are being considered unless otherwise required by law.~~

~~4.~~5. **Reporting and Complaint Procedure – Employees who believe they have been subjected to discrimination, harassment, or retaliation are encouraged to report the incident(s) to their immediate supervisor, the Human Resources department, or any member of management. All complaints will be taken seriously, investigated promptly, and treated with confidentiality to the extent possible.**~~Any person who believes they have experienced discrimination may file a complaint with a Human Resources representative.~~

~~5.~~6. **Retaliation Prohibited – Retaliation against an employee for filing a complaint, participating in an investigation, or opposing discriminatory practices is strictly prohibited. Any employee found to have engaged in retaliation will be subject to disciplinary action, up to and including termination.** Employees may also file a complaint with ~~the Department of Fair Employment and Housing or~~ the Equal Employment Opportunity Commission. Telephone number~~s for each agency are~~ available online.

7. **Responsibility and Enforcement – It is the responsibility of all employees to adhere to this policy and promote a work environment free of discrimination and harassment. Managers and supervisors are expected to set an example by ensuring that their actions and the actions of those under their supervision comply with this policy.**~~The Head of Human Resources has overall responsibility for implementation of this policy.~~

8. **Continuous Improvement – TCHD is committed to regularly reviewing and updating its EEO policies to ensure compliance with the latest laws and regulations and to foster a culture of inclusion and respect.**

~~6.~~9. **By upholding the principles outlines in this EEO policy, TCHD aims to provide a safe, inclusive, and equitable workplace for all employees and to maintain its reputation as a community hospital that values diversity and integrity. The Head of Human Resources has overall responsibility for implementation of this policy.**

~~To the extent that any applicable that any applicable collective bargaining agreement that is consistent with applicable law conflicts with certain provisions of this policy, the collective bargaining agreement for employees covered under that agreement prevails.~~

C. ~~-~~RELATED DOCUMENTS:

1. **Administrative Policy: Discrimination, Harassment and Retaliation Prevention 403**
2. **Administrative Policy: Coaching and Counseling for Work Performance 424**

Tri-City Medical Center
Oceanside, California

Emergency Department

ISSUE DATE:	**08/21**	**SUBJECT:**	**Ketamine for the Management of Pain in the Emergency Department**
REVISION DATE:	**08/21**		

Emergency Department Approval:	**~~05/20~~06/24**
Department of Emergency Medicine Approval:	**~~07/20~~06/24**
Pharmacy and Therapeutics Committee Approval:	**~~09/20~~08/24**
Medical Executive Committee Approval:	**~~11/20~~10/24**
Administration Approval:	**~~08/21~~11/24**
Professional Board Committee Approval	**n/a**
Board of Directors Approval:	**08/21**

A. **PURPOSE:**
1. To define guidelines for patient selection, administration, monitoring and recovery for use of Ketamine in the Emergency Department (ED).

B. **INDICATIONS FOR USE:**
1. Provide pain relief to patients with severe acute painful conditions who are likely opiate tolerant and/or would not respond to high doses of IV opiates (i.e. migraine headaches, undifferentiated abdominal pain, back/neck pain, renal colic, etc...); relief of intractable neuropathic pain, intractable chronic pain, intractable cancer pain, and moderate to severe acute post-traumatic pain.

C. **POLICY:**
1. ED Physician will assess the patient for etiology and severity of pain, as well as likelihood of response to alternative therapies
2. ED Physician will assess the patient for possible contraindications
3. ED physician will assess patient's vital signs, oximetry, and mental status
4. Exclusion criteria:
   a. Hypersensitivity to Ketamine or any component of the formulation
   b. Recent hospitalization for psychiatric disorder, or a suicide attempt
   c. History of Psychosis: schizophrenia
   d. History of seizures
   e. Hydrocephalus or acute head injury
   f. History of glaucoma or acute globe injury
   g. Known or possible CAD, CHF, and/or uncontrolled HTN
   h. History of COPD with hypercarbia, asthma, laryngospasm, or upper respiratory infection
   i. History of airway instability, tracheal surgery, tracheal stenosis, tracheomalacia, and laryngomalacia
   j. Procedures that will stimulate the posterior pharynx
   k. Acute alcohol or drug intoxication
   l. Thyroid disease
   m. Pregnancy
   n. ED RN must give IV; so should be weight based; not age.
5. Discharge Criteria:
   a. Patient is able to ambulate (unless lower extremity injury)
   b. Patient's mental status has returned to baseline
   c. Patient has a ride home or is being admitted to the hospital (ED)
   d. Patient's vital signs have returned to baseline

e. At least two hours have passed since time to last dose of ketamine was given

D. **PROCEDURE:**

1. Administration Guidelines: Restricted to adult patients being evaluated by an Emergency Medicine Physician (in ED only)
2. Recommended Dosing:
   a. Consider 0.3mg/kg IV over 10 minutes x1. (Usual dose range= 0.1mg/kg-0.5mg/kg).
      i. Use IBW in obese patients (BMI ≥ 30)
         1) Males= 50 + (2.3 x inches over 5 ft)
         2) Females= 45 + (2.3 x inches over 5 ft)
      ii. More rapid administration may result in respiratory depression/apnea and enhanced pressor response.
      iii. Maximum total dose = 50mg, although up to 35mg is usually sufficient. In the event that less than the recommended dose is used, an additional dose not to exceed the maximum total recommended dose can be considered to achieve desired effect.
   b. To be used in conjunction with other analgesics as adjuvant therapy
3. Nursing Considerations:
   a. May be administered peripherally or centrally under the supervision of MD
   b. Suction must be available at the bedside prior to administration.
   c. Monitoring:
      i. HR, BP, RR, Temperature, SPO2, and Pain Level must be monitored every 15 minutes for 1st hour, then every 30 minutes times 1 hour,
      ii. Maintain quiet area with minimal physical stimulation if possible
4. Notify ED Physician for presence of any of the following signs or symptoms:
   a. Systolic blood pressure of less than (<) 90mmHg or greater than BP (>)180mmHg
   b. Heart rate of less than (<) 60 bpm or greater than (>) 110 bpm
   c. Respiratory rate of less than (<) 10 breaths/minute
   d. Oxygen saturation of less than (<) 93% if ordered
   e. Nausea or vomiting
   f. Excess salivation
   g. Excess sedation

E. **REFRENCES:**

1. Correll GE et al. Subanesthetic Ketamine Infusion Therapy: A Retrospective Analysis of a Novel Therapeutic Approach to Complex Regional Pain Syndrome. Pain Medicine. 2004; 5(3):263-75.
2. Goldberg ME et al. Multi-day low dose Ketamine infusion for the treatment of complex regional pain syndrome. Pain physician. 2005; 8(2):175-9.
3. Bell RF et al. Peri-operative Ketamine for acute post-operative pain: a quantititative and qualitative systematic review. (Cochrane review). Acta Anaesthesiol Scand. 2005; 49(10):1405-28.
4. DeKock M et al. "Balanced Analgesia" in the perioperative period. Is there any place for Ketamine? Pain. 2001; 92:373-80.
5. Farida A. Emergency Department Visits for Chest Pain and Abdominal Pain: United States, 1999-2008, NCHS Data Brief. 2010: 43.
6. Galinski G et al. In emergency setting, small-dose ketamine reduces morphine requirement in severe acute pain. Resuscitation and emergency medicine; A-827: 214.
7. Harper TD. Perioperative Uses of Low-Dose Ketamine for Pain Management. Plastic Surgical Nursing. 2007: 27(2): 98-101.
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10. Loftus RW et al. Intraoperative Ketamine Reduces Perioperative Opiate Consumption in Opiate-dependent Patients with Chronic Back Pain Undergoing Back Surgery. Anesthesiology. 2010;

113(3): 639-46.

11. Zempsky WT et al. Use of Low-dose Ketamine Infusion for Pediatric Patients with Sickle Cell Disease-related Pain: A Case Series. Clinical Journal Pain. 2010; 26(2):163- 7.
12. Urban KU et al. Ketamine as an Adjunct to Postoperative Pain Management in Opioid Tolerant Patients After Spinal Fusions: A Prospective Randomized Trial. HSSJ. 2008; 4:62-5.
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14. Finkel JC et al. Ketamine as an Adjuvant for Treatment of Cancer Pain in Children and Adolescents. J of Pain. 2007; 6:515-21.
15. Clinical Practice Guideline for Emergency Department Ketamine Dissociative Sedation: 2011 Update Steven M. Green, Mark G. Roback, Robert M. Kennedy, Baruch Krauss Annals of emergency medicine 1 May 2011;57(5):449-461.

Tri-City Medical Center
Oceanside, California

LABORATORY PATHOLOGY
HISTOLOGY POLICIES AND PROCEDURES

ISSUE DATE: 09/96

SUBJECT: Chain of Custody for Forensic Specimens or Foreign Objects Removed from Patients

REVISION DATE: 05/21, 07/23
REVIEW DATE: 05/15, 05/16, 05/17, 05/18, 05/19, 05/20, 05/21,-05/23

Department Approval:	**08/24**
Laboratory Medical Director Approval:	**07/14, 10/21, 08/24**
Medical Executive Committee Approval:	**09/24**
Administrative Approval:	**08/2211/24**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	

A. **DEFINITION(S):**

1. **Chain of Custody: the chronological documentation and control of physical evidence or information from the moment it is obtained or collected until its final disposition in a legal or investigative process. Maintaining a strong chain of custody is essential to ensure the credibility and validity of evidence in legal proceedings and investigations. It is a critical process that requires care attention to detail and strict adherence to established protocols and procedures.**

B. **POLICY:**

1. Bullets or other forensic objects removed from patients may have future medical/legal consequences. ~~It is therefore necessary that~~**It is mandatory that** Chain of Custody be maintained on these objects and **that** ~~it is~~they are stored in a safe location.
2. It is the responsibility of the operating room (or location explanting the specimen) to initiate the Chain of Custody ~~procedure~~**process**. Chain of custody ~~begins~~ **starts** with the **explanting** physician and not in the lab, so the lab does not initiate the Chain of Custody form.
3. It is the responsibility of the laboratory to retain **the specimen or object** for safekeeping, to maintain the ~~"CHAIN OF CUSTODY"~~**chain of custody form**, and turn over to law enforcement authorities upon request with proper identification such items that constitute **forensic specimens or** foreign objects that might be used as legal evidence.
4. **Forensic specimens or** foreign objects will be retained for not less than two years unless requested for evidence by law enforcement authorities. ~~Then bring the matter~~**At this time, the matter should be brought** to the attention of Lab Management for disposition of the materials.
5. **Chain of Custody Process:**
   a. All items must be received in a sealed envelope or container labeled with the patient's demographics label, specimen source, and surgeon.
      i. The person delivering the container must supply all necessary information, including a tissue requisition form.
      ii. ~~A "CHAIN OF CUSTODY" form (see Appendix A)~~**The Chain of Custody form** must also accompany the specimen at all times, bearing the appropriate signatures, dates, and times of all ~~the~~ persons who ~~have~~ relayed the specimen to the Laboratory and who received the specimen in the Laboratory.
   b. The envelope or container must be personally received by Histology personnel, the Lab Shift Supervisor or ranking tech in charge, from the person who last signed for custody of the container.

c. Chain of Custody must be maintained by the person accepting the specimen into the lab, by signing the form and recording the date and time the specimen was received.

d. If the specimen is received by a Pathology Lab Assistant or a Histotechnician, the specimen will be given an accession number and a gross dictation will be performed immediately by a Pathologist or Pathology Assistant. If no one is available to dictate, **the** specimen will be placed in the lock box in the ~~Pathology Assistants~~**Administrative Lab Director's** -office.

   i. **The Chain of Custody Form must first be signed on the "Released Intact By" line and include the notation "to Lock Box". Failure to do so will break the chain of custody.** ~~Sign the "CHAIN OF CUSTODY" form on the line "Released Intact By" and make a notation "to Lock Box".~~

e. If the specimen is received by the Lab Shift Supervisor or tech in charge, the specimen container and Chain of Custody Form will be filled out and placed immediately in the lock box in the **Administrative Lab Director's office** ~~Pathology Assistant's office~~. The order form will be clocked in and placed on the counter in the Histology Department, with a note stating where the specimen was placed.

f. If the object is removed from the lock box for any reason such as grossing, the Chain of Custody Form must be signed on the line "Received Intact By" and ~~make a notation~~**must include the notation** "From Lock Box".

g. The object may be released to the custody of law enforcement authorities upon demand and verification of proper identification. The Chain of Custody Form must be completed and signed by the ~~person~~ **Officer** taking custody of the specimen. Attach a business card or a copy of photo **identification** ~~I.D.~~ of the Officer receiving **the** specimen.

h. The original Chain of Custody Form must be made a part of the patient's permanent medical record. -Therefore, when the specimen is **removed from**~~released~~ or placed in the lock box in the ~~Pathology Assistant's~~**Administrative Lab Director's** office, ~~the "CHAIN OF CUSTODY" form~~**a copy of the Chain of Custody Form** will be sent to Medical Records. A copy will also be kept in the Laboratory and filed as part of the pathology report.

   i. **If/when the forensic specimen or foreign object is released to law enforcement, a copy of the completed Chain of Custody form will be sent to Medical Records. It is required that these forensic specimens and foreign objects are tracked throughout the hospital from the time of removal from the patient to the time the specimen/object is no longer in the hospital's custody.**

i. The object will be discarded after two years ~~per lab management instructions~~**upon the authority of Lab Management**.

C. **PROCEDURE**: N/A

D. **FORM(S)**:
1. Chain of Custody Form

E. **RELATED DOCUMENT(S)**: N/A

F. **EXTERNAL LINK(S)**: N/A

G. **REFERENCES**: N/A

Tri-City Medical Center
Oceanside, California

LABORATORY
LABORATORY GENERAL/QUALITY ASSURANCE

ISSUE DATE: 08/18 **SUBJECT: Individualized Quality Control Plan**

REVISION DATE(S):

Department Approval:	**10/21**
Laboratory Director Approval:	**10/21**
Department of Pathology Approval:	**n/a**
Medical Executive Committee Approval:	**n/a**
Professional Affairs Committee Approval:	**n/a**
Administration Approval:	**~~02/22~~11/24**
Board of Directors Approval:	**02/22**

A. **DEFINITION(S):**

1. Individualized Quality Control Plan (IQCP): A framework for customizing a quality control program for the test systems in each laboratory's unique environment.
2. Risk Assessment (RA): The process of identifying and evaluating the potential failures and errors that could occur during the pre-analytical (before testing), analytical (testing), and post-analytical (after testing) phases of testing.
3. Quality Control Plan (QCP): Describes practices, procedures and resources needed by the laboratory to ensure the quality of a testing process. The QCP includes measures to assure the accuracy and reliability of test results, and that the quality of testing is adequate for patient care.
4. Quality Assessment (QA): The implementation of policies and procedures to monitor and assess, and when indicated, correct problems identified related to test performance,
5. California Department of Public Health (CDPH): A licensing and accreditation department for the State of California.
6. College of American Pathologists (CAP): A member-based physician organization advocating best practices in pathology and laboratory medicine and provides accreditation of laboratories under deemed authority by CMS and CDPH.

B. **POLICY:**

1. List of Individualized Quality Control Plans: The laboratory has identified all tests using an IQCP on the CAP's List of Individualized Quality Control Plans form. (COM.50200).
   a. ~~Note: The use of the CAP form is required, even if standardized forms and templates are used by the laboratory. The laboratory is responsible for maintaining the accuracy of the data on the form and for providing a current copy to the inspector during an on-site CAP inspection.~~
2. Risk Assessment: The IQCP for a test, device, or instrument includes a risk assessment to evaluate potential sources of error. The risk assessment should include the following attributes. (COM.50300)
   a. Pre-analytic, analytic, and post-analytic phases of the testing process
   b. Intended medical uses of the test and impact if inaccurate results are reported (clinical risk)
   c. Components of the tests including reagents, environment, specimen, testing personnel, and test system
   d. Variations in the components based on use of the tests (e.g. use in different environments, by different personnel, or multiple identical devices)

e. Data from the laboratory's own environment, instrument/equipment performance, and testing personnel demonstrating acceptable performance over the maximum time interval between external quality control runs defined in the IQCP
f. Manufacturer's instructions and recommendations
g. The process used to identify the sources of potential failures and errors for a test system, and evaluate frequency and impact of those failures and sources of error.

3. Quality Control Plan Approval: The IQCP includes a written quality control plan approved by the laboratory director prior to implementation. (COM.50400)
   a. NOTE: The quality control plan may be part of a test procedure or be a separate written plan.
4. Quality Control Plan Elements: The IQCP must define all aspects monitored based on the potential errors identified during the risk assessment, including the following parameters as applicable. (COM.50500).
   a. The number, type (external and internal quality control systems), and frequency of quality control
   b. Criteria for acceptable performance
   c. Monitoring of the testing environment and reagents
   d. Specimen quality
   e. Instrument calibration, maintenance, and function checks
   f. Training and competency of testing personnel
   g. Provisions for multiple identical devices and variation for uses covered under one IQCP
5. The components of the quality control plan must meet regulatory and CAP accreditation requirements and ~~be in compliance with~~**follow** the manufacturer instructions, at minimum. The quality control plan must control the quality of the test process and ensure accurate and reliable test results.
6. External control material samples must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions.
7. Ongoing Quality Assessment Monitoring: Ongoing quality assessment monitoring is performed by the laboratory to ensure that the quality control plan is effective in mitigating the identified risks for the IQCP and includes the following records. (COM.50600)
   a. Review of quality control and instrument/equipment maintenance and function check data at least monthly
   b. Evaluation of errors relating to pre-analytic, analytic and post analytic phases of the testing process
   c. Review of complaints from clinicians and other healthcare providers regarding the quality of testing to confirm the clinical efficacy of testing
   d. Evaluation of corrective actions taken if problems are identified
   e. Re-evaluation of the quality control plan if changes to the reagents, environment, specimen, testing personnel, or test system elements of the risk assessment occur
   ~~f. Re-approval of the quality control plan by the laboratory director or designee at least annually~~
   ~~g.~~**f.** NOTE: If ongoing assessments identify failures in one or more components of the quality control plan, the laboratory must investigate the cause and consider if modifications are needed to the quality control plan to mitigate potential risk.

C. **PROCEDURE:**

1. Use the Eligibility Determination for Individualized Quality Control Plan (IQCP) Option to determine if the test, device, or instrument is eligible for an IQCP.
2. Complete a risk assessment in accordance with this policy.
3. Develop and document the quality control plan for the test, device, or instrument based upon the risk assessment and in accordance with this policy.
4. Review the IQCP with the laboratory director and obtain approval prior to implementation.
5. Complete ongoing quality assessment monitoring as part of regular quality assurance activities.
6. ~~Document, at least annually, the effectiveness of the IQCP on the Annual Assessment of Individualized Quality Control Plan Form.~~

D. **FORM(S):**

1. ~~Annual~~ Assessment of Individualized Quality Control Plan Form
2. List of Individualized Quality Control Plans Form

E. **RELATED DOCUMENT(S):**

1. Eligibility Determination for Individualized Quality Control Plan (IQCP) Option

F. **REFERENCES:**

~~1. Department of Health and Human Services. (2014). Considerations When Deciding to Develop an IQCP [Brochure]. CMS. Retrieved from https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure12.pdf~~

~~2. Department of Health and Human Services. (2014). What is an IQCP? [Brochure]. CMS. Retrieved from https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure13.pdf~~

~~3. Department of Health and Human Services. (2014). Developing an IQCP - A Step-by-Step Guide [Brochure]. CMS. Retrieved from https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf~~

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Tri-City Medical Center
Oceanside, California

LABORATORY GENERAL
INFECTION PREVENTION AND CONTROL / LABORATORY INFECTION PREVENTION AND CONTROL

ISSUE DATE:	**01/03**	**SUBJECT:**	**Laboratory Infection Prevention and Control**
REVISION DATE:	**07/03, 07/06, 10/09, 09/12**		

Department Approval:	**10/21**
Laboratory Medical Director Approval:	**10/21**
Medical Executive Committee Approval:	**~~11/21~~09/24**
Administrative Approval:	**~~11/21~~11/24**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	**12/21**

A. **DEFINITION(S):**
1. Infection Prevention and Control: The discipline concerned with preventing healthcare-associated infections.
2. Personal Protective Equipment (PPE): The protective clothing, helmets, goggles, or other garments or equipment designed to protect the wearer's body from injury or infection.
3. Universal Precautions: The concept of bloodborne disease control requiring all human blood and other potentially infectious materials to be treated as if infectious for **Human Immunodeficiency Virus** (HIV), **Hepatitis B Virus** (HBV), **Hepatitis C Virus** (HCV) or other bloodborne pathogens, regardless of the perceived "low risk" status of a patient or patient population.
4. Hand Hygiene: the act of cleaning one's hands with soap and water to remove viruses/bacteria/microorganisms, dirt, grease, or other harmful and unwanted substances stuck to the hands.

B. **POLICY:**
1. Infection Control: The laboratory follows written policies and procedures for infection control that comply with national, federal, state (or provincial), and local guidelines on occupational exposure to bloodborne pathogens and other infectious pathogens, and to the institution's exposure control plan. (GEN.74000).
   a. Refer to **the** ~~Infection Control Policy Manual:~~ Bloodborne Pathogen Exposure **Control** Plan.
2. Specimen Handling/Processing: **The laboratory safely handles and processes specimens, including those suspected to contain highly infectious pathogens.**~~The laboratory safely handles specimens suspected to contain highly infectious pathogens~~. (GEN.74050).[PRHI]
   a. Universal Precautions must be adhered to when obtaining, handling or processing all blood and other potentially infectious materials.
      i. This includes control sera and reagents from biological sources.
      ii. See department-specific Blood Borne Pathogen Task Assessments in the Laboratory Safety Manual.
   b. After drawing a blood culture specimen, do not change the needle, and inject the specimen directly into the blood culture bottle.
   c. Needleless systems will be used whenever possible.
   d. Safety needle devices must be used at all times.
   e. All containers of biological samples shall be sealed or covered or kept in sealed containers unless currently being analyzed.
   f. Care should be taken to avoid all spillage and creation of aerosols during transfer steps.

3. Personal Protective Equipment (PPE) Provision and Usage: Appropriate personal protective equipment (gloves, gowns, masks and eye protectors, etc.) is provided and maintained in a sanitary and reliable condition in all work areas whenever blood and other potentially infectious materials are handled and in circumstances during which exposure is likely to occur. (GEN74100).
   a. All Laboratory personnel must wear laboratory issued coats or fluid resistant gowns supplied by Tri-City Medical Center (TCMC) when performing specimen collection including venipuncture, when handling specimens not in a secondary container such as a bag, when performing testing of specimens, and when performing tasks that require its use.
   b. Lab coats and gloves may not be worn outside the laboratory and may not be worn in areas within the lab where food and drinks are allowed.
      i. The exception is lab coats may be worn from a work area through a clean area to another work area such as a phlebotomist dispatched to a unit.
   c. Laboratory coats or fluid resistant gowns upon which biological material has been spilled are a biohazard and must be expeditiously removed, placed in the dirty linen hamper, or disposed of appropriately. The fluid resistant gown may be placed in the regular trash, if it is disposable.
   d. **Refer to the Laboratory Attire related document for additional information.**
4. PPE Instruction: **Personnel are trained on and follow instructions for the proper use of personal protective clothing/equipment (eg, gloves, gowns, masks, eye protectors, footwear).** ~~Personnel are instructed in the proper use of personal protective clothing/equipment (e.g., gloves, gowns, masks, eye protectors, footwear) and records are retained.~~ (GEN.74200).[PRH2]
   a. Training for laboratory staff in proper use of PPE is performed during the initial department competency training and records are kept in their employee file.
   b. See department specific Blood Borne Pathogen Task Assessments for PPE use in specific tasks.
5. Hand Hygiene: All personnel remove gloves and clean hands using an effective antimicrobial method following contact with blood or other potentially infectious materials or after each patient contact. (GEN.74250).
   a. See Infection Control Policy Manual: Hand Hygiene.
6. Manual Manipulation of Needles: There is a written policy that prohibits the recapping, purposeful bending, breaking, removing from disposable syringes, or other manual manipulations of needles. (GEN.74300).
   a. Needles must never be recapped by hand.
   b. Needles must not be not cut or bent, broken or removed from disposable syringes.
7. ~~Eating/Mouth Pipetting~~**Prohibited Practices**: **The facility prohibits smoking, vaping, eating, gum chewing, drinking, application of cosmetics and lip balm, manipulation of contact lenses, and mouth pipetting in all technical work areas.** ~~There is a written policy that prohibits smoking, vaping, eating, gum chewing, drinking, application of cosmetics and lip balm, manipulation of contact lenses, and mouth pipetting in all technical work areas~~. (GEN.74400).
   a. Mouth pipetting of any substance is prohibited. Mechanical pipettes or suitable alternative devices are used.
   b. No foods or beverages may be present in any part of the Laboratory where specimen handling and/or testing is performed. This includes front office and phlebotomy areas.
   c. Food and beverages may be consumed in the administrative offices, employee break room, conference room pathology offices and transcription area.
   d. No smoking, vaping, eating, drinking, chewing gum, donning earrings or application of cosmetics are permitted in any Laboratory working area.
   e. Oral and ocular contact with any surface, including hands, capable of harboring and transmitting infectious agents, is prohibited.
8. Specimen Transport Procedures: The laboratory receives, handles, and transports specimens (blood and other potentially infectious materials) in appropriately labeled and well-constructed containers with secure lids to prevent leakage during transport. (GEN.74500).

a. See ~~Pre-Analytical General Procedure:~~**the** Specimen Handling, Transportation, Special Collection, Processing, Aliquoting, and Criteria for Rejection **procedure**.
b. See ~~Safety Manual Related Document:~~**the** Laboratory Pneumatic Tube System Spill Cleanup **related document**.

9. Spill Handling: **The laboratory safely handles spills of blood and other potentially infectious materials.** ~~The laboratory follows written procedures for handling spills of blood and other potentially infectious materials.~~ (GEN.74600).
   a. See ~~General Safety and Safety Training Manual Procedure:~~**the** Laboratory Spills **procedure**.
10. Hepatitis B Vaccinations: Personnel reasonably expected to have direct contact with blood and other potentially infectious materials are identified and offered hepatitis B vaccinations free of charge. Personnel that decline the vaccine sign a declination form. (GEN.74700).
    a. See ~~Employee Health and Wellness Policy Manual: Employee Health – Hepatitis B Vaccination~~**the Bloodborne Pathogen Exposure Control Plan**.
11. Viral Exposure: There is a policy for follow-up after possible and known percutaneous, mucous membrane or abraded skin exposure to HIV, HBV or HCV that includes the following elements (GEN.74800):
    a. HIV, HBV and HCV testing of the source patient after consent is obtained.
    b. Appropriate clinical and serologic evaluation of personnel.
    c. Consideration of appropriate prophylaxis for personnel acutely exposed to HIV, HBV or HCV, based upon medical indications, the serologic status and the individual's informed consent.
    d. Reporting of the exposure as required by law.
    e. See ~~Employee Health and Wellness Policy Manual:~~**the** Occupational Exposure to Blood/Body Fluid Secretions **policy**.
    f. Records of occupational exposure and follow up are kept in the Employee Health and Wellness Department.
12. Tuberculosis (TB) Exposure Plan: The laboratory follows a written tuberculosis exposure control plan that includes the following (GEN.74900):
    a. TB exposure screening at defined intervals for all personnel who may have occupational exposure to tuberculosis.
    b. Use of engineering and practice controls for hazardous activities that may potentially aerosolize Mycobacterium tuberculosis.
    c. See **the** ~~Infection Control Policy Manual:~~ Aerosol Transmissible Diseases and Tuberculosis Control Plan.
13. Sterilizing Device Monitoring: All sterilizing devices are monitored periodically with a biologic indicator (or chemical equivalent) for effectiveness of sterility under conditions that simulate actual use. (GEN.75000).
    a. See **the** ~~Sterile Processing Department Procedure:~~ Sterilization Standards Procedure.
14. Cleaning Procedures:
    a. Bench tops are cleaned after use, and at least daily at the end of the shift, with a 1:10 aqueous solution of bleach or hospital-approved disinfectant.
    b. The Environmental Services Department personnel clean floors, hand washing sinks, and furniture.
    c. Department personnel clean refrigerators, machines and computers on a routine basis.

C. **PROCEDURE:** N/A

D. **FORM(S):** N/A

E. **RELATED DOCUMENT(S):**
1. ~~Safety Manual Related Document:~~ Laboratory Pneumatic Tube System Spill Clean Up
2. Laboratory Department-Specific Blood Borne Pathogen Task Assessments
3. ~~Infection Control Policy Manual:~~ Bloodborne Pathogen Exposure **Control** Plan
4. ~~Infection Control Policy Manual:~~ Hand Hygiene

5. ~~Pre-Analytical General Procedure:~~ Specimen Handling, Transportation, Special Collection, Processing, Aliquoting, and Criteria for Rejection
6. ~~General Safety and Safety Training Manual Procedure:~~ Laboratory Spills
~~7. Employee Health and Wellness Policy Manual: Employee Health – Hepatitis B Vaccination~~
~~8.~~ **Occupational Exposure Blood/Body Fluid Secretions** ~~Employee Health and Wellness Policy Manual: Occupational Exposure to Blood/Body Fluid Secretions~~
~~9.~~**7.** ~~Infection Control Policy Manual:~~ Aerosol Transmissible Diseases and Tuberculosis Control Plan
~~10.~~**8.** ~~Sterile Processing Department Procedure:~~ Sterilization Standards Procedure
~~11.~~**9. Laboratory Attire**

F. **EXTERNAL LINK(S):** N/A

G. **REFERENCES:** N/A

Tri-City Medical Center
Oceanside, California

LABORATORY
PATHOLOGY / PATHOLOGIST

ISSUE DATE:	**SUBJECT:**	**Pathology Staff Professional Competency Policy**
REVISION DATE: 05/140, 05/16, 05/18		
Department Approval:	**10/21**	
Laboratory Director Approval:	**10/21**	
Medical Executive Committee Approval:	**~~01/22~~09/24**	
Administration Approval:	**~~02/22~~11/24**	
Professional Affairs Committee Approval:	**n/a**	
Board of Directors Approval	**02/22**	

A. **DEFINITION(S):**
1. CAP: the College of American Pathologists. The accrediting body for the laboratory at Tri-City Medical Center.

B. **POLICY:**
1. Professional Competency (ANP.10010): The laboratory director ensures the professional competency of pathologists who provide interpretive services to the anatomic pathology laboratory.
2. The policy of the Anatomic Pathology Service of the Clinical Laboratory is to assure the interpretive professional competency of the physician staff of the Division of Pathology. These physician attributes are verified by the following activities listed immediately below. The results of these activities are reviewed annually by the Laboratory Director.
   a. Each pathologist is reappointed to the Medical Staff biennially, and as part of that process a required number of surgical pathology and cytopathology cases are peer-reviewed, authenticated, and submitted as part of the reapplication process. Successful reappointment of each physician to the Medical Staff constitutes de-facto evidence of successful compliance with this standard.
   b. In real-time, individual patient cases are circulated internally within the Division prospectively to multiple pathologist observers, in order to solicit their diagnostic opinions. These intradepartmental consultations are weighed, and incorporated into the final diagnosis, and are recorded by documenting the event in each affected final pathology report.
   c. All pathologist members of the Division participate in the four quarterly surveys per year, denoted A- D, of the College of American Pathologists (CAP) Surgical Pathology PIP (Performance Improvement Program) to earn their respective Continuing Medical Education (CME) credits in Anatomic Pathology. This assures that at least part of the CME credits of each practitioner are directly relevant to his or her daily pathology diagnostic responsibilities.

C. **PROCEDURE**: N/A

D. **FORM(S)**: N/A

E. **RELATED DOCUMENT(S)**: N/A

F. **EXTERNAL LINK(S)**: N/A

G. **REFERENCES:**

1. College of American Pathologists. (2019). *Anatomic Pathology Checklist*. Northfield, IL.

Tri-City Medical Center
Oceanside, California

MEDICAL STAFF

ISSUE DATE: 09/07

SUBJECT: Unintended Intraoperative Awareness During General Anesthesia

REVISION DATE(S): 04/17, 08/20

POLICY NUMBER: 8710 – 546

Medical Staff Department Approval:	**~~02/20~~06/23**
Department of Anesthesiology Approval:	**~~03/20~~09/24**
Pharmacy and Therapeutics Approval:	**n/a**
Medical Executive Committee Approval:	**~~06/20~~10/24**
Administration Approval:	**~~07/20~~11/24**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	**08/20**

A. **PURPOSE:**

1. To establish a process for preventing and dealing with unintended intraoperative awareness during general anesthesia.

B. **DEFINITION(S):**

1. Anesthesia Awareness: Unintended intraoperative awareness occurs when a patient receiving general anesthesia as the primary anesthetic becomes cognizant of some or all events during surgery, or other procedure. Anesthesia awareness does not include the time before the complete induction of anesthesia, or during intended emergence.
2. Background:
   - i. The incidence of awareness during general anesthesia is reported to be greater in patients, for whom a smaller-than-usual dose of general anesthetic is necessary to decrease dangerous side effects (e.g., hemodynamic instability). Procedures identified as typically failing into this category are some cardiac, obstetric, and major trauma cases. Because unintended intraoperative awareness during general anesthesia is not always preventable, health care practitioners should be prepared to anticipate, acknowledge, and manage this occurrence with compassion and diligence.
   - ii. Monitoring patients during general anesthesia to prevent intraoperative awareness can be challenging. Despite a variety of available monitoring methods, awareness is difficult to recognize while it is occurring. Typical indicators of physiologic and motor response, such as hypertension, tachycardia, or movement are often masked by the use of neuromuscular blocking agents to achieve necessary muscle relaxation during the procedure, as well as the concurrent administration of other drugs necessary to the patient's management, such as beta-blockers or calcium channel blockers.

C. **GUIDELINES:**

1. Prevention:
   - a. Equipment Maintenance:
     - i. Periodic maintenance of the anesthesia machines and its vaporizers will be performed and documented.
2. Preoperative Identification:
   - a. Certain procedures may entail a higher risk of unintended intraoperative awareness and some patients with certain characteristics may be at an increased risk for the occurrence of intraoperative awareness. These include:
     - i. Cardiac surgery patients
     - ii. Acute trauma patients with hypovolemia

iii. Cesarean section patients under general anesthesia
iv. Patients undergoing emergency surgery
v. ASA Physical Status 4 and 5 patients
vi. Patients with impaired cardiovascular status
vii. Patients with anticipated difficult intubation
viii. Patients with a history of awareness
ix. Patients with a history of heavy alcohol intake
x. Patients with a history of chronic use of benzodiazepines, opioids or both.
1) Patients considered by the anesthesiologist to present significantly higher risk for an awareness experience should be informed of the potential for awareness in preoperative discussions with their anesthesiologists.

3. Reducing the risk of intraoperative awareness during general anesthesia:
a. The appropriate anesthesia techniques and medications are determined by clinical judgment based on each patient's unique circumstances.
b. The anesthesia provider should consider pre-medication with an agent that may reduce the incidence of awareness (e.g. a benzodiazepine or scopolamine) when deemed appropriate.
c. If intubation of the trachea is difficult, consideration should be given to the administration of additional dosages of the induction or amnestic agent.
d. Anesthesia practitioners should realize that certain medications (e.g. beta-blockers, calcium channel blockers, alpha-2 agonists) and neuromuscular blocking agents may mask the homodynamic and physiologic responses to inadequate anesthesia.

4. Managing an Episode of Unintended Intraoperative Awareness During General Anesthesia:
a. When an anesthesiologist learns that a patient may have had unintended intraoperative awareness of surgical or procedural events during general anesthesia, the anesthesiologist should explore, document, and report the experience and provide for any necessary follow-up care. When other personnel learn that a patient may have experienced unintended intraoperative awareness during general anesthesia, the personnel should inform the anesthesiologist of record about the suspected occurrence.
b. If an episode of unintended intraoperative awareness during general anesthesia occurs or is suspected, the anesthesiologist who was responsible for the patient's care, or a qualified designee, should interview the patient and document the details of the patient's experience. If the anesthesiologist determines that unintended intraoperative awareness during general anesthesia has occurred the following steps may serve mitigate serious patient sequelae:
i. Assure the patient of the credibility of his or account and sympathize with the patient's experience;
ii. Explain what happened and why, if a reason can be given (e.g., the necessity to administer light anesthesia in the presence of significant cardiovascular instability);
iii. Offer the patient support, including referral of the patient to a psychiatrist, psychologist, or the Hospital Counseling Services if appropriate;
iv. Document any referrals or treatment provided to the patient;
v. Notify the patient's surgeon and nurse;
vi. Complete an occurrence report concerning the event for the purpose of quality management.

D. **REFERENCES:**

1. Mashour, G., Orser, B., & Avidan, M. (2011, May 01). Intraoperative Awareness:From Neurobiology to Clinical Practice. Retrieved February 3, 2020, from https://anesthesiology.pubs.asahq.org/article.aspx?articleid=2034780
2. Sentinel Event Alert 32 Preventing and managing the impact of anesthesia awareness. (n.d.). Retrieved February 3, 2020, from https://www.jointcommission.org/en/resources/patient-safety-topics/sentinel-event/sentinel-event-alert-newsletters/sentinel-event-alert--issue-32-preventing-and-managing-the-impact-of-anesthesia-awareness/

3. Practice Advisory for Intraoperative Awareness and Brain Function Monitoring:A Report by the American Society of Anesthesiologists Task Force on Intraoperative Awareness. (2006, April 01). Retrieved February 3, 2020, from https://anesthesiology.pubs.asahq.org/article.aspx?articleid=1923386

Tri-City Medical Center
Oceanside, California

OUTPATIENT BEHAVIORAL HEALTH SERVICES

ISSUE DATE: NEW **SUBJECT:** Psychotropic Medications

REVISION DATE:

Department Approval:	**07/20**
Division of Psychiatry Approval:	**06/24**
Pharmacy and Therapeutics Approval:	**10/24**
Medical Executive Committee Approval:	**10/24**
Administration Approval:	**11/24**
Professional Affairs Committee Approval:	
Board of Directors Approval:	

A. **PURPOSE:**

1. To identify Patient, Physician and R.N. responsibilities regarding medication consent, education, documentation and reconciliation.

B. **POLICY:**

1. Patients are responsible for providing their own medications needed during Program hours. Patients, a responsible caregiver, or their licensed residential care facility assume the responsibility for administration of medications. Program physicians may prescribe medications for their patients or work in collaboration with a community physician who is the prescribing physician. Program RNs are responsible for medication education, reconciliation, taking medication orders and documentation.

C. **PROCEDURE:**

1. All patients will be informed of medications purpose, side effects and long-term use and will sign a medication consent form, which will be kept as a permanent part of the medical record.
2. No patient will receive medications without his or her consent, unless an emergency exists.
3. A physician may, in an emergency, order medications for the patient without his/her consent, such as in a case of an emergency.
4. If medications are being managed by the attending Program physician they may enter orders for medications in the medical record, after obtaining informed consent from the patient. They may enter the prescription directly in the electronic medical record and in some cases also give a written prescription to the patient. The RN may call the order in to the pharmacy and reconcile by notifying the licensed residential care facility or the caregiver of the medication or medication change.
5. The RN is responsible for assessing the patient for capacity to take medications independently and educating the patient about their medications.
6. The RN maintains a current list of each patient's medications. Medications must be reconciled upon admission, when medication changes occur or routinely on a quarterly basis, and upon discharge. Reconciliation may be completed with the patient, the patient's pharmacy, other physicians who may be treating the patient concurrently, the patient's caregiver, the Board and Care Manager and upon discharge with the clinician or agency that will be treating the patient in the community.
7. If the patient is co-treated with another community physician, the medication list must be updated and reconciled when medication changes occur.
8. The Program physician may authorize the RN to notify the pharmacy for medication refills.
9. Telephone orders are signed by the ordering physician within 48 hours.
10. If a patient is ordered an injectable medication, a Program RN may perform this process. All

injectable medications must be verified by the issuing pharmacy for accuracy prior to the injection. Injectable medications will be stored by the RN properly and according to manufacturer's directions.

11. After opening multi dose vials, the RN will date, time, and initial the bottle.
12. The use of psychopharmacological agents for patients will be monitored for appropriateness and safety. In the event that patients are prescribed more than seven psychopharmacological agents, including hypnotics, antipsychotics, sedatives, anxiolytics, mood stabilizers, and antidepressants, a peer review of the patient record must occur by the medical director.
13. When circumstances warrant larger doses than approved by the FDA label, the physician will document specific rationale in the medical record.
14. As described in item C (12), it is the responsibility of the prescribing physician to order psychopharmacologic agents in an appropriate and safe manner. Nursing staff will review the physician's orders, assist in maintaining patient safety, and will request a peer review of the record in the event of polypharmacy.

D. **FORM(S)**:

1. Consent to Receive Psychotropic Medication 6340-1001

Tri-City Medical Center
Oceanside, California

PHARMACY

ISSUE DATE: 01/18 **SUBJECT: Drug Supply Chain Security Act**

REVISION DATE:

Pharmacy Department Approval:	~~11/21~~09/24
Pharmacy and Therapeutics Committee Approval:	~~11/21~~10/24
Medical Executive Committee Approval:	~~01/22~~10/24
Administration Approval:	~~02/22~~11/24
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	02/22

A. **BACKGROUND:**

1. The Drug Quality and Security Act (DQSA) was signed into law in November 2013. Title II of the act, The Drug Supply Chain Security Act (DSCSA) established new definitions and requirements related to product tracing and outlines steps to building an electronic system that 10 years after enactment will identify and trace prescription drugs distribution in the United States. Many milestones will be implemented until DSCSA completion in 2023. Initial milestones are implemented for enforcement in 2015. This policy reflects the first phase.
2. The DSCSA replaces pedigree requirements of the Prescription Drug Marketing Act (PDMA) and preempts state requirements unless state requirements are more stringent.
3. The DSCSA requirements apply to transactions or changes in ownership of finished dosage forms performed by authorized trading partners including dispensers (pharmacies).

B. **PURPOSE:**

1. To establish procedures in compliance with federal regulations defined in Title II of the Drug Quality and Security Act (DQSA), Drug Supply Chain Security that protect consumers by improving detection and removal of potentially dangerous, adulterated and/or counterfeit products from the pharmaceutical distribution supply chain.

C. **DEFINITIONS:**

1. Trading partner - A manufacturer, repackager, wholesale distributor, dispenser or third-party logistics provider.
2. Dispenser - A retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor.
3. Third-party logistics provider - An entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.
4. Product - A prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution); does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products, imaging drugs, intravenous products, medical gas, homeopathic drugs, or a drugs compounded in compliance with section 503A or 503B.
5. Transaction - The transfer of product between persons in which a change of ownership occurs. Exemptions: The term transaction does not include the distribution of; sample medications, blood and blood component products, IV fluids, dialysis solutions, medical gases, etc. See Exceptions to the DSCSA Tracing Requirements.

6. Transaction History (TH) - A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.
7. Transaction Information (TI) – TI includes:
    a. Proprietary or established name or names of the product
    b. Strength and dosage form
    c. National Drug Code number
    d. Container size and the number of containers
    e. Lot number
    f. Date of the transaction
    g. Date of the shipment, if more than 24 hours after the date of the transaction
    h. Business name and address of the person from whom ownership is being transferred
    i. Business name and address of the person to whom ownership is being transferred
8. Transaction Statement(TS) - A statement or attestation, in paper or electronic form, that the entity transferring ownership:
    a. Is authorized as required under the Drug Supply Chain Security Act
    b. Received the product from a person that is authorized
    c. Received transaction information and a transaction statement from the prior owner of the product
    d. Did not knowingly ship a suspect or illegitimate product
9. Suspect product - A product for which there is reason to believe that such product is:
    a. Potentially counterfeit, diverted, or stolen
    b. Potentially intentionally adulterated
    c. Potentially the subject of a fraudulent transaction; or
    d. Appears otherwise unfit for distribution such that the product would result in serious
        i. adverse health consequences or death to humans

D. **POLICY:**

1. It is the policy of Tri-City Hospital District (TCHD) to maintain awareness about suspicious activity or potential threats to the drug supply chain, and to devote attention and effort to detect suspect product.
2. Obtain pharmaceuticals only from authorized trading partners as defined by the Food Drug and Cosmetic Act
3. Trace, quarantine, investigate, retain samples, clear, notify others and dispose of suspect or illegitimate products
4. Accept ownership of product only if the prior owner provides the transaction history (TH), transaction information (TI), and transaction statement (TS)
5. Provide subsequent owners with the TH/TI/TS unless the transaction is exempt or the sale is from dispenser to dispenser to fill a specific patient need
6. Retain records of TH/TI/TS for no less than 6 years after the transaction
7. Respond to request for TH/TI/TS due to a recall or investigation of suspect or illegitimate product from the Secretary of Health and Human Services or other appropriate Federal or State official within 2 business days
8. Return a product to the trading partner where the product was obtained without providing tracing information
9. Have a written agreement with a third-party provider (i.e. authorized wholesaler, distributor or other third-party service provider) to maintain the required TH/TI/TS on behalf of the facility.

E. **PROCEDURE:**

1. Confirm authorized trading partners
    a. Pharmaceuticals are only obtained from authorized trading partners
    b. Trading partners (manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers) are confirmed to be authorized as defined by the Food Drug and Cosmetic Act
    c. Manufacturer's and repackagers are confirmed as authorized trading partners using the

FDA's drug establishment registration database.

d. Wholesale distributors, third-party logistic providers and dispensers, are validated with the state authority to confirm licensure

2. Identification or suspect product
   a. Characteristics that might increase the likelihood that a product is a suspect or illegitimate product are listed in Characteristics of Suspect or Illegitimate.
   b. Strategies employed to identify suspect product include, but are not limited to:
      i. Avoid unsolicited offers and offers for product for sale at a very low price or one that is "too good to be true."
      ii. Examine the package and the transport container (case or tote) for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or altered).
         1) Identify any unexplained changes since it was last received
         2) Identify if product inserts are missing or do not correspond to the product
         3) Verify shipping addresses, postmarks, or other materials to validate that
            a) the product did not come from an unexpected foreign entity or source
      iii. Examine the label on the package, or the label on the individual retail unit, for;
         1) Missing information, such as the lot number or other lot identification, NDC, or strength of the drug
         2) Altered product information, such as smudged print or print that is very difficult to read
         3) Misspelled words
         4) Bubbling in the surface of a label
         5) Lack of an Rx symbol
         6) Foreign language with little or no English provided
         7) Foreign language that is used to describe the lot number
         8) A product name that differs from the name of the FDA-approved drug
         9) A product name that is the product name for a foreign version of the drug
         10) Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container

3. Quarantine:
   a. Identified suspect products are quarantined to prevent distribution or transfer until they are cleared for distribution or dispensing; or are determined to be illegitimate
   b. Suspect products are quarantined in a physically separate area that is clearly identified

4. Notifications:
   a. Upon determination that a product is suspect or illegitimate, immediate trading partners and the FDA are notified within 24 hours of the determination
   b. FDA notification:
      i. FDA Form 3911 accessed at the FDA website.
   c. Termination of notification in consultation with the FDA:
      i. To terminate notification in consultation with the FDA when the notification is believed to be no longer necessary access the FDA website.

5. Investigation:
   a. Upon identification of a suspect product, an investigation is promptly conducted in coordination with trading partners (wholesale distributor, manufacturer) to determine if the product is illegitimate.
   b. Validate transaction history and transaction information and otherwise investigate to determine if the product is illegitimate
   c. If investigation determines that the product is not illegitimate and the product is cleared, the FDA is notified and the product may be distributed or dispensed
   d. If investigation determines that the product is an illegitimate product
      i. The product is removed from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal

ii. A sample of the product is retained for further physical examination or laboratory analysis of the product by the manufacturer or other appropriate Federal or State official upon request

e. Records of the investigation are retained for at least 6 years after the conclusion of the investigation.

6. Obtaining, retaining and retrieving transaction records TH/TI/TS
   a. Transaction records (TH/TI/TS) are obtained from authorized trading partners for all applicable products.
   b. The records are maintained and retained in a readily retrievable manner for at least 6 years from date of the transaction
   c. Wholesaler/ Distributor records are provided electronically and are retrievable at any time.
   d. Direct Purchase from the Manufacturer – all packing slips are verified to contain the required transaction records. Packing slips are scanned into electronic database and maintained bu buyer.
   e. Borrow/Loan vs. Drug Transfer/Sale – all non, patient-specific transactions will require documentation of T3.
7. Record retention requirements
   a. Transaction records (TH/TI/TS), suspect product investigations and notifications must be retained for 6 years

F. **EXTERNAL LINK(S):**
1. FDA's Drug Establishment Registration Database: https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm
2. FDA Form 3911: http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm
3. FDA Terminate Notification: http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm

G. **RELATED DOCUMENT(S):**
1. Exceptions to the DSCSA Tracing Requirements
2. Characteristics of Suspect Products

H. **REFERENCE(S):**
1. Title II of the Drug Quality and Security Act-Drug Supply Chain Security (DSCSA) http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm Accessed April 2015
2. Draft Guidance: Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Accessed April 2015
3. Draft Guidance: DSCSA Standards for the Interoperable Exchange of Information for Tracing of Human, Finished Prescription Drugs: How to exchange product tracing information Accessed April 2015
4. FDA Drug Supply Chain Security Act Implementation Plan: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm382022.htm

Tri-City Medical Center
Oceanside, California

PHARMACY MANUAL

ISSUE DATE: 4/12

SUBJECT: General and Concentrated Electrolytes Policy

REVISION DATE: 06/12, 10/15

Department Approval:	**~~11/21~~09/24**
Pharmacy and Therapeutics Approval:	**~~11/21~~10/24**
Medical Executive Committee Approval:	**~~01/22~~10/24**
Administration Approval:	**~~02/22~~11/24**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	**02/22**

A. **PURPOSE:**

1. To provide an organization—wide drug safety policy to prevent medication errors associated with concentrated electrolytes as recommended by the Institute for Safe Medication Practices (ISMP) and The Joint Commission (TJC).- These guidelines and procedures are to be followed by all personnel involved in the intravenous administration of concentrated electrolytes.
2. This policy addresses the non-emergent prescribing, administration, dispensing, and storage of intravenous electrolytes for maintenance and replacement supplementation. In addition, this policy will address prescribing of hypotonic and hypertonic solutions.

B. **POLICY**:

1. There shall be safety measures in place to minimize the potential for medication errors regarding the ordering, preparation, labeling, distribution, administration, storage, and monitoring of all intravenous electrolytes.
   a. Concentrated electrolyte solutions include~~,~~ but are not limited to: potassium chloride, potassium phosphate, potassium acetate, 3% sodium chloride, 23.4% sodium chloride, sodium acetate, and sodium phosphate.
   b. This policy shall also encompass the safe use of all other intravenous electrolytes, including~~,~~ but ~~are~~ not limited to: calcium chloride, calcium gluconate, magnesium sulfate, sodium bicarbonate, and sterile water for injection.
2. Tri-City Medical Center **(TCMC)** maintains supplies of concentrated electrolytes in the Pharmacy Department. -Concentrated electrolytes will not be stocked in patient care areas.
   a. 3% hypertonic saline shall not be stored in automated dispensing machines (ADM) and shall be dispensed patient--specific from the pharmacy one bag at a time.
   b. 23.4% hypertonic saline shall not be stored in an ADM and shall be dispensed patient specific from the pharmacy.- To prevent accidental infusion, pharmacy shall dispense one VIAL at a time and shall never dilute further and/or dispense in a bag to prevent accidental infusion.
      i. Can only be ordered- by a neurologist,~~-or~~ neurosurgeon**, or critical care physician**
   c. Large volume (1000mL or larger) sterile water for injection shall not be stored in patient care areas and will not be dispensed without additives to avoid hemolysis.
   d. Exceptions:
      i. Potassium chloride vials may be stored in perfusion carts only.
      ii. Pre-mixed mini-bags for electrolyte replacement pursuant to approved protocol are available in automated dispensing machines (ADM). Different strengths shall be separated to avoid look-a-like errors.

iii. Magnesium sulfate vials, **sodium bicarbonate vials/syringes, and** calcium chloride and/or calcium gluconate vials/syringes are stored in emergency medication trays and automated dispensing machines for emergency use only.

3. The number of drug concentrations available at ~~Tri-City Medical Center~~**TCMC** are standardized whenever possible and limited to the minimum required to meet patient care needs.
4. All orders for concentrated electrolyte solutions must be entered electronically into Cerner.
   a. Exceptions: verbal/telephone orders followed by a written order will be accepted during an emergency.
5. When infusion of concentrated electrolytes ~~are~~**is** required for patient use, only commercially prepared products (whenever possible), with patient-specific labeling, shall be dispensed.
6. Solution orders that require admixture (i.e., ~~there is not a~~**no** pre-mixed solution ready for administration available) will be prepared by Pharmacy and delivered to the patient care area of use on a per patient basis.
7. Route of electrolyte administration is dependent on the specific electrolyte, concentration, and urgency. (Appendix II: Dosing and Administration Guidelines).
8. All intravenous electrolytes shall be administered with an electronic infusion device (**e.g.,**~~i.e.~~ Alaris Smart Pump) and will not be given via IV Push.
   a. Exception: -Calcium chloride may be administered via slow IV push in central line during code blue only; calcium gluconate may be administered via slow IV push in a large vein over 5 to 10 minutes; magnesium sulfate may be administered via slow IV push not to exceed 150mg/min (may administer over 1 to 2 minutes in patients with persistent pulseless VT or VF with known hypomagnesemia) and must be diluted to a concentration ~~of ≤~~ 20% **or less**.
9. Hypertonic solutions MUST be administered via central line with an electronic infusion device. If a central line is not available, then~~,~~ the largest patent vein should be utilized until a central line is placed.

C. **PROCEDURE:**

1. Prescribing
   a. Pharmacy shall require prescriber's orders for maintenance electrolytes to specify the name of the electrolyte, name of diluent, concentration, and infusion rate (e.g. D5 ½ NS with 20 mEq KCl/liter at 20 mL per hour).
   b. Pharmacy shall require prescriber's orders for bolus electrolytes to specify the name of the electrolyte, dose (in mEq, mmoL, **g,** or mg), concentration of electrolyte, administration rate (dose/hour or mL/hour), and route of administration.
   c. For children less than or equal to 13 years of age, the prescriber's order shall include patient's weight in kg, dose of- electrolyte on a per kg basis, and volume of electrolyte to be administered.
   d. Dosing of electrolyte in obese patients (i.e., ~~actual~~**total body** weight **(TBW) greater than** ~~>~~ 130% **ideal body weight** (IBW) or **body mass index** (BMI) **greater than** ~~>~~ 30 kg/m2) should be based on an adjusted body weight **(ABW)** when weight--based dosing is required (Consult pharmacist for weight adjustment calculations).
   e. Electrolyte replacement in patients ~~that~~ **who** are asymptomatic should be treated with oral supplement**ation** whenever possible if there is a functional gastrointestinal tract,~~.~~ EXCEPT IN THE CASE OF MAGNESIUM. (Appendix IV: Selected Available Oral Electrolyte Replacement Products.
   f. Pharmacy shall provide the prescriber with a selection of standardized electrolyte solutions to order from. Tri City Medical Center-Intravenous Electrolyte Administration Guide (Appendix I: Selection of standardized solutions available at TCMC).
   g. In the event that one of the standardized solutions cannot satisfy the patient's needs, a pharmacist will contact the prescriber to assure that the requested solution is clinically indicated. Only then will the solution be compounded.
   h. In the event of an order for a hypotonic or hypertonic solution, the order will be discussed with **the** prescriber to assure **that** the solution is ~~clinically~~ indicated **clinically**. It will be dispensed on a patient--specific basis following dosing guidelines.
      i. Serum osmolarity range 240-340 mOsm/L.

1) Hypotonic solution-lower osmolarity than serum.
2) Hypertonic solution-higher osmolarity than serum.

ii. Sterile water for injection **and~~or~~** 0.225% sodium chloride **are very hypotonic solutions and** will not be dispensed without additives in order to avoid hemolysis.

2. Administration

a. Potassium Administration Guidelines:

i. Potassium shall not be administered IV push. It shall be administered via a slow infusion, diluted with a suitable volume of solution.

ii. Potassium shall never be added to an infusing IV, as doing so results in the pooling of potassium and a resultant bolus concentration of the drug being administered.

iii. Patients with concomitant hypomagnesemia should have the magnesium deficit corrected prior to potassium supplementation to prevent refractory hypokalemia.

iv. Administration of Potassium in Non-Critical Care setting:

1) Potassium Intermittent Infusions "Piggybacks"

a) Maximum infusion rate via peripheral line is 10 mEq/hour. Maximum infusion rate via central line is 20 mEq/hour and must be on continuous **electrocardiogram** (ECG) monitoring.

2) Potassium large volume continuous infusions (1000 mL or more)

a) Maximum concentration of potassium is 40 mEq/liter of solution with a maximum infusion rate of 10 mEq/hour (20 mEq/hour if the patient is on continuous ECG monitoring **and infusion is administered via a central line**).

3) **Generally, ~~D~~doses ~~up to~~should not exceed** 200 mEq in 24 hours ~~generally should not be exceeded~~.

v. Administration of Potassium in Critical Care setting

1) Maximum concentration and infusion rates are recommended as listed above.

2) Exceptions: ~~-~~Depending upon the estimated potassium deficiency and the urgency of the situation [for example: severe hypokalemia (potassium below 2.5 mEq/L), cardiac arrhythmias, diabetic ketoacidosis] rare patients require a concentration, dosage and/or rate of administration which temporarily exceeds those guidelines stated above. **In these rare cases:**

a) Maximum concentration of potassium is 80 mEq/liter in a critical care setting on continuous ECG monitoring.

b) Maximum rate of potassium infusion is established at 40 mEq per hour, which requires continuous ECG monitoring in critical care settings **and infusion via a central line**. **Generally, ~~-d~~D**oses ~~up to~~should not exceed** 200 mEq in 24 hours ~~generally should not be exceeded~~.

vi. Potassium level must be checked after administration of 60 mEq potassium prior to administration of additional potassium.

b. Potassium Phosphate and Sodium Phosphate Administration Guidelines:

i. Intravenous phosphate is potentially dangerous, since it can precipitate with calcium and produce a variety of adverse effects including hypocalcemia, renal failure, and ~~potentially~~ **sometimes** fatal arrhythmias.

1) Phosphate solutions shall not be infused via the same IV catheter as calcium--containing solutions **(e.g., ceftriaxone, parenteral nutrition, etc.)**.

ii. Potassium phosphate or sodium phosphate shall not be administered IV push and shall be administered via a slow infusion, diluted with a suitable volume of solution.

iii. In situations of hypophosphatemia requiring parenteral administration of intravenous phosphate, it may be necessary to administer concentrated solutions of potassium phosphate or sodium phosphate.

1) The salt chosen depends on the patient's serum sodium and potassium levels.

a) Potassium phosphate should not be used if serum potassium GREATER than 4.5 mEq/L. Sodium phosphate should not be used if serum sodium is GREATER than 145 mEq/L.
b) If both potassium and phosphate replacement required, subtract the mEq of potassium given as potassium phosphate from total amount of potassium required (7 mmol of Potassium phosphate = 10 mEq of potassium).

2) Maximum phosphate concentration for peripheral line administration = 7 mmol/100mL (10 mEq of potassium/100mL, if using potassium phosphate).
3) Maximum phosphate concentration for central line administration = 15 mmol/100mL (20 mEq of potassium/100mL, if using potassium phosphate).
4) Maximum infusion rate of phosphate 7 mmol/hr (10 mEq/hr potassium, if using potassium phosphate) via peripheral line or central line without cardiac monitoring.
5) Maximum infusion rate of phosphate up to 14 mmol/hr (20 mEq/hr potassium, if using potassium phosphate) via central line with cardiac monitoring in the Critical Care Setting.
6) Potassium level must be checked after administration of 60 mEq potassium (**~40**~~27~~ mmol phosphate) prior to administration of additional potassium.

c. Sodium Chloride 3%- Administration Guidelines:
i. Sodium chloride 3% is available in 500mL bag (3g NaCl/100mL = 15g NaCl/500mL = 513 mEq NaCl/1000mL = 1027 mOsm/1000 mL)
ii. Use of Hypertonic Saline (Sodium Chloride 3%) is primarily reserved for patients for:
1) Treatment of increased intracranial pressure
2) Treatment of cerebral edema
3) Clinical signs of cerebral herniation
4) Treatment of acute and chronic euvolemic symptomatic hyponatremia
iii. Central line preferred due to high osmolarity. For emergent situations, peripheral (large bore vein with good blood flow) may be utilized.
iv. Usual Dosing:
1) Bolus: 100-250 mL over 15-20 minutes
2) Infusion: 5-150 mL/hr (start at 5-30 mL/hr)
a) Rate of correction should generally not exceed 10-12 mEq/L in **the** first 24 hours and 18 mEq/L in **the** first 48 hours to prevent osmotic demyelination syndrome
v. Bolus doses of hypertonic saline may only be prescribed by Neurology, Neurosurgery, **or** Critical Care ~~or Pulmonary~~ physicians and shall be reserved for administration in critical care settings.
1) Exception: Any location in emergent situation with continuous monitoring pending transfer to critical care area.
vi. Administration of hypertonic saline continuous infusions shall be reserved for critical care areas and telemetry. Administration is not permitted on acute care, L&D, and post-partum floors.
1) Exception: Any location in emergent situation with continuous monitoring pending transfer to critical care or telemetry unit.
vii. All orders require renewal by MD after every 500mL administered.
viii. The provider will determine the overall sodium replacement goal, initial sodium goal for the first four (4) hours of the intervention, and rate of correction.
1) The plasma sodium [Na+] should be raised at a rate of 1 to 2 mEq/L per hour in patients with severe symptoms (seizures, coma, evidence of brainstem dysfunction).
2) The plasma sodium [Na+] should be raised by no more than 10 **to** -12 mEq/L in 24 hours and no more than 18 mEq/L in 48 hours.
3) The pharmacist shall have the ability to hold any hypertonic saline infusion whereby the sodium [Na+] has increased by GREATER than 12 mEq/L in a

24–hour period OR GREATER than 18 mEq/L in a 48–hour period per pharmacy protocol.

a) Exceptions: ~~-~~hypertonic saline infusions for cerebral edema, herniation or any brain condition.

4) The pharmacist must contact the prescriber immediately upon holding of the hypertonic saline infusion and for further orders.

ix. The pharmacist shall verify the indication for all hypertonic saline infusions.

x. The pharmacist will verify the calculations regarding the dose and rate of the infusion ordered by the provider via the following process:

1) Determine the overall sodium replacement goal and the initial sodium replacement goal as documented by the Provider.
2) Determine the actual serum sodium level of the patient.
3) Calculate the total body sodium deficit by:
   a) [0.6 for males or 0.5 for females] x Weight** (in kg) x (Desired Na - Patient's Na)
      i) **Note: For weight **greater than**~~>~~ 130% of ~~ideal body weight (~~IBW~~)~~, use ~~adjusted weight~~**ABW**. ~~Adjusted weight~~ **ABW** = 0.~~45~~ x (~~A~~TBW-IBW) + IBW up to maximum of 100 kg.
4) Verify the replacement rate for the first 24 hours.
   a) [0.6 for males or 0.5 for females] x Desired increase in Serum Na x _____kg = mEq sodium to be replaced.
      i) Note: Not to exceed an increase of 10 **to** -12 mEq/L in a 24-hour period or 18 mEq/L in 48 hours.
   b) 3% sodium chloride contains 513 mEq/L sodium and 513 mEq/L chloride.
   c) Volume of 3% sodium chloride to be infused = ____ mEq sodium to be replaced/(513) x 1000 = _____ mL/24 hours.
   d) Rate (-mL/hour) = total number of mL per 24 hours.
5) See Appendix V for Quick Estimation for Asymptomatic Hyponatremia
6) See Appendix VI for Quick Estimation for Chronic Hyponatremia

xi. The order should be assessed periodically by the prescriber for continued therapy (every 12 hours is recommended).

xii. Recheck electrolytes (serum sodium, chloride, potassium, bicarbonate, serum osmolarity) and clinical status every 2 to 4 hours, with a minimum of every 4 hours.

xiii. Precautions:

1) Severe neurologic complications may result from rapid changes in serum sodium concentration and serum osmolality.
2) Patients with a history of cirrhosis or alcoholism may be at increased risk for osmotic demyelination syndrome with rapid sodium correction.
3) Rapid withdrawal of hypertonic saline infusion may result in rebound cerebral edema.
4) Plasma volume expansion may worsen pre-existing heart failure or cause pulmonary edema
5) Administration of hypertonic saline via peripheral line may result in phlebitis and skin necrosis.

D. **RELATED DOCUMENTS:**

1. Maintenance Solutions Containing Potassium
2. Guidelines for Dosing & Administration of Electrolyte Replacement
3. Osmolarity of Selected IV Fluids
4. Selected Available Oral Electrolyte Replacement Products
5. Quick Estimation for Asymptomatic Hyponatremia
6. Quick Estimation for Symptomatic Hyponatremia

MAINTENANCE SOLUTIONS CONTAINING POTASSIUM

Solution	KCl content (mEq/L)	Volume		Solution	KCl content (mEq/L)	Volume
1/2NS	20	1000 mL		D5 1/2 NS	10	1000 mL
NS	20	1000 mL		D5 1/2 NS	20	1000 mL
NS	40	1000 mL		D5 1/2 NS	30	1000 mL
D5W	20	1000 mL		D5 1/2 NS	40	1000 mL
D5 NS	20	1000 mL				

Multi-electrolyte MAINTENANCE SOLUTIONS

Solution	Content	Volume
Lactated Ringer's Injection	K 4 mEq/L, Na 130 mEq/L, Ca 3 mEq/L, Cl 109 mEq/L, Lactate 28 mEq/L	1000 mL
Dextrose 5% in Lactated Ringer's Injection with 20 KCl	Dextrose 5%, K 24 mEq/L, Na 130 mEq/L, Ca 2.7 mEq/L, Cl 129 mEq/L, Lactate 28 mEq/L	1000 mL
Dextrose 5% in Lactated Ringer's with 40 KCl Injection	Dextrose 5%, K 44 mEq/L, Na 130 mEq/L, Ca 2.7 mEq/L, Cl 149 mEq/L, Lactate 28 mEq/L	1000 mL

Solutions Available for BOLUS ADMINISTRATION*

Solution (all provided in D5W or NS)	Electrolyte Content	Volume	Route of Administration
Calcium chloride 10 mg/mL	1 gram	100 mL	Central only
Calcium gluconate 10 mg/mL	1 gram	100 mL	Peripheral or Central
Magnesium sulfate 10 mg/mL	1 gram	100 mL	Peripheral or Central
Magnesium sulfate 40 mg/mL	4 grams	100 mL	Central only
Potassium acetate 0.1 mEq/mL	10 mEq- potassium	100 mL	Peripheral or Central
Potassium acetate 0.2 mEq/mL	20 mEq- potassium	100 mL	Central only
Potassium chloride 0.1 mEq/mL	10 mEq- potassium	100 mL	Peripheral or Central
Potassium chloride 0.2 mEq/mL	10 mEq potassium	50 mL	Central only
Potassium phosphate 0.1 mEq/mL	7.5 mmol phosphate = 11 mEq potassium	100 mL	Peripheral or Central
Potassium phosphate 0.1 mEq/mL	15 mmol phosphate = -22 mEq potassium	250 mL	Peripheral or Central
Potassium phosphate 0.2 mEq/mL	30 mmol phosphate = 44 mEq potassium	500 mL	Peripheral or Central
Sodium phosphate 0.1 mEq/mL	7.5 mmol phosphate = 10 mEq ~~of~~ sodium	100 mL	Peripheral or Central
Sodium phosphate 0.1 mEq/mL	15- mmol phosphate = 20 mEq ~~of~~ sodium	250 mL	Peripheral or Central
Sodium phosphate 0.2 mEq/mL	30 mmol phosphate = -40 mEq ~~of~~ sodium	500 mL	Peripheral or Central

Guidelines for Dosing & Administration of Electrolyte Replacement
****This is meant to serve as a reference please see TCMC electrolyte replacement protocol ****

Potassium Acetate and- Potassium Chloride Bolus Dosing and Administration (IV)				
Serum Level	**Adult Dose**	**Pediatric Dose**	**Infusion Rate**	**Hourly Maximum**
3.0 - 3.5 mEq/L	10 mEq	0.2 - 0.3 mEq/kg/dose	Over 1 - 2 hours	10 mEq
2.5 - 3.0 mEq/L	20 — 40 -mEq	0.5 mEq/kg/dose*	Over 1 - ~~42~~ hours	20 mEq*
<2.5 mEq/L	40 - 80 mEq	1 mEq/kg/dose*	Over 2 - ~~84~~ hours	20 mEq*

- Patients with renal insufficiency should receive less than or equal to 50 % of the dose.
- Check a magnesium level especially in patients with hypokalemia and hypocalcemia.
  - Magnesium deficiency should be corrected to facilitate the correction of hypokalemia.

Potassium Phosphate and Sodium Phosphate Bolus Dosing and Administration (IV)			
Serum Phosphate Level	**Adult Dose**	**Pediatric Dose**	**Infusion Rate**
Mild, 2.3-2.7 mg/dL	7.5 mmoL	0.08 mmol/kg/dose	Over 2 hours
Moderate, 1.5-2.2 mg/dL	15 mmoL	0.16-0.24 mmol/kg/dose	Over 4-6 hours
Severe, <1.5 mg/dL	30 mmoL	0.36 mmol/kg/dose	Over 6 hours

- Equivalencies~~-~~: ~~-~~3 mmol/mL phosphate = 285 mg/mL
  ~~————————~~4.4 mEq/mL potassium = 170 mg/ mL
- Risk of calcium-phosphate precipitation when infused in the same IV catheter as solutions containing ~~C~~calcium!

Magnesium Sulfate Bolus Dosing and Administration (IV)				
Serum Magnesium Level	**Adult Dose**	**Pediatric Dose**	**Infusion Rate**	**Hourly Maximum**
Mild/ Moderate: 1 - 1.5 mg/dL	1-4 grams	25-50 mg/kg/dose	Over 2-4 hours	1 gram
Severe: < 1 mg/dL	4-8 grams	50 mg/kg/dose	Over 4-8 hours	1 gram

- Equivalencies: -1 gram ~~M~~magnesium s~~S~~ulfate = 8.2 mEq magnesium
- -Adult total dose should not exceed 12 gram over 12- hours

Calcium Dosing and Administration (IV)		
Dosing	**Adult Dose**	**Pediatric Dose**
Intermittent	Mild: 1-2 gram over 30 -60 minutes Severe: 1 gram ~~of~~ c~~C~~alcium chloride or 3 gram ~~of~~ calcium gluconate over 10 minutes;	Calcium chloride:10-20 mg/kg/dose Calcium gluconate: 50-100 mg/kg/dose Administration: over 30 - 60 minutes
Continuous Infusion (Severe hypocalcemia)	~~500 mg~~**0.5** - 1 gram/hour	Calcium chloride: 5-10 mg/kg/hr Calcium gluconate:10 -20 mg/kg/hr

- Equivalencies: ~~————————~~1 gm calcium chloride = 13.6 mEq (elemental calcium)
  1 gm calcium gluconate = 4.56 mEq (elemental calcium)
- Corrected calcium for low albumin: [(4 - **serum** alb) x 0.8] + **serum** calcium level

- Risk of calcium-phosphate precipitation when infused in the same IV catheter in solutions containing phosphate!
- Potential risk for cardiac arrhythmias associated with rapid calcium infusion.
- Blood products preserved with citrate may cause hypocalcemia: Administer 1.35 mEq of calcium for each 100 mL of blood transfused
- Not for IM or Subcutaneous~~Q~~ administration (severe necrosis and sloughing may occur).
- Avoid rapid administration (do not exceed 100mg/min except in emergency situations)
- For intermittent IV infusion, infuse diluted solution over 1 hour or no greater than 45-90 mg/kg/hour (0.6-1.2 mEq/kg/hr); administration via central or deep preferred; do not use scalp **or** small hand-~~or/~~ foot veins for IV administration.
- Monitor ECG if calcium is infused faster than 2.5 mEq/minute; stop the infusion if the patient complains of pain or discomfort.
- Warm solution to body temperature prior to administration.

Sodium Bicarbonate

- Metabolic acidosis: sodium bicarbonate dosage should be based on blood gases and pH measurements.
- HCO_3 dose (mEq) = 0.5 X weight (kg) X ~~(~~24 – serum HCO_3 (mEq/L)~~)~~ or use following equations:

Pediatrics:- HCO_3 dose (mEq) = 0.3 X weight (kg) X base deficit (mEq/L)

Adults:- HCO_3 dose (mEq) = 0.2 X weight (kg) X base deficit (mEq/L)

KEY POINT: Neonates & infants use 0.5 mEq/mL solution.

- Maximum rate of administration should not exceed 1 mEq/kg/hr. Rapid or excessive administration of sodium bicarbonate may produce tetany or cerebral edema/hemorrhage especially in infants.
- Recommendations for the addition of sodium bicarbonate to IV fluids:

IV stock- solution	Volume	Maximum Sodium Bicarbonate Addition	Resultant Na^+ concentration
0.45 % NaCl	500 mL	37.5 mEq (–0.75 vial)	152 mEq/L
0.45 % NaCl	1000 mL	75 mEq (-1.5 vials)	152 mEq/L
D5-W	500 mL	75 mEq (-1.5 vials)	150 mEq/L
D5W	1000 mL	150 mEq (-3 vials)	150 mEq/L
D5 0.45% NaCl	500 mL	37.5 mEq (0.75 vials)	152 mEq/L
D5 0.45-% NaCl	1000 mL	75 mEq (1.5 vials)	152 mEq/L
D10W	500 mL	75 mEq (1.5 vials)	150 mEq/L
D10W	1000 mL	150 mEq (3 vials)	150 mEq/L

Each vial/amp of sodium bicarb contains 50 meq of sodium

- Addition of sodium bicarbonate to IV fluids should not result in a hypertonic solution.
- Sodium bicarbonate should not be added to 0.9 % sodium chloride containing solutions.
- Exceptions: Preparation and dispensing of hypertonic sodium bicarbonate solutions require discussion with prescriber and approval by Clinical Manager. Also see Sodium Chloride 3% Administration Guidelines above.

Osmolarity of Selected IV Fluids

Solution	mOsm/liter

½ Normal Saline (0.45% NaCl)	154
Normal Saline (0.9% NaCl)	308
Dextrose 5% in Water	252
Dextrose 10 % in Water	505
Dextrose 5% and 0.2% NaCl	321
Dextrose 5% and 0.45% NaCl	406
Dextrose 5% and 0.9 % NaCl	560
Dextrose 5% and 0.2% NaCl with 20 mEq KCl	361
Dextrose 5% and 0.45% NaCl With 20 mEq KCl	447
Lactated Ringers	273
Dextrose 5% and Lactated Ringers	525

- Consult with pharmacist and/or standard references for osmolarity of other solutions.
- Sterile water for injection or 0.225% sodium chloride will not be dispensed without additives to avoid hemolysis

Selected Available Oral Electrolyte Replacement Products

Phosphate Replacement PO* Products				
Formulation	**mg PO_4**	**mmol PO_4**	**mEq Na^+**	**mEq K^+**
K-Phos Neutral	250	8	13.1	1.1

Potassium Replacement Products (PO)		Comments
Formulation	**Strengths**	• Oral route preferred over IV • Do not crush extended–release products • Need to correct hypomagnesemia **first** in order to correct potassium levels • Excess chloride salts may cause metabolic acidosis • Excess acetate salts may cause metabolic alkalosis •
Potassium chloride (Extended release capsule)	10- mEq ER- (Micro-K)	
Potassium chloride (Liquid)	20 mEq/15 mL 40 mEq/30 mL	
Potassium ~~chloride~~bicarbonate (Effervescent tablet)	25 mEq ~~effervescent~~	

Calcium Replacement PO Products				
Formulation	**Strength**	**Route**	**Elemental Calcium (mEq/dL)**	**Elemental Calcium (%)**
Calcium acetate (Tablet)	667 mg (169 mg Elemental)	I.V. or Oral[B]	12.7	25
Calcium carbonate (Tablet/Suspension)	650 mg 1250 mg/5mL	Oral[B]	20	40

Quick Estimation for Asymptomatic Hyponatremia

IBW kg	40 kg	50 kg	60 kg	70 kg	≥ 80 kg
Estimated Rate of -3% NaCl to correct Serum Na by 8mEq/L/24h (mL/hr)	**13 mL/hr**	**16 mL/hr**	**20 mL/hr**	**23 mL/hr**	**26 mL/hr**

Quick Estimation for Symptomatic Hyponatremia

IBW kg	40 kg	50 kg	60 kg	70 kg	≥ 80 kg
Initial rate of 3% NaCl to increase Na by approx 3-5 mEq/L	80 mL/hr x 2hrs STAT Na level at 2 hours	100 mL/hr x 2hrs STAT Na level at 2 hours	120 mL/hr x 2hrs STAT Na level at 2 hours	140 mL/hr x 2hrs STAT Na level at 2 hours	160 mL/hr x 2hrs STAT Na level at 2 hours
If seizures do not resolve continue 3% NaCl	80 mL/hr	100 mL/hr	120 mL/hr	140 mL/hr	160 mL/hr
Maintenance rate (patient not seizing) for the 1st 24 hours	↓ Infusion to 7 mL/hr x 22 hrs Serial Na levels Q4h	↓ Infusion to 9 mL/hr x 22 hrs Serial Na levels Q4h	↓ Infusion to 11 mL/hr x 22 hrs Serial Na levels Q4h	↓ Infusion to 13 mL/hr x 22 hrs Serial Na levels Q4h	↓ Infusion to 15 mL/hr x 22hrs Serial Na levels Q4h
3% NaCl may be continued until serum Na >120.					

Tri-City Medical Center
Oceanside, California

PHARMACY

ISSUE DATE: 04/73 **SUBJECT:** Licensure and Professional Standards

REVISION DATE: 06/05, 07/06, 07/09, 01/12, 07/15, 03/18

Department Approval:	~~11/21~~09/24
Pharmacy & Therapeutics Committee Approval:	~~11/21~~10/24
Medical Executive Committee Approval:	~~01/22~~10/24
Administration Approval:	~~02/22~~11/24
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	02/22

A. **POLICY**:

1. The Pharmacy Department will operate within all applicable state and federal laws, regulations and licensure requirements. In matters of professional judgment or practice standards, recommendations from the American Society of Health-System Pharmacists (ASHP) and The Joint Commission will be given first consideration and priority.
2. State of California: (Example)
   a. Pharmacy Department services will be provided according to the regulations of the Department of Health Services as stated in Title 22 for licensed acute care hospitals. These requirements will be integrated into policies and procedures where necessary.
      i. Pharmaceutical Services Definition (section 70261)
      ii. Pharmaceutical Services General Requirements (section 70263)
      iii. Pharmaceutical Services Staff (section 70265)
      iv. Pharmaceutical Services Equipment and Supplies (section 70267)
      v. Pharmaceutical Services Space (section 70269)
   b. All laws, regulations and licensure requirements of the California State Board of Pharmacy will be met and followed.
      i. The hospital's Pharmacy Department will have at all times a valid and current pharmacy permit issued by the board which will be posted in public view.
      ii. All Pharmacists, Pharmacist Interns and Pharmacy Technicians must maintain valid and current licensure with the board according to law and hospital policy.
      iii. All Pharmacists, Intern Pharmacists, and Pharmacy Technicians shall renew licensure per Administrative Policy: Monitoring Licenses, Professional Registrations, and Certificates 430.
      iv. A current copy of State Pharmacy Law with Rules and Regulations is available on the California Board of Pharmacy website.
3. Federal:
   a. The hospital will comply with all laws, regulations and requirements of the Drug Enforcement Administration (DEA).
      i. The hospital will maintain current and valid registration with DEA. The registration certificate will be posted in public view in the Pharmacy.
      ii. All required records will be maintained by the Pharmacy Department, including order forms (DEA-222), disposal (DEA-41), loss (DEA-106) and the biannual inventory.
      iii. In accordance with DEA regulations, all schedules II, III, IV and V (CII, CIII, CIV & V) drugs will be stored separately in a locked cabinet in the main Pharmacy,

automated drug dispensing machines on the patient care units or double-lock storage cabinets in ancillary areas. Access is restricted to licensed personnel.

b. The Pharmacy Department will comply with the Conditions of Participation for Medicare of the Centers of Medicare and Medicaid Services.

4. Practice Standards:
   a. Dispensing: A Pharmacist will review each medication prior to dispensing. Exceptions to this can be found in the Pharmacy Policy: Technician Checking Technician Program.
   b. Staffing Guidelines: The ratio of Pharmacy Technicians to Pharmacists will not exceed two to one (2:1), except that this ratio shall not apply to personnel performing clerical functions pursuant to California Code of Regulations and the ratio of Intern Pharmacists to Pharmacists will not exceed two to one (2:1) at any time.

B. **RELATED DOCUMENT(S):**
1. Administrative Policy: Monitoring Licenses, Professional Registrations, and Certificates 430
2. Pharmacy Policy: Technician Checking Technician Program

C. **EXTERNAL LINK(S):**
1. California State Board of Pharmacy http://www.pharmacy.ca.gov/
2. Pharmacy Law Book with Rules and Regulations (2017). *California State Board of Pharmacy* http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf

D. **REFERENCE(S):**
1. Pharmaceutical Services Definition, Title 22 California Code of Regulations Division 5 § 70261.
2. Pharmaceutical Services Equipment and Supplies, Title 22 California Code of Regulations Division 5 § 70267.
3. Pharmaceutical Services General Requirements, Title 22 California Code of Regulations Division 5 § 70263.
4. Pharmaceutical Services Space, Title 22 California Code of Regulations Division 5 § 70269.
5. Pharmaceutical Services Staff, Title 22 California Code of Regulations Division 5 § 70265.

Tri-City Medical Center
Oceanside, California

PHARMACY

ISSUE DATE: 11/11 **SUBJECT: Pharmaceutical Representatives**

REVISION DATE: 03/12, 07/17

Department Approval:	**~~11/21~~09/24**
Pharmacy and Therapeutics Committee Approval:	**~~11/21~~10/24**
Medical Executive Committee Approval:	**~~01/22~~10/24**
Administration Approval:	**~~02/22~~11/24**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	**02/22**

A. PURPOSE:

1. Interactions between medical centers and industry are vital to public health, but they must be conducted in a way that is principled and upholds the public trust.
2. The purpose of this policy is to address the specific interactions between Tri City Healthcare District (TCHD) personnel and the pharmaceutical vendor industry.

B. SCOPE:

1. Applicable to all medical, nursing, pharmacy, and other healthcare professionals at TCHD.
2. All pharmaceutical representatives (including but not limited to sales representatives and medical science liaisons).

C. DEFINITION(S):

1. Gift: Any favor, discount, hospitality, loan, forbearance, gratuity, or other item having economic value.
   a. Excludes food or meals provided as part of an educational presentation/meeting and items of educational ~~value~~ (such as text books). ~~that are $100 or less in value.~~
2. Pharmaceutical representative: An employee or consultant representing the interests of one or more pharmaceutical manufacturers by providing educational material and/or promoting the sale of drug products.

D. POLICY:

1. The Pharmacy Clinical Manager or his/her designee is the primary point of contact for all pharmaceutical representatives conducting business within TCHD.
2. Signed Statement:
   a. Each pharmaceutical vendor must sign a statement acknowledging his/her familiarity with this policy.
   b. A copy of this policy will be presented for acknowledgement to all pharmaceutical vendors via ~~RepTrax.~~**vendor management software.**
3. Scheduling Appointments:
   a. Pharmaceutical vendors are not permitted on the TCHD campus without an appointment approved by the ~~Pharmacy Clinical Manager~~ **Director of Pharmacy or designee**.
   b. Appointments will be limited to business hours (Monday – Friday 0800-1700) unless specific authorization is given by the **Director of Pharmacy or designee** ~~Pharmacy Clinical Manager~~ on a case by case basis.
4. Permitted Activities:

a. With prior approval, pharmaceutical sales representatives are allowed in the facility for the following activities at the request of the **Director of Pharmacy or designee**~~Pharmacy Clinical Manager or designee~~:
   i. To provide educational programs and scheduled in-services. See section Educational Programs below.
   ii. To exhibit informational / promotional displays in assigned areas. See section Drug Displays below.

5. Physician Contact by Sales Representatives:
   a. Contact with physicians on hospital property requires the prior approval of the **Director of Pharmacy or designee**~~Pharmacy Clinical Manager~~.
   b. Contact with physicians is limited to those services having offices on the hospital premises (e.g., radiology staff, cardiology services staff).
   c. Contact with physicians at their office regarding Pharmacy and Therapeutics Committee activities is not permitted.
6. Restricted Formulary:
   a. Pharmaceutical sales representatives must promote products according to approved FDA guidelines and facility approved guidelines.
   b. Medications not on the formulary may not be promoted unless so authorized and with the permission of the Pharmacy Clinical Manager.
7. Prohibited Activities:
   a. Presenting false, undocumented, misleading statements or claims to any physician or other healthcare professional associated with the hospital, whether or not made while on hospital or campus grounds, that serve to misrepresent a drug's usage in therapy.
   b. Distributing gifts.
   c. Providing information or distributing promotional material regarding non-formulary, newly-approved, restricted or non-contracted drugs within the facility, without first obtaining approval ~~in writing~~ from the **Director of Pharmacy or designee**~~Pharmacy Clinical Manager~~. This includes providing and distributing information to Pharmacy & Therapeutics (P&T) and Medical Executive Committee (MEC) members.
   d. Exhibiting drug displays is strictly prohibited, unless requested by the **Director of Pharmacy or designee**~~Pharmacy Clinical Manager~~ and approved by administration prior to display.
   e. Distributing pharmaceutical samples at the hospital (and acceptance by hospital staff) is strictly prohibited except as specifically outlined in the Pharmacy Services Policy: "Drug Samples".
   f. Obtaining or completing any part of the hospital's Formulary Request Form.
   g. Soliciting the names of the Pharmacy and Therapeutics Committee members or other related committee with regard to the formulary management process.
8. Site Access and Hospital Security:
   a. Upon entering the facility, pharmaceutical sales representatives will check in at the ~~RepTrax~~ **vendor management** kiosk located in the Main Lobby.
   b. The representative is required to wear an identification badge provided by the ~~RepTrax~~ **vendor management** kiosk.
   ~~c. Representative must be escorted to the area to be visited and accompanied, at all times while in the facility, by a hospital employed or contracted personnel a physician, or a physician's representative. Representatives not escorted will be asked to leave the premises.~~
   ~~d.~~**c.** Representatives are not allowed in any patient care areas without express permission by the **Director of Pharmacy or designee**~~Pharmacy Clinical Manager~~.
   ~~e.~~**d.** Representatives discovered not wearing a badge, or working outside approved locations, will be asked to leave the premises. In such cases, hospital security and the Department of Pharmacy will be notified.
   ~~f.~~**e.** Representatives may not access any patient specific information.

9. Drug Displays:
   a. Drug displays are promotional in nature and are discouraged. The **Director of Pharmacy or designee** ~~Pharmacy Clinical Manager~~ evaluates and advises the facility about whether displays support the mission of the facility and the care of patients. If it is determined that displays are needed, they are limited to products on the facility formulary unless the promotion of a non-formulary product has been approved.
   b. Displays, when approved, are held in an area away from patient and visitor traffic and may not restrict the passage of medical or other staff through an area.
10. Educational Programs:
   a. The topic and content of all educational programs sponsored or presented by pharmaceutical representatives must be approved by the **Director of Pharmacy or designee**~~Pharmacy Clinical Manager~~.
   b. This approval is required prior to scheduling the program of any materials to staff or physicians within the facility.
   c. If the educational program is approved, representatives will visit only the approved designated area as scheduled.
   d. Any pharmaceutical representative found to have distributed educational materials/information or held programs within the facility that have not been authorized by the **Director of Pharmacy or designee** ~~Pharmacy Clinical Manager~~ will be in violation of this policy and will be subject to restricted access to the facility.
11. Penalties for Pharmaceutical Representatives for Policy Deviations:
   a. Activities deemed inappropriate by the Pharmacy Department or any other department of the hospital, will result in a recommendation to the P&T Committee, MEC, and subsequently to hospital administration to bar the representative involved from visiting the facility. This ban will be in effect until lifted by written permission from an administrative officer of the hospital.
12. Gifts:
   a. All gifts from pharmaceutical representatives, regardless of value are strictly prohibited.
   b. Vendors may offer a hospital incentive (i.e. discounted pricing, supplies/equipment, maintenance support) pursuant to contract agreement if a buyer agrees to purchase the vendor's company goods or services. Personal incentives (e.g., merchandise, tickets to special events, vacation trips, etc.) are considered gifts and cannot be accepted under any circumstances.
   c. Employees may not accept gifts, gratuities, or compensation in exchange for listening to a sales talk by an industry representative, for prescribing or changing a patient's prescription, or for attending a CME or non-CME activity (unless the individual is a speaker or is otherwise actively participating or presenting at the event).
13. Participation in Industry Sponsored Programs, Speaker's Bureaus, and Consulting:
   a. Employees may accept only fair market compensation for specific, legitimate services provided by them to industry. The terms of the arrangements, services provided, and compensation must be set forth in writing and signed by both parties.
   b. Employees may not accept compensation for listening to a sales presentation (e.g. detailing) by an industry representative.
   c. Employees who are simply attending a CME or other instructional activity, and are not speaking or otherwise actively participating or presenting at the meeting, may not accept compensation from companies either for attending or defraying costs related to attending the meeting.
   d. Employees must disclose any honorarium or payment received for all industry sources when requesting medication be added to the formulary or before presenting at Pharmacy and Therapeutics Committee meetings.
14. Industry Sponsored Scholarships and Other Educational Funds for Trainees:
   a. TCHD staff and trainees may not accept scholarships or other special funding directly from a vendor.

b. Vendors may make donations to the Education Department fund through the Foundation; the department will use its own criteria to select trainees to receive support for participation in educational events.
c. Under no circumstance can a trainee be paid by a commercial sponsor to attend an educational event where the trainee is not speaking.
d. For CME/non-CME-certified activities, reimbursement for travel, lodging, honoraria, or personal expense may not come directly from industry.
e. Exception to this rule applies only if the attendee is speaking at the event.
f. The policy is not intended to preclude industry support for staff to travel to evaluate major clinical equipment for prospective acquisition by TCHD.

15. Purchasing:
    a. Staff involved in institutional decisions concerning the purchase of or approval of medications or equipment, or the negotiation of other contractual relationships with industry must not have any financial interest (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy or other forms of compensation) in the vendor that might benefit from the institutional decision.
    b. This provision is not intended to preclude indirect ownership, through mutual funds or other investment vehicles, of equities in publicly traded companies.
    c. Staff must disclose their actual and potential conflicts of interest related to any institutional deliberations and generally may not participate in deliberations in which he or she has an actual or potential conflict of interest.

E. RELATED DOCUMENT(S):

1. Administrative Policy: 203 Business Visitor Visitation Requirements

F. REFERENCE(S):

1. Pharmaceutical Research and Manufacturers of America (PhRMA). Washington D.C., ~~January 2009~~**August 6, 2021**. *Code on Interactions with Healthcare Professionals.*
2. CMS Conditions of Participation §482.13(c)(1)
3. Health Insurance Portability and Accountability Act (HIPAA) of 1996

Tri-City Medical Center
Oceanside, California

PHARMACY

ISSUE DATE:	**11/93**	**SUBJECT:**	**Unlabeled Uses of FDA-Approved Medications**
REVISION DATE:	**12/93, 06/96, 05/97, 09/99, 08/00, 09/01, 02/03, 06/05, 07/06, 07/09, 01/12, 07/15, 01/18**		

Department Approval:	**~~11/21~~09/24**
Pharmacy & Therapeutics Committee Approval:	**~~11/21~~10/24**
Medical Executive Committee Approval:	**~~01/22~~10/24**
Administration Approval:	**~~02/22~~11/24**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	**02/22**

A. **DEFINITION(S):**

1. For purposes of this policy "unlabeled use" includes the use of a drug product in (1) doses, (2) patient populations, (3) indications, (4) routes of administration that are not reflected in Federal Drug Admiration (FDA) approved product labeling.

B. **POLICY:**

1. Pharmacy shall consider the off-label use of FDA approved drugs as prescribed by a physician/Allied Health Professional (AHP) to treat chronic, disabling, or acute, life-threatening illnesses medically necessary when:
   a. The drug has been approved by the FDA for at least one (1) indication and
   b. The drug is listed in a standard drug reference compendium for the off-label indication, such as:
      i. The United States Pharmacopoeia Drug Information (USPDI)
      ii. American Hospital Formulary Drug Information (AFHS-DI)
      iii. National Comprehensive Cancer Network (NCCN)
      iv. Thompson Micromedex DrugDex
      v. Lexicomp
      vi. Clinical Pharmacology

      or,
   c. The off-label use is supported substantially by accepted peer-reviewed medical literature
2. Off-label use of a drug shall not be considered if the FDA has determined said use to be absolutely contraindicated.
3. If the unlabeled use is not identified in the aforementioned compendia, the physician/AHP must present a proposal for said unlabeled use, along with documentation of safety and efficacy, to the Pharmacy and Therapeutics Committee at Tri-City Healthcare District (TCHD) for approval.
4. If the physician/AHP insists upon immediate use of a medication for unlabeled use not identified in the aforementioned compendia, the pharmacist will contact the physician/AHP for information regarding off label use and seek approval from the Clinical Manager. If information supporting off label use is verified by pharmacy, the electronic medication order will be verified by the pharmacist for immediate administration of the drug by nursing personnel.
5. If there is disagreement between the pharmacist and the prescribing physician/AHP, the Chairman of the Pharmacy and Therapeutics or his/her designee must be contacted for approval.
6. If the Pharmacy and Therapeutics Chairman is unavailable, the chain of command is as follows:

a. Division Chief
b. Department Chairman or Vice-Chairman
c. Chief of Staff

7. Once a decision is made regarding the "unlabeled use" of a medication by the Chairman of the Pharmacy and Therapeutics Committee, or Division Chief, or Department Chairman, or Department Vice-Chairman, or Chief of Staff, the decision is final.
8. The decision will be communicated to the Pharmacy Department, and documentation in the chart will be noted by the pharmacist regarding the final decision.

Tri-City Medical Center
Oceanside, California

PULMONARY SERVICES

ISSUE DATE:	**05/09**	**SUBJECT:**	**Respiratory Medication Administration**
REVISION DATE:	**09/09, 01/12, 06/15, 09/17**		

Department Approval:	~~**03/20**~~**06/24**
Medical Staff Pulmonary Division:	~~**12/20**~~**08/24**
Pharmacy and Therapeutics Approval:	~~**05/21**~~**10/24**
Medical Executive Committee Approval:	~~**07/21**~~**10/24**
Administration Approval:	~~**08/21**~~**11/24**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval	**08/21**

A. **POLICY**:

1. Respiratory medication treatments will be ~~rendered~~ **administered** as close to the Respiratory medication standard times as possible. Patient diagnostic testing, meals trays, Codes, Rapid Response calls and urgent PRN (as needed) calls may impact the times that therapy is being provided.
2. The Respiratory Care Practitioner (RCP) may stagger times to keep the intervals between treatments appropriate.
3. The general expectation is that treatments will be given within one hour before or after the targeted treatment scheduled time.

B. **PROCEDURE**:

1. The RCP will stay with the patient during the treatment **in all patient care areas** with the exception ~~being~~ **of** the Emergency ~~department~~ **Department** and ICU where close monitoring is provided.
2. The RCP must compare the Medication Administration Record (MAR) and the physician's medication order to ensure accuracy.
3. **Thorough and clear documentation by the RCP must be provided when ordered medication administration is missed.**

Tri-City Medical Center
Oceanside, California

SURGICAL SERVICES
SURGERY

ISSUE DATE: 02/04 **SUBJECT: Admission / Discharge Criteria**

REVISION DATE~~(S)~~: 07/06~~;~~, 06/09~~;~~, 09/12~~;~~, 06/14~~;~~, 06/16, 03/21

Department Approval:	~~02/20~~10/23
Operating Room Committee Approval:	~~03/20~~02/24
Department of Anesthesiology Approval:	~~11/20~~09/24
Pharmacy & Therapeutics Committee Approval:	n/a
Medical Executive Committee Approval:	~~01/21~~10/24
Administration Approval:	~~03/21~~11/24
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	03/21

A. **PURPOSE:**
1. To provide guidelines for admission and discharge of patients to or from the Operating Room.

B. **DEFINITION(S):**
1. Operating Room: A specially equipped and staffed unit designed to meet the surgical needs of patients within the defined Scope of Service.

C. **POLICY:**
1. The Medical Staff shall be defined by administration.
2. All hospital personnel rendering patient care in surgery are skilled in performing basic perioperative care and equipment operation related to their position descriptions.
3. Additional training is provided for personnel in specialty areas.
4. The admission of patients to Surgical Services is based on physician-determined surgical need.
   a. Patients admitted to surgery for elective scheduled procedures must have orders for preoperative admission available to the hospital per surgery scheduling guidelines.
   b. Patients admitted to surgery from the Emergency Department or Inpatient/Outpatient areas must be seen by their surgeon and consent for surgery obtained prior to transportation from the ED or Inpatient/Outpatient Area to the Operating Room/Pre-op Holding Area.
   c. On admission to Pre-op Hold/Surgery, the following documents shall be present: (Note: Patients will not be taken into the Operating room if required documentation is missing from the chart):
      i. Correctly completed consent form(s)
      ii. History and Physical (must be viewable in electronic medical record) or updated within the 24 hours prior to the procedure
         1) For complete History and Physical requirements, see Medical Staff Policy "Medical Record Documentation Requirements".
      iii. Physician Pre-Procedure Documentation form
      iv. Physician Orders
      v. Completed Preoperative Checklist
      vi. Other documents may include but are not limited to:
         1) Anesthesia Questionnaire
         2) Anesthesia Consent

3) Results of lab work and any other diagnostic tests per physician's orders
4) Previous medical record

d. For cases requiring surgical site marking (per Patient Care Services Procedure "Universal Protocol"), the surgical site must be marked by surgeon prior to transporting patient to the OR.
e. Endoscopy procedures performed with RN-administered moderate sedation: refer to Patient Care Services Procedure "Sedation/Analgesia Used During Therapeutic or Diagnostic Procedures" for complete pre-operative requirements.
f. The requirements above do not preclude rendering emergency surgical care to a patient in dire circumstances.

5. Patient care is assigned to personnel with at least two surgical team members, one of which is the Registered Nurse circulator.
6. Patients shall be discharged from the Operating Room by the surgeon and/or anesthesiologist upon completion of the surgical procedure.
   a. The post-operative level of care is determined by the surgeon and/or anesthesiologist.
   b. Discharge to a level of care other than what was anticipated shall be communicated to all involved parties as early as possible.
   c. Information related to the patient's post-operative assessment and plan of care shall be communicated to the receiving unit by the anesthesiologist and Surgery RN.
   d. Post-operative transport shall be directed by the surgeon and/or anesthesiologist (when applicable) and involve the appropriate personnel and equipment to safely transport the patient.
      i. Endoscopy patients receiving RN-administered moderate sedation shall be transported by the RN to the designated recovery area, as determined by the procedural physician.

Tri-City Medical Center
Oceanside, California

SURGICAL SERVICES
PERI-ANESTHESIA NURSING SERVICES

ISSUE DATE: 07/2012

SUBJECT: Discharge of Post Anesthesia and Post Sedation Patients to Inpatient Units

REVISION DATE:

Surgical Services Department Approval:	~~**03/20**~~**08/24**
Department of Anesthesia Approval:	~~**03/20**~~**09/24**
Operating Room Committee Approval:	**n/a**
Pharmacy & Therapeutics Committee Approval:	**n/a**
Medical Executive Committee Approval:	~~**06/20**~~**10/24**
Administration Approval:	~~**07/20**~~**11/24**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	**08/20**

A. **DEFINITION:**
1. ASPAN- American Society of PeriAnesthesia Nurses

B. **PURPOSE:**
1. To define criteria and processes for discharge of post-anesthesia and post-sedation patients to an inpatient unit.

C. **PROCEDURE:**
1. Recovery: Post Anesthesia Care Unit (PACU) recovery is performed according to ASPAN standards of Perianesthesia nursing practice. RNs who have completed PACU competencies may discharge to inpatient unit when the following criteria are met or as ordered by an anesthesiologist:
   a. Modified Aldrete score $\geq$ 8, except when discharge is authorized by anesthesiologist or patient is transferred to critical care, or documented limitations are present prior to anesthesia.
   b. Airway:
      i. Patent airway and protective airway reflexes are intact
   c. Patient is able to cough and deep breathe
   d. Vital signs are stable with no significant changes for at least 30 minutes.
      i. Temperature $\geq$ 36°C (96.8°F)
      ii. Blood pressure within $\pm$ 20 mmHg of patient's baseline
   e. Pain level meets target pain level or is appropriate for procedure.
      i. Paseo Opioid-Induced Sedation Scale (POSS) score $\leq$2
   f. No active emesis and/or acceptable level of nausea.
   g. Post-procedural/operative bleeding controlled or acceptable with procedure
      i. Dressing/surgical site is clean, dry and intact or has mild to moderate drainage with no marked increase
      ii. Patent tubes, catheters and drains
   h. For spinal or epidural block, dermatome level $\geq$ L3 and patient is able to move toes.
      i. No evidence of bleeding at puncture site
   i. For regional anesthesia, protection of patient's extremity
   j. For obstetrical patients fundus is firm, lochia is small to moderate.

k. If Flumazenil or Naloxone are administered to reverse the effects of sedative or opioid medications, the patient must be monitored for re-sedation for two hours after administration.

2. The discharge process and transport will be done according to PCS Policy Transfer of Patients, Intra-Facility and ASPAN Standards of PeriAnesthesia nursing practice.
   a. The PACU RN should accompany patients that include, but not limited to:
      i. Require evaluation, treatment or are at risk of cardiopulmonary compromise during transport
      ii. Require a higher level of care
      iii. Have a potential for bleeding
      iv. Airway compromise
   b. The PACU RN should consider factors when evaluating the patient for transport including, but not limited to
      1) Patient stability
      Higher level of care
      2) Distance the patient needs to travel
      3) Required monitoring

D. **DOCUMENTATION:**
1. Document the following in the electronic health record (EHR):
   a. Vital signs
   b. Pain assessment
   c. Aldrete score
   d. Intake and Output
   e. Dermatome level (if applicable)
   f. Surgical site assessment
   g. Presence of nausea/vomiting
   h. Additional elements of assessment as indicated by procedure and anesthesia/sedation type
   i. PACU Expected Outcomes
   j. For patients who have had moderate sedation without anesthesia care, document sedation outcomes.
   k. PACU Departure
2. Document patient education
3. Document all medications given in the eMAR

E. **RELATED DOCUMENT(S):**
1. Modified Aldrete Score

F. **REFERENCES:**
1. American Society of Perianesthesia Nurses. (2018). *Perianesthesia Nursing Standards, Practice Recommendations and Interpretive Statements 2019-2020.* Cherry Hill, NJ: American Society of Perianesthesia Nurses.
2. Schick, L., & Windle, P. E. (Eds.). (2016). *PeriAnesthesia Nursing Core Curriculum: Preprocedure, Phase I and Phase II PACU Nursing* (3rd ed.). St. Louis, MO: Elsevier.

MODIFIED ALDRETE SCORE*		
Activity	Moves all extremities voluntarily on command.	2
	Moves two extremities voluntarily on command.	1
	Unable to move extremities.	0
Respiration	Breathes deeply and coughs freely.	2
	Shallow or limited breathing.	1
	Apneic.	0
Circulation	BP ± 20 mm of preanesthetic level.	2
	BP± 21-49 mm of preanesthetic level.	1
	BP ± 50 mm of preanesthetic level.	0
Consciousness	Fully awake.	2
	Arouseable on calling.	1
	Not responding.	0
Oxygen Saturation	Sp02 >92% on room air	2
	Supplemental 02 required to maintain Sp02 >90%	1
	Sp02 <90% with supplemental O_2	0

Tri-City Medical Center
Oceanside, California

TELEMETRY

ISSUE DATE: 10/96 **SUBJECT: Orientation of Registry Staff**

REVISION DATE(S): 04/00, 10/02, 01/04, 05/05, 06/06, 08/10, 02/11

Department Approval:	06/15
Division of Cardiology Approval:	n/a
Pharmacy and Therapeutics Approval:	n/a
Medical Executive Committee Approval:	n/a
Administration Approval:	~~07/20~~11/24
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	08/20

A. **PURPOSE:**

1. The purpose of this policy is to assist temporary nursing staff with written answers to the most frequently asked questions.

B. **POLICY:**

1. Patient Assignments:
   - a. Each unit will be staffed according to TCMC staffing practices.
   - b. Each unit will have an identified Resource Registered Nurse (RN).
   - c. Registry RNs who have completed a class in ECG rhythm recognition may interpret cardiac tracing (strips)
     - i. Inform the charge nurse at the beginning of the shift if you have not completed an ECG rhythm recognition class or need assistance
   - d. Electrocardiogram (ECG) tracings (strips) will be posted
     - i. The primary RN will record a six (6) second ECG tracing (strip) at the beginning of their shift.
     - ii. The strip will be measured, interpreted, and posted in the patient's EHR within a timely manner and as needed.~~.~~
     - iii. The heart rate, the lead interpreted and measurements of following wave forms, if present, will be documented in the medical record; PR interval, QRS interval, and QT interval
     - iv. Each RN nurse will document their assigned patient's rhythm every four hours and as needed with any significant rhythm or rate changes in the medical record.
2. Telemetry Monitors:
   - a. All patients will be monitored in leads II and V1. ~~A Monitor Technician (MT) is located on 3 Pavilion..~~
   - b. Telemetry patients will have cardiac monitoring per physician order.
   - c. Telemetry monitoring may be interrupted for transport to tests/procedures with a physician order.
   - d. All Telemetry patients requiring cardiac monitor will have a patent intravenous (IV) access at all times unless otherwise ordered.
   - e. Admissions, transfers, and patients returning to the unit from test/procedures will be placed on a cardiac monitor immediately upon arrival to the unit. Review the Management of Telemetry Patient Policy and consult with the Resource RN, Clinical Nurse Manager or Charge RN.

f. Telemetry box batteries will be maintained in working order at all times and changed as indicated.
g. The patient's telemetry box will be removed during hygiene care or for transport as ordered.
   i. Notify the MT at extension 3466 or 3467 if you are removing the telemetry box from the patient for other reasons.
   ii. It is the primary RN's responsibility to ensure the telemetry box is removed, ~~cleaned~~**cleaned,** and properly stored when a patient is discharged**, transferred** or their accommodation is changed to a medical / ~~,~~surgical **level of care.** ~~unit or Medical Monitored.~~
   iii. Clean telemetry box and lead wires with the appropriate disinfectant.
   iv. Consult with the RNs or primary Telemetry ACT.

3. Documentation:
   a. Document the following in the Electronic Heath Record (EHR) in a timely manner:
      i. Delays in placement of cardiac monitor not related to direct patient care being provided
      ii. Patient's status during delay in cardiac monitoring or visualization of cardiac rhythm
4. Vital Signs:
   a. Routine Telemetry vital signs are every four (4) hours while awake.
   b. Vitals should be taken as needed based on clinical judgment and/or orders.
   c. Routine recommended Telemetry vital sign times are 0700-0800, 1200, 1600, 2000, and 2400 while awake and/or as ordered.
5. Intake and Output:
   a. All Telemetry patients are on measured intake and output.
   b. Ensure the correct urine collection device is available in patient room.
   c. Intravenous Infusion pumps will be zeroed and documented at every twelve hours (12) 0600 and 1800. See Standards of Patient Care.
      i. See the Telemetry unit specific procedure: Weighing Telemetry Patients for fluid restriction requirements.
6. Weights:
   a. All patients will be weighed in kilograms on admission using a chair scale unless contraindicated stated weights are not acceptable.
   b. See Telemetry unit specific procedure: Weighing Telemetry Patients Weighing for more information on the patient population requiring daily or weekly weights.
   c. All patients will have their height assessed and documented on admission.
7. Documentation of Patient Acuities:
   a. Acuities will be documented every shift and as needed.
   b. See: Patient Care Services Policy Manual, Subject: Documentation, Policy Number VII.A
8. Physician Orders and Chart Checks:
   a. Registered Nurses are responsible for reviewing and verifying orders per TCMC policy. See
      i. PCS: Physician Orders.
9. Communication:
   a. Healthcare providers will communicate new, changes or updates in patient information throughout a shift.
   b. Prior to transferring patients to another healthcare provider' care.
      i. See PCS: Hand-off, Communication and Telemetry Shift-to-Shift Hand-off Policy

C. **RELATED DOCUMENT(S):**

3. Management of Telemetry Patients. Telemetry Manual
4. -Documentation in the Medical Record, Patient Care Service Manual
5. Hand-off, Communication, Patient Care Service Manual
6. Physician's Orders. Patient Care Service Manual
7. Standards of Patient Care, Patient Care Service Manual

8. ~~Telemetry Shift-to-Shift Hand-off Process. Telemetry Manual~~

TRI-CITY HEALTHCARE DISTRICT
MINUTES FOR A SPECIAL MEETING
OF THE BOARD OF DIRECTORS

September 26, 2024 – 1:30 o'clock p.m.

A Special Meeting of the Board of Directors of Tri-City Healthcare District was held at 1:30 p.m. on September 26, 2024.

The following Directors constituting a quorum of the Board of Directors were present via teleconference:

Director Nina Chaya
Director George W. Coulter
Director Marvin Mizell
Director Adela Sanchez
Director Tracy M. Younger

Absent were:

Director Rocky J. Chavez
Director Gigi S. Gleason

Also present were:

Dr. Gene Ma, Chief Executive Officer
Henry Showah, M.D., Chief of Staff
Jeff Scott, Board Counsel
Teri Donnellan, Executive Assistant

1. The Chairperson, Director Tracy M. Younger. called the meeting to order at 1:30 p.m. with attendance as listed above.

2. Approval of Agenda

   It was moved by Director Mizell and seconded by Director Coulter to approve the agenda as presented. The motion passed 5-0-0-2 with Directors Chavez and Gleason absent.

3. Oral Announcement of Items to be discussed during Closed Session

   Chairperson Younger made an oral announcement of the items listed on the September 26, 2024 Special Board of Directors Meeting Agenda to be discussed during Closed Session which included Reports Involving Trade Secrets, one matter of Potential Litigation and Conference with Labor Negotiators.

6. Motion to go into Closed Session

   It was moved by Director Coulter and seconded by Director Sanchez to go into Closed Session at 1:30 p.m. The motion passed 5-0-0-2 with Directors Chavez and Gleason absent.

7. At 3:30 p.m. the Board returned to Open Session with attendance as previously noted.

8. Report from on any action taken in Closed Session.

Board Counsel Scott stated the report out from closed session will be given at the beginning of today's Regular Board meeting immediately following.

9. Consideration of Retaining Consulting Firm to provide Affiliation Advisory Services.

The Board indicated they would continue consideration of retaining a Consulting Firm to provide Advisory Services.

10. Adjournment

There being no further business, Chairperson Younger adjourned the meeting at 3:35 p.m.

_____
Tracy M. Younger
Chairperson

ATTEST:

_____
George W. Coulter
Assistant Secretary

TRI-CITY HEALTHCARE DISTRICT
MINUTES FOR A REGULAR MEETING
OF THE BOARD OF DIRECTORS
September 26, 2024 – 3:30 o'clock p.m.

A Regular Meeting of the Board of Directors of Tri-City Healthcare District was held at 3:30 p.m. on September 26, 2024. Chairperson Younger reported Directors Chavez, Chaya and Gleason are absent due to illness.

The following Directors constituting a quorum of the Board of Directors were present:

Director George W. Coulter
Director Marvin Mizell
Director Adela Sanchez
Director Tracy M. Younger

Absent: Director Rocky Chavez
Director Nina Chaya, M.D.
Director Gigi Gleason

Also present were:

Dr. Gene Ma, Chief Executive Officer
Donald Dawkins, Chief Nurse Executive
Jeremy Raimo, Chief Operating Officer
Janice Gurley, Chief Financial Officer
Roger Cortez, Chief Compliance Officer
Dr. Henry Showah, Chief of Staff
Susan Bond, General Counsel
Jeff Scott, Board Counsel
Teri Donnellan, Executive Assistant

1. Chairperson Younger called the meeting to order at 3:30 p.m. with attendance as listed above.

2. Report from Closed Session

   Board Counsel Jeff Scott reported the Board in Closed Session discussed Reports involving Trade Secrets and took no action. The Board also discussed one Potential Litigation matter and took no action. Lastly, the Board heard a report concerning Labor Negotiations with CNA and SEIU with their District Labor Negotiator and took no action.

3. Pledge of Allegiance

   Director Younger led the Pledge of Allegiance.

4. Approval of Agenda

   It was moved by Director Mizell and seconded by Director Coulter to approve the agenda as presented. The motion passed (4-0-0-1) with Directors Chavez, Chaya and Gleason absent.

5. Public Comments – Announcement

Chairperson Younger read the Public Comments section listed on the September 26, 2024 Regular Board of Directors Meeting Agenda.

6. August, 2024 Financial Statements – Janice Gurley, Chief Financial Officer

Janice Gurley, CFO reported on the current and fiscal year to date financials as follows (Dollars in Thousands):

- Net Operating Revenue – $52,295
- Operating Expense – $54,151
- EBITDA – $3,491
- EROE –$452

Janice reported on the fiscal year to date Key Indicators as follows:

- Average Daily Census – 116
- Adjusted Patient Days – 13,110
- Surgery Cases – 891
- ED Visits – 8,099

Janice reported on the current month financials as follows (Dollars in Thousands):

- Net Operating Revenue – $26,595
- Operating Expense – $27,362
- EBITDA – $1,972
- EROE – $470

Janice reported on the current month Key Indicators as follows:

- Average Daily Census – 116
- Adjusted Patient Days – 6,558
- Surgery Cases – 492
- ED Visits – 4,097

The financials reflect eight months of consecutive positive earnings before interest, tax, depreciation and amortization.

7. Consideration to accept the Fiscal Year 2024 Financial Statement Audit – Moss Adams/CFO

Janice Gurley introduced Stacy Stelzriede, Audit Partner and Kyle Rogers, Senior Manager with Moss Adams.

Ms. Stacy Stelzriede presented the results of the Fiscal Year 2024 Financial Statement Audit. Ms. Stelzriede reported the Auditors will issue an unmodified opinion which reflects the Financial Statements are presented fairly and in accordance with US Generally Accepted Accounting Principles. Mr. Stelzriede also reported there were no material weaknesses or proposed adjustments.

Stacy provided information on the single audit, which is mandatory due to the HUD loan which is considered a federal program. Single audit findings included IT

Controls related to documentation for user access, Cyber Security incident and the late filing of last year's financials due to awaiting CA Distressed Hospital Loan proceeds.

Stacy noted the financial health of the hospital is improving, however challenges remain. Operating losses are reduced from $46.8 million to $36.4 million, and working capital deficit improved from $37 million to $33 million.

In closing, Stacy stated no significant difficulties were encountered during the audit, and no corrected or uncorrected misstatements were identified, which is a commendable outcome reflecting the finance team's diligence.

Hearing no questions or comments, Director Sanchez moved to accept the FY2024 Financial Statement Audit. Director Mizell seconded the motion.

The vote on the motion via a roll call vote was as follows:

AYES:	**Directors:**	**Coulter, Mizell, Sanchez and Younger**
NOES:	**Directors:**	**None**
ABSTAIN:	**Directors:**	**None**
ABSENT:	**Directors:**	**Chavez, Chaya and Gleason**

8. Special Presentations:

a) Legislative Update –Dr. Robert Hertzka, Government Affairs Consultant

Dr. Robert Hertzka provided a Legislative Update, highlighting federal uncertainties, key state legislative priorities and specific bills with potential impacts.

The Distressed Hospital Loan, issued through the CA Healthcare Financing Authority, is under review to potentially adjust its terms, either by extending it or delaying payments, with a decision timeline expected early next year.

On federal issues, significant decisions impacting hospital financing are expected. At CHA's request, Congressman Levin was briefed on various issues, especially the importance of the 340B program.

With regard to state issues, Proposition 35 is critical as it would make the MCO tax permanent, adding $3-5 billion to state healthcare funding. While the governor opposes it, the California Republican Party has endorsed it.

A union-backed bill would require medical detectors at hospital entrances.

A workforce bill could allow some community colleges to offer bachelor's degrees, potentially benefiting nursing training.

A controversial bill seeks to ban private equity transactions for hospitals, but its impact appears minimal for Tri-City.

b) Psychiatric Health Facility Update – Benito Oporto, Director/Facilities

Benny Oporto, Director of Facilities at Tri-City Medical Center, provided an update on the new Psychiatric Health Facility. This 13,000 sq. ft., $27.6 million state-of-the-art facility is the first major operational construction project completed in over 30 years. With county support, construction began in January 2023 after groundbreaking in October 2022. A final walkthrough with the contractor is set for tomorrow, where keys and closeout documents will be handed over. Minor finishing touches will follow in the coming weeks. Plans for an open house and ribbon-cutting ceremony will be coordinated with the county and Exodus, highlighting this valuable community resource.

9. New Business – None

10. Old Business - None

11. Chief of Staff –

Dr. Henry Showah, Chief of Staff presented the September Credentialing Actions and Reappointments Involving the Medical Staff as recommended by the Medical Executive Committee on September 23, 2024.

It was moved by Director Coulter to approve the Medical Staff Credentialing Actions involving the Medical Staff as recommended by the Medical Executive Committee on September 23, 2024. Director Sanchez seconded the motion.

The vote on the motion via a roll call vote was as follows:

AYES:	**Directors:**	**Coulter, Mizell, Sanchez and Younger**
NOES:	**Directors:**	**None**
ABSTAIN:	**Directors:**	**None**
ABSENT:	**Directors:**	**Chavez, Chaya, Gleason**

12. Consideration of Consent Calendar

It was moved by Director Sanchez to approve the Consent Agenda as presented. Director Coulter seconded the motion.

The vote on the motion was as follows:

AYES:	**Directors:**	**Coulter, Mizell, Sanchez and Younger**
NOES:	**Directors:**	**None**
ABSTAIN:	**Directors:**	**None**
ABSENT:	**Directors:**	**Chavez, Chaya, Gleason**

13. Discussion of items pulled from Consent Calendar

There were no items pulled from the Consent Calendar.

14. Comments by Members of the Public

There were no comments from members of the public.

15. Comments by Chief Executive Officer

Dr. Ma reported details are forthcoming on the terms of the agreement with the County for the Psychiatric Health Facility. It has been an extremely collaborative process and achieves the goals that were intended. We are excited to be able to offer this service to the community.

Secondly, Dr. Ma acknowledged Ellen Langenfeld who has announced her retirement. Ellen significantly improved the pharmacy department's operations and budget management, and helped Tri-City transition away from an expensive third-party pharmacy vendor. Dr. Ma stated the new Director has been hired, and Ellen will assist during the transition.

Lastly, Dr. Ma reported in partnership with SEIU, Tri-City was awarded a $3 million grant from the Department of Labor, which will support entry-level employees in advancing to skilled roles through technical training, benefiting employees, their families, and the community. This effort is indicative of the power of unity and collaboration to better the lives of our employees by creating generational opportunity.

Dr. Ma expressed gratitude for the Board's ongoing support.

16. Board Communications

Director Sanchez expressed her gratitude to the executive team for consistently exceeding her expectations and advancing the hospital's mission for the community. She stated she takes pride in being part of the Board and serving alongside such dedicated professionals.

Director Sanchez also recognized Ellen Langenfeld and thanked her for her phenomenal work.

Chairperson Younger extended her congratulations to Ellen as well.

Chairperson Younger thanked today's presenters, Stacy Stelzriede, Dr. Robert Hertzka and Benny Oporto.

17. Adjournment

There being no further business Chairperson Younger adjourned the meeting at 4:25 p.m.

_____
Tracy M. Younger
Chairperson

ATTEST:

_____
George Coulter
Assistant Secretary

Tri-City Medical Center

ADVANCED HEALTH CARE FOR YOU

Building Operating Leases
Month Ending September 30, 2024

Lessor	Sq. Ft.	Base Rate per Sq. Ft.		Total Rent per current month	Lease Term Beginning	Lease Term Ending	Services & Location	Cost Center
6121 Paseo Del Norte, LLC 6128 Paseo Del Norte, Suite 180 Carlsbad, CA 92011 V#83024	Approx 9,552	$3.59	(a)	55,379.19	07/01/17	06/30/27	**OSNC - Carlsbad** 6121 Paseo Del Norte, Suite 200 Carlsbad, CA 92011	7095
Cardiff Investments LLC 2729 Ocean St Carlsbad, CA 92008 V#83204	Approx 10,218	$2.58	(a)	30,114.17	07/01/17	09/30/24	**OSNC - Oceanside** 3905 Waring Road Oceanside, CA 92056	7095
Creek View Medical Assoc 1926 Via Centre Dr. Suite A Vista, CA 92081 V#81981	Approx 6,200	$2.70	(a)	20,594.69	07/01/20	06/30/25	**PCP Clinic Vista** 1926 Via Centre Drive, Ste A Vista, CA 92081	7090
SoCAL Heart Property LLC 1958 Via Centre Drive Vista, Ca 92081 **V#84195**	Approx 4,995	$2.50	(a)	22,289.17	10/01/22	06/30/27	**OSNC - Vista** 1958 Via Centre Drive Vista, Ca 92081	7095
BELLA TIERRA INVESTMENTS, LLC 841 Prudential Dr, Suite 200 Jacksonville, FL 32207 V#84264	Approx 2,460	$2.21	(a)	7,945.96	04/01/23	03/31/25	**La Costa Urology** 3907 Waring Road, Suite 4 Oceanside, CA 92056	7082
Mission Camino LLC 4350 La Jolla Village Drive San Diego, CA 92122 V#83757	Appox 4,508	$1.75	(a)	14,027.63	05/14/21	10/31/31	**Seaside Medical Group** 115 N EL Camino Real, Suite A Oceanside, CA 92058	7094
Nextmed III Owner LLC 6125 Paseo Del Norte, Suite 210 Carlsbad, CA 92011 V#83774	Approx 4,553	$4.00	(a)	25,156.00	09/01/21	08/31/33	**PCP Clinic Calrsbad** 6185 Paseo Del Norte, Suite 100 Carlsbad, CA 92011	7090
500 W Vista Way, LLC & HFT Melrose P O Box 2522 La Jolla, CA 92038 V#81028	Approx 7,374	$1.67	(a)	16,045.50	07/01/21	06/30/26	**Outpatient Behavioral Health** 510 West Vista Way Vista, Ca 92083	7320
OPS Enterprises, LLC 3617 Vista Way, Bldg. 5 Oceanside, Ca 92056 #V81250	Approx 7,000	$4.12	(a)	31,749.00	10/01/22	09/30/25	**North County Oncology Medical Clinic** 3617 Vista Way, Bldg.5 Oceanside, Ca 92056	7086
SCRIPPSVIEW MEDICAL ASSOCIATES P O Box 234296 Encinitas, CA 234296 V#83589	Approx 3,864	$3.45	(a)	14,880.52	06/01/21	05/31/26	**OSNC Encinitas Medical Center** 351 Santa Fe Drive, Suite 351 Encinitas, CA 92023	7095
BELLA TIERRA INVESTMENTS, LLC 841 Prudential Dr, Suite 200 Jacksonville, FL 32207 V#84264	Approx 3,262	$2.21	(a)	12,636.11	05/01/23	06/30/25	**Pulmonary Specialists of NC** 3907 Waring Road, Suite 2 Oceanside, CA 92056	7088
Total				**250,817.94**				

(a) Total Rent includes Base Rent plus property taxes, association fees, insurance, CAM expenses, etc.

Tri-City Medical Center

ADVANCED HEALTH CARE FOR YOU

Education & Travel Expense
Month Ending September 2024

Cost Centers	Description	Invoice #	Amount	Vendor #	Attendees
8610	HASD&IC ANNUAL MEETING	91024 EXP	250.00	78648	MA GENE
8740	CCRN RENEWAL	91924 EDU	150.00	80655	SETTLE, CHRISTA
8740	ASRT TECH	91324 EDU	125.00	82014	O'GRADY, MAUREEN
8740	ONCOLOGY NURSING	90524 EDU	107.00	82125	AVILEZ. MARIA
8740	MASTER DEGREE	91024 EDU	5,000.00	84318	ALLEN CHRISTINA
8740	AA DEGREE	91024 EDU	2,000.00	84411	MORALES GARCIA JIMENA

**This report shows reimbursements to employees and Board members in the Education & Travel expense category in excess of $100.00.
**Detailed backup is available from the Finance department upon request.