

**TRI-CITY HEALTHCARE DISTRICT
AGENDA FOR A REGULAR MEETING
April 28, 2022 – 3:30 o'clock p.m.**

In accordance with California Government Code Section 54953 teleconferencing will be used by the Board members and appropriate staff members during this meeting. Members of the public will also be able to participate by telephone, using the following dial in information:

**Dial in #: (669-900-6833) To Listen and Address the Board when called upon:
Meeting ID:840 0611 4460; Passcode: 016453**

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	Approval of agenda	2 min.	Standard
3	Roll Call / Pledge of Allegiance	3 min.	Standard
4	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
5	March 2022 Financial Statement Results	10 min.	CFO
6	New Business a) Consideration to approve Resolution No. 813, a Resolution of Tri-City Healthcare District Board of Directors Authorizing Execution and Delivery of a Loan and Security Agreement, Promissory Note, and Certain Actions in Connection therewith for the California Health Facilities Financing Authority Non-Designated Public Hospital Bridge Loan Program	10 min.	CFO

Note: Any writings or documents provided to a majority of the members of Tri-City Healthcare District regarding any item on this Agenda will be made available for public inspection in the Administration Department located at 4002 Vista Way, Oceanside, CA 92056 during normal business hours.

Note: If you have a disability, please notify us at 760-940-3347 at least 48 hours prior to the meeting so that we may provide reasonable accommodations.

	Agenda Item	Time Allotted	Requestor
	b) Consideration to certify SEIU-UHW as the exclusive bargaining representative for the following groups: <ol style="list-style-type: none"> 1) Psychiatric Liaisons in the Emergency Department; 2) Medical Assistant, Clinical Research Coordinator, Medical Laboratory Assistant, Front Desk Reception and Medical Biller in the Oncology Clinic; 3) Medical Assistant, Medical Receptionist and Authorization/Referral Coordinator in the Infusion Center. 	10 min.	VP/HR
7	Old Business – None		
8	Chief of Staff <ol style="list-style-type: none"> a) April 2022 Credentialing Actions and Reappointments Involving the Medical Staff and Allied Health Practitioners as recommended by the Medical Executive Committee on April 25, 2022. 	5 min.	COS
9	Consideration of Consent Calendar <u>Requested items to be pulled require a second</u> <ol style="list-style-type: none"> (1) Approval of the establishment of the Medical Directorship for Opioid Stewardship Program with services provided by Ole Snyder, M.D. for a term of 12 months, beginning May 1, 2022 through April 30, 2023, with an annual and total term cost not to exceed \$18,000. (2) Approval of the renewal of the ED On-Call Coverage Panel for Orthopedics to include Erin Farrelly, M.D. and Serge Kaska, M.D. for a term of 25 months, beginning June 1, 2022 and ending June 30, 2024, at a total term cost of \$1,172,400 for the shared call panel. (3) Approval of the renewal of the ED On-Call Coverage Panel for Orthopedics to include David Amory, MD, Arash Calafi, MD, David Daugherty, MD, Andrew Hartman, MD, Harish Hosalkar, MD, Grant Seiden, MD, Morgan Silldorff MD and Erik Stark, MD for a term of 24 months, beginning July 1, 2022 and ending June 30 2024, at a total term cost of \$1,126,200 for the shared call panel. (4) Approval of an agreement with Dr. Emad Tadros for the co-medical directorship of Outpatient Behavioral Health for a term of 25 months, beginning June 1, 2022 and ending June 30, 2023, for an hourly rate of \$144.00, an annual cost of \$89,856 and a total term cost for the term of \$187,200. (5) Approval of the renewal of an agreement with Sharon Slowik, MD as the Coverage Physician for Inpatient Wound Care for a term of 12 months beginning May 1, 2022 and ending April 30, 2023, not to exceed an average of 20 hours a month, at an hourly rate of \$180 for a total annual and term cost of \$43,200. (6) Approval of the renewal of an agreement with Henry Showah, MD as the Coverage Physician for Inpatient Wound Care for a term of 12 months beginning May 1, 2022 and ending April 30, 2023, not to exceed an average of 20 hours a month, at an hourly rate of \$180 for a total annual and term cost of \$43,200. 		

	Agenda Item	Time Allotted	Requestor
	<p>(7) Approval of the renewal of an agreement with Sharon Slowik, MD as the Coverage Physician for Outpatient Wound Care for a term of 12 months beginning May 1, 2022 and ending April 30, 2023, not to exceed an average of 20 hours a month, at an hourly rate of \$180 for a total annual and term cost of \$43,200.</p> <p>(8) Approval of the renewal of an agreement with Henry Showah, MD as the Coverage Physician for Outpatient Wound Care for a term of 12 months beginning May 1, 2022 and ending April 30, 2023, not to exceed an average of 20 hours a month, at an hourly rate of \$180 for a total annual and term cost of \$43,200.</p> <p>(9) Approval of the renewal of the agreement with ARUP for Laboratory Testing for a term of 29 months, beginning June 1, 2022 and ending October 31, 2024, for an annual cost of \$207,852 and a total cost for the term of \$502,309.</p> <p>(10) Approval of the renewal of an agreement with Rady Children's Specialists of San Diego for Retinopathy (ROP) testing for a term of 12 months, beginning May 1 2022 and ending April 30, 2023, for a cost of \$3,570 per month and a total cost for the term of \$42,840.</p> <p>(11) Approval of the renewal of an agreement with Team Physicians of Southern California Medical Group, Inc. (Team Health) to provide professional physician services for the Emergency Department, for a term of 24 months, beginning June 1, 2022 through May 31, 2024 at no cost to the District.</p> <p>(12) Approval of Resolution 812, a Resolution of the Board of Directors of the Tri-City Healthcare District Re-Ratifying the State of Emergency and Re-Authorizing Remote Teleconference Meetings.</p> <p>(13) Administrative & Board Committees</p> <p>A. Policies</p> <p>1. Patient Care Services Policies & Procedures</p> <ul style="list-style-type: none"> a. Assessing and Managing Patients at Risk for Suicide Policy b. Automatic Stop Orders Policy c. Bed Utilization, Temporary Opening and Closing of Inpatients Beds/Unit Policy d. Black Box Warnings, Drugs with Policy e. Clinical Alarm Management f. Discharge Planning, Homeless Patient Policy g. Emergency Cart (Crash Cart) Cardiopulmonary Arrest Policy h. Medication Administration Policy i. Medications, High Risk/High Alert/Look Alike Sound Alike Policy j. Physician/Allied Health Professionals (AHP) Orders for Outpatient Services k. Potential Food and Drug Interactions, Patient Education Policy l. Pre, Intra and Post-op Assessment of Fetal Heart Rate and Uterine Activity Procedure m. Release of Deceased to a Family Member policy n. Sponge, Sharps and Instrument Counts Prevention of Retained Surgical Objects o. Universal Protocol Procedure 		

	Agenda Item	Time Allotted	Requestor
	<p>p. Vaccination Administration</p> <p>2. Administrative 200 District Operations 300 Patient Care</p> <p>a. Failure Mode and Effects analysis (FMEA) 389</p> <p>b. Hospital Records Retention 237</p> <p>c. Space and Office Allocation 289</p> <p>3. Administrative 600 Information Technology</p> <p>a. Fax Transmissions 616</p> <p>b. Internet Access 603</p> <p>c. Network Access 602</p> <p>d. Voicemail Access 617</p> <p>4. Unit Specific – Cardiology</p> <p>a. 12 Lead EKG Procedure</p> <p>b. 24 Hour Holter Monitor System – Scanning</p> <p>c. 24 Hour Holter Monitor System Hook Up and Initiate Recording Procedure</p> <p>d. Echocardiogram – Contrast Bubble Study (Agitated Saline Contrast Injection)</p> <p>e. Transesophageal Echocardiogram (TEE)</p> <p>5. Unit Specific – Medical Staff</p> <p>a. Cultural and Linguistic Proficiency 8710-601</p> <p>6. Unit Specific – Pharmacy</p> <p>a. Peri-operative Antimicrobials Policy</p> <p>7. Unit Specific – Security</p> <p>a. Authorized Security Department Uniform and Safety Equipment 401</p> <p>8. Unit Specific – Surgical Services</p> <p>a. Scheduling Surgical Procedures Policy</p> <p>9. Unit Specific – Women & Newborn Services</p> <p>a. Surrogacy</p> <p>b. WNS Admission Registration Policy</p> <p>c. WNS Disaster Response Plan</p> <p>(14) Minutes – Approval of:</p> <p>a) March 31, 2022 Regular Meeting</p> <p>(15) Meetings and Conferences – None</p> <p>(16) Dues and Memberships - None</p> <p>(17) Reports</p> <p>(a) Dashboard – Included</p> <p>(b) Construction Report – None</p> <p>(c) Lease Report – (March, 2022)</p> <p>(d) Reimbursement Disclosure Report – (March, 2022)</p> <p>(e) Seminar/Conference Reports – None</p>		Standard
10	Discussion of Items Pulled from Consent Agenda	10 min.	Standard

	Agenda Item	Time Allotted	Requestor
11	Comments by Members of the Public NOTE: Per Board Policy 19-018, members of the public may have three (3) minutes, individually and 15 min	5-10 minutes	Standard
12	Comments by Chief Executive Officer	5 min.	Standard
13	Board Communications (three minutes per Board member)	18 min.	Standard
14	Report from Chairperson	3 min.	Standard
15	Total Time Budgeted for Open Session	1.5 hour	
16	Adjournment		

RESOLUTION NO. 813

**RESOLUTION OF TRI-CITY HEALTHCARE DISTRICT BOARD OF
DIRECTORS AUTHORIZING EXECUTION AND DELIVERY OF A LOAN AND
SECURITY AGREEMENT, PROMISSORY NOTE, AND CERTAIN ACTIONS
IN CONNECTION THEREWITH FOR THE CALIFORNIA
HEALTH FACILITIES FINANCING AUTHORITY
NONDESIGNATED PUBLIC HOSPITAL BRIDGE LOAN PROGRAM**

WHEREAS, Tri-City Healthcare District (the "Borrower") is a non-designated public hospital as defined in Welfare and Institutions Code Section 14165.55, subdivision (l), excluding those affiliated with county health systems pursuant to Chapter 240, Statutes of 2021 (SB 170), Section 25; and

WHEREAS, Borrower has determined that it is in its best interest to borrow an aggregate amount not to exceed **\$2,346,338.70** from the California Health Facilities Financing Authority (the "Lender"), such loan to be funded with the proceeds of the Lender's Non-designated Public Hospital Bridge Loan Program; and

WHEREAS, the Borrower intends to use the funds solely to fund its working capital needs to support its operations;

NOW, THEREFORE, BE IT RESOLVED by the Board of Directors of the Borrower as follows:

Section 1. The Board of Directors of Borrower hereby ratifies the submission of the application for a loan from the Non-designated Public Hospital Bridge Loan Program.

Section 2. Steven L. Dietlin, CEO an ("Authorized Officer") is hereby authorized and directed, for and on behalf of the Borrower, to do any and all things and to execute and deliver any and all documents that the Authorized Officer(s) deem(s) necessary or advisable in order to consummate the borrowing of moneys from the Lender and otherwise to effectuate the purposes of this Resolution and the transactions contemplated hereby.

Section 3. The proposed form of Loan and Security Agreement (the "Agreement"), which contains the terms of the loan is hereby approved. The loan shall be in a principal amount not to exceed **\$2,346,338.70**, shall not bear interest, and shall mature 24 months from the date of the executed Loan and Security Agreement between the Borrower and the Lender. The Authorized Officer(s) is hereby authorized and directed, for and on behalf of the Borrower, to execute the Agreement in substantially said form that includes the redirection of up to 20% of Medi-Cal reimbursements (checkwrite payments) to Lender in the event of default, with such changes therein as the

Authorized Officer(s) may require or approve, such approval to be conclusively evidenced by the execution and delivery thereof.

Section 4. The proposed form of Promissory Note (the "Note") as evidence of the Borrower's obligation to repay the loan is hereby approved. The Authorized Officer is hereby authorized and directed, for and on behalf of the Borrower, to execute the Note in substantially said form, with such changes therein as the Authorized Officer(s) may require or approve, such approval to be conclusively evidenced by the execution and delivery thereof.

Date of Adoption

SECRETARY'S CERTIFICATE

I, Gigi Gleason, Secretary of Tri-City Healthcare District, hereby certify that the foregoing is a full, true and correct copy of a resolution duly adopted at a regular meeting of the Board of Directors of Tri-City Healthcare District duly and regularly held at the regular meeting place thereof on the ____ day of _____ 2022, of which meeting all of the members of said Board of Directors had due notice and at which the required quorum was present and voting and the required majority approved said resolution by the following vote at said meeting:

AYES: DIRECTORS:

NOES: DIRECTORS:

ABSENT: DIRECTORS:

I further certify that I have carefully compared the same with the original minutes of said meeting on file and of record in my office; that said resolution is a full, true and correct copy of the original resolution adopted at said meeting and entered in said minutes; and that said resolution has not been amended, modified or rescinded since the date of its adoption, and is now in full force and effect.

Dated: _____

By: _____
Gigi Gleason
Secretary



TRI-CITY MEDICAL CENTER
MEDICAL STAFF INITIAL CREDENTIALS REPORT
April 13, 2022

Attachment A

INITIAL APPOINTMENTS (Effective Dates: 4/29/2022 – 3/31/2024)

Any items of concern will be “red” flagged in this report. Verification of licensure, specific training, patient care experience, interpersonal and communication skills, professionalism, current competence relating to medical knowledge, has been verified and evaluated on all applicants recommended for initial appointment to the medical staff. Based upon this information, the following physicians have met the basic requirements of staff and are therefore recommended for appointment effective 4/29/2022 through 3/31/2024:

- GILL, Puneet MD/Internal Medicine – Telemedicine (Sound)
- LUO, Ran MD/General Surgery (Kaiser)
- MORNEAU, Leonard MD/Teleradiology (StatRad)
- NGUYEN, Joseph MD/Anesthesiology (ASMG)
- RUTTENBERG, Todd DO/Emergency Medicine (TeamHealth)
- SANTIAGO-DIEPPA David MD/Neurosurgery (UCSD)
- SHARMA, Anjali MD/OB/GYN (TeamHealth)
- TADROS, Emad MD/Psychiatry (Tri-City)
- TAPIA, Viridiana MD/Anesthesiology (ASMG)



TRI-CITY MEDICAL CENTER
MEDICAL STAFF CREDENTIALS REPORT – Part 1 of 3
April 13, 2022

Attachment B

BIENNIAL REAPPOINTMENTS: (Effective Dates 5/01/2022 – 4/30/2024)

Any items of concern will be "red" flagged in this report. The following application was recommended for reappointment to the medical staff office effective 05/01/2022 through 4/30/2024, based upon practitioner specific and comparative data profiles and reports demonstrating ongoing monitoring and evaluation, activities reflecting level of professionalism, delivery of compassionate patient care, medical knowledge based upon outcomes, interpersonal and communications skills, use of system resources, participation in activities to improve care, blood utilization, medical records review, department specific monitoring activities, health status and relevant results of clinical performance:

- CHIAO, Hellen, MD/Gastroenterology/Active
- CLANCY, John, DO/Internal Medicine/Refer and Follow
- DELANEY, Michael, MD/Neurology/Active
- EIKERMANN, Eric, MD/Anesthesiology/Active
- ELCHICO, Erick, MD/Anesthesiology/Active
- FARRELL, Jr., Robert, MD/Teleradiology/Provisional
- FIERER, Adam, MD/General Surgery/Active
- HURD, Melissa, MD/Family Medicine/Active-Affiliate
- IAIN, Atul, MD/Ophthalmology/Active
- IESWANI, Sunil, MD/Neurological Surgery/Active
- KAYAL, Anas, MD/Nephrology/Active
- LEE, Robert, MD/Internal Medicine/Active
- PAZ, Pedro, MD/Neonatology/Active
- PERTL, Ursula, MD/Pediatrics/Active
- RAJAMANICKAM, Anitha, MD/Interventional Cardiology/Active
- REEN, Sandeep, MD/Family Medicine/Active
- SEIF, David, MD/Anesthesiology/Active
- SHABANIAN, Leila, MD/Internal Medicine/Active



TRI-CITY MEDICAL CENTER
MEDICAL STAFF CREDENTIALS REPORT – Part 1 of 3
April 13, 2022

Attachment B

- SHABRANG, Cyrus, MD/Interventional Radiology/Active
- SPRINGER, Dewain, DPM/Podiatric Surgery/Active

CHANGE OF STATUS:

- MATTHEWS, Oscar, MD/Cardiology/Active

UPDATE TO PREVIOUS REAPPOINTMENT:

- BHATIA, Shagun, MD/Pediatric Ophthalmology/Active Affiliate

RESIGNATIONS: (Effective date 4/30/2022 unless otherwise noted)

Automatic:

- KELLY, Jon, MD/Orthopedic Surgery

Voluntary:

- KOKA, Anuradha, MD/Radiation Oncology
- PURI, Muhammad, MD/Psychiatry



TRI-CITY MEDICAL CENTER
CREDENTIALS COMMITTEE REPORT – Part 3 of 3
April 12, 2022

PROCTORING RECOMMENDATIONS

Any items of concern will be “red” flagged in this report.

- CLEMENTS, George, MD Cardiology
- COLEY, Nicholas, MD Pathology
- FARNSWORTH, William, MD Neurology
- FARRELL, Robert, MD Teleradiology
- KERN, Hannah, MD Infectious Disease
- PASHMFOROUGH, Mohammad, MD Cardiology
- POLLACK, Melanie, MD Emergency Medicine
- SEIF, Joseph, MD Critical Care
- VISEROL, Marius, MD Pulmonary
- WU, Darrell, MD Cardiothoracic Surgery
- YUNG, Aaron, MD Cardiology



TRI-CITY MEDICAL CENTER
INTERDISCIPLINARY PRACTICE COMMITTEE REPORT
April 19, 2022

INITIAL APPOINTMENTS (Effective Dates: 4/29/2022 – 1/31/2024)

Any items of concern will be “red” flagged in this report. Verification of licensure, specific training, patient care experience, interpersonal and communication skills, professionalism, current competence relating to medical knowledge, has been verified and evaluated on all applicants recommended for initial appointment to the medical staff. Based upon this information, the following physicians have met the basic requirements of staff and are therefore recommended for appointment effective 4/29/2022 through 1/31/2024:

- **HEARN, Kevin PA-C/Allied Health Professional (Orthopedic Specialists of North County)**



TRI-CITY MEDICAL CENTER

INTERDISCIPLINARY PRACTICE REAPPOINTMENT CREDENTIALS REPORT - Part 1 of 1 April 19, 2022

Attachment B

BIENNIAL REAPPRAISALS: (Effective Dates 05/01/2022 - 04/30/2024)

Any items of concern will be "red" flagged in this report. The following application was recommended for reappointment to the medical staff office effective 05/01/2022 through 04/30/2024, based upon practitioner specific and comparative data profiles and reports demonstrating ongoing monitoring and evaluation, activities reflecting level of professionalism, delivery of compassionate patient care, medical knowledge based upon outcomes, interpersonal and communications skills, use of system resources, participation in activities to improve care, blood utilization, medical records review, department specific monitoring activities, health status and relevant results of clinical performance:

- **BULGER, Jeffrey, PAC/Allied Health Professional**
- **CARLTON, Vivian, PAC/Allied Health Professional**
- **GUTHRIE, Lesli, AuD/Allied Health Professional**
- **KAUP, Allison, PhD/Allied Health Professional**
- **NGUYEN, Diana, CNM/Allied Health Professional**

RESIGNATIONS: (Effective date 04/30/2022 unless otherwise noted)

Voluntary:

- **SCOTT, Katie, PA-C/Allied Health Professional**
- **STENZEL, Alison, PA-C/Allied Health Professional**



TRI-CITY MEDICAL CENTER
INTERDISCIPLINARY PRACTICE COMMITTEE REPORT- Part 3 of 3
April 19, 2022

PROCTORING RECOMMENDATIONS

- **BULGER, Jeffrey PA-C** **Allied Health Professional**
- **NGUYEN, Diana CNM** **Allied Health Professional**

TCHD Board of Directors
DATE OF MEETING: April 28, 2022
PHYSICIAN AGREEMENT for Medical Director-Opioid Stewardship Program

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

Vendor's Name: Ole Synder, M.D.

Area of Service: Medical Director- Opioid Stewardship Program

Term of Agreement: 12 months, Beginning May 1, 2022 until April 30, 2023

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

Hourly Rate	Maximum Hrs/Month	Maximum Cost/Month	Annual Cost
\$150/hr	10 hours	\$1500	\$18,000(NTE)
Total Term Cost NTE			\$18,000 (NTE)

Description of Services/Supplies:

- Medical Directorship agreement with responsibilities to establish an opioid stewardship program with duties to include establishing and leading a multidisciplinary team to provide best practice recommendations in inpatient, ED, and outpatient settings.
- In collaboration with District representatives, the Medical director will help create policies and protocols that will drive community standards to reduce opioid consumption, dispensing, and dependence through innovative programs. Not only are these programs expected to provide a service that enhances the health and wellness of the community we serve, but will work to establish a positive alliance and reputation within our local community.
- The medical director will have shared responsibility for the quality of the program

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: Gene Ma, Chief Medical Officer.

Motion:

I move that the TCHD Board of Directors authorize the establishment of the Medical Directorship for Opioid Stewardship Program with services provided by Ole Synder, M.D. for a term of 12 months, beginning May 1, 2022 and ending, April 30, 2023, with an annual and total term cost not to exceed \$18,000.

TCHD Board of Directors
DATE OF MEETING: April 28, 2022
PHYSICIAN AGREEMENT for ED ON-CALL COVERAGE – Orthopedics

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

Physician's Names: Erin Farrelly, MD, & Serge Kaska, MD

Area of Service: Emergency Department On-Call: Orthopedics

Term of Agreement: 25 months, Beginning, June 1, 2022 – Ending June 30, 2024

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

Rate/Day	Panel Days during Term	Panel Annual Cost
Monday-Friday: \$1,500	544 days	\$816,000
Saturday-Sunday: \$1,650	216 days	\$356,400
Total Term Cost:		\$1,172,400

Position Responsibilities:

- 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: Sherry Miller, Manager, Medical Staff Services / Gene Ma, Chief Medical Officer

Motion: I move that the TCHD Board of Directors approve the renewal of the ED On-Call Coverage Panel for Orthopedics to include Erin Farrelly, M.D. and Serge Kaska, M.D. for a term of 25 months, beginning June 1, 2022 and ending June 30, 2024, at a total term cost of \$1,172,400 for the shared call panel.

TCHD Board of Directors

DATE OF MEETING: April 28, 2022

PHYSICIAN AGREEMENT for ED ON-CALL COVERAGE – Orthopedics

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

Physician’s Names:

David Amory, MD, Arash Calafi, MD, David Daugherty, MD, Andrew Hartman, MD, Harish Hosalkar, MD, Grant Seiden, MD, Morgan Silldorff, MD, Erik Stark, MD

Area of Service:

Emergency Department On-Call: Orthopedics

Term of Agreement:

24 months, Beginning, July 1, 2022 – Ending June 30, 2024

Maximum Totals:

Within Hourly and/or Annualized Fair Market Value: YES

Shared Call agreement with Entire ED call panel for Orthopedic Surgery

Rate/Day	Panel Days during Term	Panel Annual Cost
Monday-Friday: \$1,500	522 days	\$783,000
Saturday-Sunday: \$1,650	208 days	\$343,200
Total Term Cost:		\$1,126,200

- Position Responsibilities:
- 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:

Sherry Miller, Manager, Medical Staff Services / Gene Ma, Chief Medical Officer

Motion:

I move that the TCHD Board of Directors approve the renewal of the ED On-Call Coverage Panel for Orthopedics to include David Amory, MD, Arash Calafi, MD, David Daugherty, MD, Andrew Hartman, MD, Harish Hosalkar, MD, Grant Seiden, MD, Morgan Silldorff, MD, and Erik Stark, MD. for a term of 24 months, beginning July 1, 2022 and ending June 30, 2024, at a total term cost of \$1,126,200 for the shared call panel.



TCHD BOARD OF DIRECTORS

DATE OF MEETING: April 28, 2022

PHYSICIAN AGREEMENT Co-Medical Director – Outpatient Behavioral Health Services

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

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

Area of Service: Outpatient Behavioral Health-Morning and Afternoon Program

Term of Agreement: 25 months, Beginning, June, 1, 2022 – Ending, June 30, 2024

Maximum Totals: Within Hourly Fair Market Value

This agreement has the exact terms as Dr. Martina Klein, who will be leaving Tri-City May 2022. Dr. Tadros will be replacing Dr. Klein.

	Rate/Hour	Hours per Month	Hours per Year	Monthly Cost	Annual Cost	25-Month (Term) Cost
Medical Director Duties	\$144	32	384	\$4,608	\$55,296	\$115,200
Case Care Management Duties	\$144	16	192	\$2,304	\$27,648	\$57,600
Vacation Coverage	\$144	As needed	48 max	\$576	\$6,912	\$14,400
Total:		52	624	\$7,488	\$89,856	\$187,200

Co-Medical Director Responsibilities:

- Provide medical supervision and direction to the unit, including the morning, afternoon and evening programs
- Supervise and promote the quality of care and evaluate delivery systems.
- Oversee the development of evidence-based clinical services and provide psychiatric expertise.
- Facilitate weekly problem solving and treatment team meetings with clinical staff.
- Review all treatment plans at least monthly to determine appropriateness of problems and treatment goals.
- Evaluate and review policies and procedures and make suggestions for changes as appropriate.
- Provide education to other physicians at <https://kasa-solutions.com/proposed-legislation-allows-lmft-lmhc-bill-medicare/nd> departments regarding intensive outpatient level of care

Case Care Management and other Duties:

- Take on utilization management duties and respond to insurance authorization calls for IOP and communicate clinical determination of medical necessity.
- Evaluate patients at least once per month for medical necessity and discharge readiness
- Evaluate whether patients are medically stable and meet inclusion/exclusion criteria for IOP on admission and monthly thereafter.
- Prepare reports and records as requested by hospital and regulatory bodies
- Provide professional guidance to staff Monday through Friday and evaluate risk/protective factors and recommend whether a patient needs inpatient treatment or can be managed with safety planning. Respond to calls Mondays through Fridays, 8 am-5 pm.

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: Sarah Jayyousi-Operations Manager, Outpatient Behavioral Health / Candice Parras, Chief Patient Care Services

Motion:

I move that the TCHD Board of Directors authorize the agreement with Dr. Emad Tadros for the co-medical directorship for a term of 25 months, beginning June 1, 2022 and ending June 30, 2024, for an hourly rate of \$144, an annual cost of \$89,856, and a total cost for the term of \$187,200.

**TCHD BOARD OF DIRECTORS
DATE OF MEETING: April 28, 2022
PHYSICIAN AGREEMENT for Covering Physician - Inpatient Wound Care**

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

Physician's Name: Sharon Slowik, M.D.
Area of Service: Inpatient Wound Care
Term of Agreement: 12 months, Beginning, May 1, 2022 - Ending, April 30, 2023
Maximum Totals: Within Hourly and/or Annualized Fair Market Value: YES
 No Change in Rates

Rate/Hour	Hours per Month	Hours per Year	Cost per Month	12 Month (Term) Cost
\$180	20	240	\$3,600	\$43,200

Position Responsibilities:

- Provide supervision for the clinical operation of the Inpatient Wound Care Team
- Provide staff education to improve outcome of care
- Resolve conflicts that are intra-departmental or inter-departmental in nature to ensure or improve timeliness of patient treatment and intervention
- Ensure that services provided are in compliance with regulatory standards
- Participate in Quality Assurance and Performance Improvement activities
- Timely communication with primary care physicians and/or other community health resources
- Documentation: Full and timely documentation for all patients. Comply with all legal regulatory, accreditation, Medical Staff and billing criteria, including applying Medicare guidelines, including, Title 1X for admission and discharge decisions
- Utilization Review, Quality Improvement: Actively participate in hospital and Medical Staff utilization review, quality, performance improvement and risk programs

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: Kim Posten, Manager-Clinical, Wound Care, Carlsbad / Candice Parras, Chief Patient Care Services

Motion: I move that the TCHD Board of Directors authorize Dr. Sharon Slowik as the Coverage Physician for Inpatient Wound Care for a term of 12 months from May 1, 2022, and ending April 30, 2023, not to exceed an average of 20 hours a month, at an hourly rate of \$180 for a total annual and term cost of \$43,200.



TCHD BOARD OF DIRECTORS

DATE OF MEETING: April 28, 2022

PHYSICIAN AGREEMENT for Covering Physician - Inpatient Wound Care

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

Physician's Name: Henry Showah, M.D.

Area of Service: Inpatient Wound Care

Term of Agreement: 12 months, Beginning, May 1, 2022 - Ending, April 30, 2023

Maximum Totals: Within Hourly and/or Annualized Fair Market Value: YES
No Change in Rates

Rate/Hour	Hours per Month	Hours per Year	Cost per Month	12 Month (Term) Cost
\$180	20	240	\$3,600	\$43,200

Position Responsibilities:

- Provide supervision for the clinical operation of the Inpatient Wound Care Team
- Provide staff education to improve outcome of care
- Resolve conflicts that are intra-departmental or inter-departmental in nature to ensure or improve timeliness of patient treatment and intervention
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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: Kim Posten, Manager-Clinical, Wound Care, Carlsbad / Candice Parras, Chief Patient Care Services

Motion: I move that the TCHD Board of Directors authorize Henry Showah, MD as the Coverage Physician for Inpatient Wound Care for a term of 12 months from May 1, 2022, and ending April 30, 2023, not to exceed an average of 20 hours a month, at an hourly rate of \$180 for a total annual and term cost of \$43,200.

**TCHD BOARD OF DIRECTORS
DATE OF MEETING: April 28, 2022
PHYSICIAN AGREEMENT for Covering Physician - Outpatient Wound Care**

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

Physician's Name: Sharon Slowik, M.D.

Area of Service: Outpatient Wound Care

Term of Agreement: 12 months, Beginning, May 1, 2022 - Ending, April 30, 2023

Maximum Totals: Within Hourly and/or Annualized Fair Market Value: YES
No Change in Rates

Rate/Hour	Hours per Month	Hours per Year	Cost per Month	12 Month (Term) Cost
\$180	20	240	\$3,600	\$43,200

Position Responsibilities:

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- Provide staff education to improve outcome of care
- Resolve conflicts that are intra-departmental or inter-departmental in nature to ensure or improve timeliness of patient treatment and intervention
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- Utilization Review, Quality Improvement: Actively participate in hospital and Medical Staff utilization review, quality, performance improvement and risk programs

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: Kim Posten, Manager-Clinical, Wound Care, Carlsbad / Candice Parras, Chief Patient Care Services

Motion: I move that the TCHD Board of Directors authorize Sharon Slowik, MD as the Coverage Physician for Outpatient Wound Care for a term of 12 months from May 1, 2022, and ending April 30, 2023, not to exceed an average of 20 hours a month, at an hourly rate of \$180 for a total annual and term cost of \$43,200.

TCHD BOARD OF DIRECTORS
DATE OF MEETING: April 28, 2022

PHYSICIAN AGREEMENT for Covering Physician - Outpatient Wound Care

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

Physician's Name: Henry Showah, M.D.
Area of Service: Outpatient Wound Care
Term of Agreement: 12 months, Beginning, May 1, 2022 - Ending, April 30, 2023
Maximum Totals: Within Hourly and/or Annualized Fair Market Value: YES
 No Change in Rates

Rate/Hour	Hours per Month	Hours per Year	Cost per Month	12 Month (Term) Cost
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- Provide staff education to improve outcome of care
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- Ensure that services provided are in compliance with regulatory standards
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- Utilization Review, Quality Improvement: Actively participate in hospital and Medical Staff utilization review, quality, performance improvement and risk programs

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: Kim Posten, Manager-Clinical, Wound Care, Carlsbad / Candice Parras, Chief Patient Care Services

Motion: I move that the TCHD Board of Directors authorize Henry Showah, MD as the Coverage Physician for Outpatient Wound Care for a term of 12 months from May 1, 2022, and ending April 30, 2023, not to exceed an average of 20 hours a month, at an hourly rate of \$180 for a total annual and term cost of \$43,200.



**TCHD BOARD OF DIRECTORS
DATE OF MEETING: April 28, 2022
ARUP Pricing Agreement Proposal**

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

Vendor's Name: ARUP

Area of Service: Laboratory - Reference Laboratory Testing

Term of Agreement: 29 months, Beginning, June 1, 2022 – Ending, October 31, 2024

Maximum Totals:

Monthly Cost	Annual Cost	Total Term Cost
\$17,321	\$207,852	\$502,309

Description of Services/Supplies:

- Pricing agreement on Laboratory testing
- ARUP Laboratories is our reference laboratory of choice for referral laboratory testing services. ARUP performs laboratory testing on our patient samples that we do not perform in our laboratory.
- TCMC has a long-standing relationship with the reference laboratory dating back more than 10 years.
- ARUP Laboratories is interfaced directly to Cerner to ensure ease of ordering, specimen processing, and result review in a timely manner. Their commitment to quality mirrors the quality patient care focus and initiatives at TCMC.

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

Person responsible for oversight of agreement: Eva England, Director-Cardiovascular Service Line

Motion:

I move that the TCHD Board of Directors authorize the agreement with ARUP for Laboratory testing for a term of 29 months, beginning June 1, 2022 and ending October 31, 2024 for an annual cost of \$207,852, and a total cost for the term of \$502,309.

TCHD BOARD OF DIRECTORS
DATE OF MEETING: April 28, 2022
Rady Children's Specialists Agreement for NICU ROP Testing PROPOSAL

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

Vendor's Name: Rady Children's Specialists of San Diego
Area of Service: NICU- Retinopathy of Prematurity (ROP) Testing
Term of Agreement: 12 months, Beginning, May 1, 2022 – Ending, April 30, 2023
Maximum Totals: Within Hourly and/or Annualized Fair Market Value: YES

Monthly Cost	Total Term Cost
\$3,570	\$42,840

Description of Services/Supplies:

- *Ophthalmic Consultation Services for NICU- Retinopathy of Prematurity (ROP) Testing*
- Negotiations took place during April 2022, regarding new rates
- Requested increase of \$170 per month, \$2,040 for the term

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, MBA, MSN, RN, CCRN, Director of Women & Newborn Services & Candice Parras, RN, Chief Nurse Executive

Motion:

I move that the TCHD Board of Directors authorize the agreement with Rady Children's Specialists of San Diego for Retinopathy of Prematurity (ROP) testing for a term of 12 months, beginning May 1, 2022 and ending April 30, 2023 for a cost of \$3,570 per month, and a total cost for the term of \$42,840.

TCHD BOARD OF DIRECTORS

DATE OF MEETING: April 28, 2022

TEAM PHYSICIANS OF SOUTHERN CALIFORNIA MEDICAL GROUP, INC. (TEAM HEALTH)

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

Vendor’s Name: Team Physicians of Southern California Medical Group, Inc. (Team Health)

Area of Service: Emergency Services for Physicians

Term of Agreement: June 1, 2022, through May 31, 2024, Fourth Amendment

Maximum Totals:

Services	Monthly Cost	Annual Cost	Total Term Cost
		Total:	No Cost

Description of Services/Supplies:

This is a professional service agreement between Team Health and Tri-City Healthcare District, to provide professional physician services for the Emergency Department.

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: Candice Parras, Chief of Patient Care Services

Motion:

I move that the TCHD Board of Directors authorize the agreement with Team Health to provide professional physician services for the Emergency Department, for a term of 24 months, beginning June 1, 2022 through May 31, 2024, at no cost to the District.

RESOLUTION NO. 812

RESOLUTION OF THE BOARD OF DIRECTORS OF TRI-CITY HEALTHCARE DISTRICT RE-RATIFYING THE STATE OF EMERGENCY AND RE-AUTHORIZING REMOTE TELECONFERENCE MEETINGS

WHEREAS, Tri-City Healthcare District (“District”) is committed to preserving and fostering access and participation in meetings of its Board of Directors; and

WHEREAS, Government Code section 54953(e) makes provisions for remote teleconferencing participation in meetings by members of a legislative body without compliance with the requirements of Government Code section 54953(b)(3), subject to the existence of certain emergency conditions; and

WHEREAS, a required condition is that a state of emergency is declared by the Governor pursuant to Government Code section 8625, proclaiming the existence of conditions of disaster or of extreme peril to the safety of persons and property within the state caused by conditions as described in Government Code section 8558; and

WHEREAS, a proclamation is made when there is an actual incident, threat of disaster, or extreme peril to the safety of persons and property within the jurisdictions that are within the District’s boundaries, caused by natural, technological, or human-caused disasters; and

WHEREAS, it is further required that state or local officials have imposed or recommended measures to promote vaccines, masking, and social distancing, and that meeting in person at the hospital would present imminent risks to the health and safety of attendees; and

WHEREAS, the Board of Directors previously adopted Resolution No. 803 on September 30, 2021, finding that the requisite conditions exist for the Board of Directors of the District to conduct remote teleconference meetings without compliance with paragraph (3) of subdivision (b) of Government Code section 54953; and

WHEREAS, as a condition of extending the use of the provisions found in Government Code section 54953(e), the Board of Directors must reconsider the circumstances of the state of emergency that exists in the District, and the Board of Directors has done so; and

WHEREAS, emergency conditions persist in the District and vaccine compliance, masking, and social distancing measures are required to be followed on the premises of the hospital for the continued health and safety of the patients, workers, and public; and

WHEREAS, as a consequence of the local emergency persisting, the Board of Directors does hereby find that the District shall conduct its meetings without compliance

with paragraph (3) of subdivision (b) of Government Code section 54953, as authorized by Government Code section 54953(e), and that such meetings shall comply with the requirements to provide the public with access to the meetings as prescribed in Government Code section 54953(e);

THEREFORE, BE IT RESOLVED by the Tri-City Healthcare District Board of Directors as follows:

Section 1: Recitals. The Recitals set forth above are true and correct and are incorporated into this Resolution by this reference.

Section 2: Affirmation that a Local Emergency Persists. The Board of Directors hereby considers the conditions of the state of emergency in the District and proclaims that a local emergency persists throughout the District.

Section 3: Re-Ratification of the Governor's Proclamation of a State of Emergency. The Board of Directors hereby ratifies the Governor's Proclamation of a State of Emergency.

Section 4: Remote Teleconference Meetings. The District's Chief Executive Officer is hereby authorized and directed to take all actions necessary to carry out the intent and purpose of this resolution, including conducting open and public meetings in accordance with Government Code section 54953(e) and other applicable provisions of the Ralph M. Brown Act.

PASSED AND ADOPTED at a regular meeting of the Board of Directors of Tri-City Healthcare District held on _____, 2022, by the following roll call vote:

AYES: Directors:

NOES: Directors:

ABSTAIN: Directors:

ABSENT: Directors:

Rocky J. Chavez, President
Board of Directors

ATTEST:

Gigi Gleason, Secretary
Board of Directors

ADMINISTRATION CONSENT AGENDA

April 19th, 2022

CONTACT: Candice Parras, CPCS

Policies and Procedures	Reason	Recommendations
Patient Care Services Policies & Procedures		
1. Assessing and Managing Patients at Risk for Suicide Policy	- 3 year review	Forward To BOD For Approval
2. Automatic Stop Orders Policy	- 3 year review	Forward To BOD For Approval
3. Bed Utilization, Temporary Opening and Closing of Inpatient Beds/Units Policy	- 3 year review, practice change	Forward To BOD For Approval
4. Black Box Warnings, Drugs with Policy	- 3 year review	Forward To BOD For Approval
5. Clinical Alarm Management	- 3 year review, practice change	Forward To BOD For Approval
6. Discharge Planning, Homeless Patient Policy	- 3 year review	Forward To BOD For Approval
7. Emergency Cart (Crash Cart) Cardiopulmonary Arrest Policy	- 3 year review, practice change	Forward To BOD For Approval
8. Medication Administration Policy	- 3 year review, practice change	Forward To BOD For Approval
9. Medications, High Risk/ High Alert/ Look Alike Sound Alike Policy	- 3 year review, practice change	Forward To BOD For Approval
10. Physician / Allied Health Professionals (AHP) Orders for Outpatient Services	- 3 year review	Forward To BOD For Approval
11. Potential Food and Drug Interactions, Patient Education Policy	- 3 year review	Forward To BOD For Approval
12. Pre, Intra and Post-op Assessment of Fetal Heart Rate and Uterine Activity Procedure	- 3 year review, practice change	Forward To BOD For Approval
13. Release of Deceased to a Family Member policy	- 3 year review, practice change	Forward To BOD For Approval
14. Sponge, Sharps and Instrument Counts Prevention of Retained Surgical Objects	- 3 year review, practice change	Forward To BOD For Approval
15. Universal Protocol Procedure	- Practice change	Forward To BOD For Approval
16. Vaccination Administration	- 3 year review, practice change	Forward To BOD For Approval
Administrative 200 District Operations 300 Patient Care		
1. Failure Mode and Effects Analysis (FMEA) 389	- 3 year review, practice change	Forward To BOD For Approval
2. Hospital Records Retention 237	- 3 year review	Forward To BOD For Approval
3. Space and Office Allocation 289	- 3 year review, practice change	Forward To BOD For Approval
Administrative 600 Information Technology		
1. Fax Transmissions 616	- 3 year review, practice change	Forward To BOD For Approval
2. Internet Access 603	- 3 year review, practice change	Forward To BOD For Approval
3. Network Access 602	- 3 year review, practice change	Forward To BOD For Approval
4. Voicemail Access 617	- 3 year review, practice change	Forward To BOD For Approval

ADMINISTRATION CONSENT AGENDA

April 19th, 2022

CONTACT: Candice Parras, CPCS

Policies and Procedures	Reason	Recommendations
Cardiology		
1. 12 Lead EKG Procedure	- 3 year review	Forward To BOD For Approval
2. 24 Hour Holter Monitor System -- Scanning Analysis	- 3 year review	Forward To BOD For Approval
3. 24 Hour Holter Monitor System Hook Up and Initiate Recording Procedure	- 3 year review	Forward To BOD For Approval
4. Echocardiogram - Contrast Bubble Study (Agitated Saline Contrast Injection)	- 3 year review	Forward To BOD For Approval
5. Transesophageal Echocardiogram (TEE)	- 3 year review	Forward To BOD For Approval
Medical Staff		
1. Cultural and Linguistic Proficiency 8710 - 601	- Practice change	Forward To BOD For Approval
Pharmacy		
1. Peri-operative Antimicrobials Policy	- NEW	Forward To BOD For Approval
Security		
1. Authorized Security Department Uniform and Safety Equipment 401	- 3 year review, practice change	Forward To BOD For Approval
Surgical Services		
1. Scheduling Surgical Procedures Policy	- Practice change	Forward To BOD For Approval
Women & Newborn Services		
1. Surrogacy	- 3 year review, practice change	Forward To BOD For Approval
2. WNS Admission Registration Policy	- 3 year review, practice change	Forward To BOD For Approval
3. WNS Disaster Response Plan	- 3 year review, practice change	Forward To BOD For Approval

PATIENT CARE SERVICES

ISSUE DATE: 01/07

SUBJECT: Assessing and Managing Patients
at Risk for Suicide

REVISION DATE(S): 11/09, 06/10, 05/13, 10/13, 07/18, 05/19

Patient Care Services Content Expert Approval:	42/4801/22
Clinical Policies & Procedures Committee Approval:	03/4902/22
Nursing Leadership Executive Committee Approval:	03/4903/22
Medical Staff Department/Division Approval:	n/a
Pharmacy & Therapeutics Committee Approval:	n/a
Medical Executive Committee Approval:	04/4903/22
Administration Approval:	05/4904/22
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	05/19

A. PURPOSE:

1. To identify patients who are at risk for suicide, including identification of specific factors and features which may increase or decrease the risk.
2. To ensure the immediate safety needs of patients identified as at risk for suicide are met in the most appropriate care setting.
3. To ensure the organization provides information to individuals and their family members for management of crisis situations.

B. DEFINITIONS:

1. Suicide Risk Screening: A screening performed by a clinician to identify patients at suicide risk.
2. Suicide Risk Assessment: An in-depth assessment using a tool which identifies risk severity (for example the Columbia Suicide Severity Rating Scale [C-SSRS]).
3. Qualified mental health professionals (QMHP) may include:
 - a. Psychiatrists
 - b. Psychologists
 - c. Allied Health Professional (AHP), masters level or above, with specific clinical or practice privileges.
4. Suicide Observation: direct continuous one to one (1:1) observation where a designated staff member is within arm's length of the patient at all times, accompanies the patient off of the unit to procedures or tests, and remains with the patient unless instructed by the primary nurse or procedure/test staff.

C. INITIAL ASSESSMENT:

1. Emergency Department:
 - a. A suicide risk screen will be performed upon triage by a Registered Nurse (RN) and/or physician/Allied Health Professional (AHP).
 - i. If the patient answers yes to **first feeling suicidal risk question today**:
 - 1) A suicide risk assessment will be performed.
 - 2) A referral will be made to the QMHP.
 - a) If indicated, the QMHP will perform an independent suicide risk assessment.
2. Outpatient Behavioral Health Services Program:
 - a. An assessment tool will be used that identifies the patient's risk for self-harm by completion of the initial intake visit.

3. Inpatient Areas:

- a. If the patient expresses suicidal ideation the RN will notify the attending physician and the AHP.
 - i. If indicated, the AHP will perform an independent assessment.

D. **REASSESSMENT:**

- 1. Reassessment of suicide risk will be completed by a QMHP as is clinically indicated to determine if there is an increase or decrease in risk.

E. **POLICY:**

- 1. Patients who have been identified as a suicide risk or who express suicidal ideation:
 - a. ~~Will receive~~ Receive interventions that meet their immediate safety needs.
 - i. In the Outpatient Behavioral Health Services Program patients considered as moderate to high risk shall be closely observed and frequently reevaluated so that the safest level of care can be determined.
 - ii. Outpatient areas will contact the physician.
 - 1) On-campus may contact the Psych Liaison as needed.
 - 2) Off-campus may call "911" as needed.
 - b. Be provided with suicide observation.
 - i. If patient is unresponsive, suicide observation will be based on the assessment and evaluation of the patient.
 - ii. Staff providing suicide observation:
 - 1) May only be assigned one (1) patient.
 - 2) Should never leave the patient alone or leave the room even when family members are present.
 - iii. Suicide Observation will be documented in the health record.
 - c. Be evaluated to identify disposition to most appropriate care setting.
 - d. If the patient attempts to leave, notify Security or call a Dr. Strong to detain the patient for his/her own safety and contact the attending physician.
 - i. The patient will be re-evaluated by a QMHP.
 - e. In the event the patient elopes, notify Security, the ~~Assistant-Nurse Leader~~ **Manager** (ANM)/designee, QMHP, attending physician and Oceanside Police Department.
 - i. Provide the police with a description of the patient.
- 2. Suicide precautions shall be implemented **as follows:**
 - a. Check patient's room each shift to ensure ~~it is ligature resistant~~; there are no objects or equipment which may be used to cause self-harm.
 - b. Ensure all prescribed medications are swallowed.
 - i. Medications may not be left unattended at any time.
 - c. Report any further statements or threats and/or description of a plan by the patient immediately to the RN for further evaluation and level of safety.
 - d. Escort patient to the bathroom.
 - i. Do not allow the door to be closed.
 - ii. Stay outside open door.
 - iii. Check patient by conversing at least once a minute and elicit a response.
 - e. Ensure Dietary supplies trays with paper containers and plasticware.
 - i. When the patient is finished eating, trays, paper containers and plasticware are to be disposed of outside the patient's room.
 - f. Monitor any item(s) brought in by visitors and identify items considered unsafe. Encourage visitor to take objects to their vehicle or hold item and return to visitor when they leave. Educate visitors this is to ensure patient safety.
 - i. In the event that the visitor is not cooperative with requests to remove items, notify Security.
 - g. Until the QMHP has identified that the patient is no longer at risk to cause harm to themselves or others.

3. Patients, caregivers or family members (when clinically appropriate) shall be provided with the Suicide Prevention Lifeline at 800-273-8255.

F. **FORM(S):**

1. Suicide Observation Documentation 8610-1002 - Sample

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

1. Environmental Safety Guidelines for Suicidal Patient

H. **REFERENCE(S):**

1. Columbia Suicide Severity Rating Scale
2. <https://suicidepreventionlifeline.org>

SAMPLE

Date _____

Activity Code		
A – Watching TV	D – Sleeping & Breathing	G – With MD / Therapist
B – With Visitors	E – Lying / Sitting	H – Transport
C – Eating	F – Walking / Pacing	I – Other: _____

Time	Staff Initials	Activity Code (Optional)	Time	Staff Initials	Activity Code (Optional)	Time	Staff Initials	Activity Code (Optional)
12:00AM			08:00			16:00		
12:15			08:15			16:15		
12:30			08:30			16:30		
12:45			08:45			16:45		
01:00			09:00			17:00		
01:15			09:15			17:15		
01:30			09:30			17:30		
01:45			09:45			17:45		
02:00			10:00			18:00		
02:15			10:15			18:15		
02:30			10:30			18:30		
02:45			10:45			18:45		
03:00			11:00			19:00		
03:15			11:15			19:15		
03:30			11:30			19:30		
03:45			11:45			19:45		
04:00			12:00			20:00		
04:15			12:15			20:15		
04:30			12:30			20:30		
04:45			12:45			20:45		
05:00			13:00			21:00		
05:15			13:15			21:15		
05:30			13:30			21:30		
05:45			13:45			21:45		
06:00			14:00			22:00		
06:15			14:15			22:15		
06:30			14:30			22:30		
06:45			14:45			22:45		
07:00			15:00			23:00		
07:15			15:15			23:15		
07:30			15:30			23:30		
07:45			15:45			23:45		

Print Name	Initials	Print Name	Initials



Environmental Safety Guidelines for Suicidal Patient

Environment for patients at risk for suicide should be checked each shift including but not limited to the following:

Sharp Objects Removed from Room

- Remove all sharp objects e.g., needles, scalpels, knives, scissors, nail files, coat hangers, cutlery, glass items

Patient Belongings That Can Be Used to Inflict Self Harm Removed From Room

- Clothing with any type of strings, shoe laces, ties, drawstrings, belts or straps, socks
- This includes but is not limited to: patient medications, glass or sharp items, matches or lighter, batteries toiletry items containing alcohol, peroxide, aerosol spray can, curling iron, hair dryer, razor, hand rub/sanitizer, dental floss, jewelry and illegal substances, washcloths
- **Allowable items:**
 - Cordless electric razor
 - Eyeglasses
 - Non-breakable or ingestible toiletries

Remove to Reduce Risk of Hanging (Ligature Points) and Eliminate Potentially Harmful Objects:

- Plastic Bags: Garbage container, linen containers and all plastic bags
- Linen: Remove extra linen (sheets, towels, pillowcases, blankets, gowns, draw sheets etc.)
- Tubing: suction and IV tubing (excessive)
- Oxygen tubing and flowmeter (unless required for continuous use)
- Cords: electric, telephone, bed, call button and detachable window blinds, curtains
- Monitoring equipment (BP/EKG cables) unless required for continuous monitoring
- Room:
 - Bathroom plumbing, fixtures
 - Bedframe, rails
 - Coat hooks
 - Curtains/blinds and curtain rails for windows or doors, tracking, wires for nets
 - Doors/cabinets handles, hooks, hinges or gaps between door and frame
 - Door closures should be mounted on outside of door
 - Furniture for potential barricade
 - Grab bars
 - Light fixtures such as lamps, bulbs, shades, cords
 - Shelving hinges, brackets, fixtures
 - Window - ensure windows are secured

Dietary:

- Ensure disposable cups, plates and plastic spoons are used and removed after meals/snacks
- Aluminum cans

Hand-off:

- Initiation of suicide precautions and 1:1 observation communicated during hand-off e.g., shift-to-shift, meal breaks, bathroom, anytime a patient is hand-off to another care provider.

Visitors:

- Monitor any item(s) brought in by visitors. Remove items considered unsafe and return it to visitor when they leave the facility.

PATIENT CARE SERVICES

ISSUE DATE: 01/03

SUBJECT: Automatic Stop Orders

REVISION DATE: 06/03, 07/09, 03/14, 04/18

Department Approval:	01/1811/21
Clinical Policies & Procedures Committee Approval:	02/1812/21
Nursing Leadership Executive Council Approval:	03/1801/22
Pharmacy and Therapeutic Committee	03/1802/22
Medical Executive Committee Approval:	03/1803/22
Administration Approval:	04/22
Professional Affairs Committee Approval:	04/18 n/a
Board of Directors Approval:	04/18

A. PURPOSE:

1. To provide guidelines for discontinuing narcotics, antibiotics, chemotherapeutic agents, and all other drugs.

B. POLICY:

1. In the absence of a specific physician/Allied Healthcare Professional (AHP)'s order indicating the desired duration of therapy, automatic medication expiration is as follows:
 - a. Opioids and benzodiazepines – seven (7) days
 - b. Antibiotics – seven (7) days
 - c. Intravenous (IV) acetaminophen- 24 hours (not to exceed 72 hours)
 - d. Ketorolac- five (5) days
 - e. Paralytic agents (i.e. cisatracurium, rocuronium, pancuronium, vecuronium)- 48 hours
 - f. Albumin- 24 hours (exceptions: status post Coronary Artery Bypass Graft, hypotension during dialysis, hepatorenal syndrome, spontaneous bacterial peritonitis; not to exceed 14 continuous days)
 - g. Mannitol – seven (7) days
 - h. Phytonadione (Vitamin K) – seven (7) days
 - i. Iron sucrose – maximum cumulative dose 1,000 mg within 14 day period
 - j. All other medications – 30 days
 - k. All medication written to be given for “duration of stay” shall be interpreted as the physician requesting therapy for the entire inpatient stay unless otherwise stated.
2. The expiration date(s) of these medications shall be monitored via the Pharmnet Pharmacy System.
3. The ordering physician/AHP will receive a renewal notice in their inbox to renew the medication electronically ~~via computerized physician order entry (CPOE).~~
4. Medications that are not renewed shall not be given after the renewal date noted on the renewal form for each medication.
5. Any medications put on “hold” by the physician/AHP shall automatically be discontinued by the nurse or pharmacist and must be reordered by the physician/AHP if and when the medication is resumed.

PATIENT CARE SERVICES

ISSUE DATE: 01/02

SUBJECT: Bed Utilization, Temporary Opening
and Closing of Inpatient Beds/Units

REVISION DATE: 03/02, 06/03, 01/04, 06/05, 03/10
08/10, 12/13, 09/17

POLICY NUMBER: III.G

Patient Care Services Content Expert/Department Approval: 05/1711/21
Clinical Policies and Procedures Committee Approval: 06/1712/21
Nursing Leadership/Executive Committee Approval: 07/1703/22
Pharmacy and Therapeutics Approval: n/a
Medical Executive Committee Approval: 08/1703/22
Administration Approval: 04/22
Professional Affairs Committee Approval: 09/17 n/a
Board of Directors Approval: 09/17

A. TEMPORARY OPENING OF BEDS/UNITS:

1. Admissions to the inpatient nursing units shall not be denied without express consent from the Director, Administrative Supervisor, Manager, or Chief Nurse Executive or designee.
2. Acute Care Services (ACS):
 - a. ACS patients may be placed outside of the designated nursing units to maximize resources.
 - b. ACS areas shall be staffed and equipped accordingly.
3. Telemetry:
 - a. During increased Telemetry census, Telemetry patients may be placed on 4 Pavilion (4P) and staffed with Telemetry Registered Nurses (RN) at a ratio of one RN to 4 patients (1:4).
 - i. All patients will be assigned a room on Telemetry by ~~the Telemetry Nursing Leader/designee~~ **Assistant Nurse Manager (ANM) or Relief Charge Registered Nurse (RN)**
 - ii. ~~Patients with admission or transfer orders not written by a cardiologist or cardiovascular surgeon may be assigned a room on 4P~~
 - iii. ~~Patients with admission or transfer orders written by a cardiologist or cardiovascular surgeon will be assigned a room on 2E, 2W, 4E or 4W~~
4. Intensive Care Unit (ICU):
 - a. During increased Telemetry census for admissions only, limited program flexibility shall be initiated. Four Intensive Care Unit (ICU) beds will be designated as Telemetry admits beds for a period not to exceed 72 hours. These beds shall be staffed using licensed nurse-to-patient ratios representative of the ICU staffing ratio 1:2.
 - i. ~~The Nursing Leader or the Administrative Supervisor~~ **Nurse Managers/ANMs relief charge nurse** shall notify **Chief Nurse Executive (CNE) or designee and the Manager of Regulatory Compliance Services** as soon as possible
 - 1) **The CNE or Manager of Regulatory Compliance will notify the county regulatory agency by phone or by email for submission of "temporary permission for increased patient accommodations request review and approval sheet."**
5. Women and Newborn Services (WNS):
 - a. Overflow of Mother/Baby outside of the designated nursing units may occur when bed demand is greater than capacity. **Any Mother/Baby overflow beds** shall be staffed and equipped accordingly.

6. ~~Neonatal Intensive Care (NICU):~~

- a. ~~Per NICU Policy: NICU Placement: Overflow to Alternate Location (Temporary Overflow).~~

B. **TEMPORARY CLOSING OF BEDS/UNITS:**

1. Inpatient beds may be closed as a result of census, staffing, infection control, emergency, or maintenance problems.
 - a. Beds shall not be closed without express consent of the Unit Director or Manager or Administrative Supervisor (nights only).
 - b. Prior to closure of a unit, the **ANM relief charge nurse** or designee is responsible for communication with the Administrative Supervisor to evaluate the potential need for beds by other departments.
2. Patient acuity and safety will be taken into consideration when deciding to close a unit.
3. The **ANM relief charge nurse** or designee must complete the Closure of Nursing Unit Checklist before the unit/beds can be considered closed and submitted to the Regulatory Compliance Department **and unit leadership.**
4. Intensive Care Unit:
 - a. Two Code Blue nurses ~~are~~ **will be** assigned to **one ICU side.** ~~from the unit that remains open.~~
 - b. The crash cart and defibrillator on the closed unit **ICU side** must still be checked every shift.
 - c. The Code Blue response defibrillator will remain on 1East and Code Blue drugs will remain in the refrigerator on 1West. It is the responsibility of the Code Blue RN to check the crash cart and defibrillator on the closed unit.
 - d. The charge nurse or designee must check the emergency procedure trays on 1 East and 1 West

C. **ADMITTED PATIENTS WAITING FOR BEDS:**

1. Registration staff shall notify the Administrative Supervisor, ~~ANM or Manager~~ **relief charge nurse or designee** when a **request for a direct admit** patient is to be admitted and a bed is not available.
2. The Administrative Supervisor, ~~ANM or Manager~~ **relief charge nurse or designee** shall assign the appropriate area for direct admits based on patient assessment, physician orders, and availability.

D. **FORM(S):**

1. Closure of NICU Overflow Area-Checklist
2. Closure of Nursing Unit Checklist - Sample
3. Opening of Nursing Unit Checklist - Sample

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

1. NICU Policy: NICU Placement: Overflow to Alternate Location (Temporary Overflow) Procedure

Closure of Nursing Unit Checklist - Sample

Location: _____ Date: _____ Person(s) Completing: _____

- ☐ Confirm the appropriate beds are available after all transfers and /or discharges are complete
- ☐ Complete Narcotic check on medication Pyxis (inventory)

Notify the Following: (These task may be delegated to an Unit Secretary)

- | | |
|--|---|
| <input type="checkbox"/> Administrative Supervisor (AS) | <input type="checkbox"/> Private Branch Exchange (PBX) |
| <input type="checkbox"/> Staffing Office | <input type="checkbox"/> Notify the Monitor Technician (MT) |
| <input type="checkbox"/> Pharmacy (to turn off Pyxis access) | <input type="checkbox"/> Environmental Services |
| <input type="checkbox"/> Information Technology (IT) /AS (nights/weekends)
(Notify to "shut down" printers) | <input type="checkbox"/> Food & Nutrition |
| <input type="checkbox"/> Facilities Management | <input type="checkbox"/> Security |
| <input type="checkbox"/> Security | <input type="checkbox"/> Medical Records |

Equipment Checks & Storage as follows (or per Unit guidelines):

- ☐ Crash Cart - Document on Crash Cart Checklist "Unit Closed" in the appropriate date field
- ☐ Plug in infusion pumps - store in a patient room
- ☐ Plug in Work Station on Wheels/WOWs and store in a locked room
- ☐ Place clean bedside commodes - in a patient room
- ☐ Place visitor's chairs in patient's room
- ☐ Store glucometer, doppler, pulse oximeter and other unit specific equipment in Medication Room
- ☐ Store Crash Cart and Defibrillator in Medication Room
- ☐ Nurse Locators - Place in the supply room located near the nurse's station
- ☐ Patient Charts – Store empty charts in designated area
- ☐ Patient Medications - transfer with patient or return medications to Pharmacy

Verify Patient PHI information is secured - if PHI is found, discard in Shred Bin. Check the unit for the following:

- ☐ Check all drawers and cabinets to ensure there is no unsecured PHI or logs with patient information
- ☐ Patient census
- ☐ SBAR and hand-off forms with patient information
- ☐ TASK list
- ☐ Check Physician's dictation room (including copier) for any PHI
- ☐ Check all printers for PHI
- ☐ Check all patient rooms for PHI
- ☐ Check all supply rooms for PHI

Telemetry boxes and lead wires:

- ☐ Count Telemetry Transmitters (boxes) and lead wires. # of Telemetry boxes = _____ # of Lead wires = _____
- ☐ Open battery latch to prevent battery contact with latch or remove batteries
- ☐ Store clean Telemetry boxes and lead wires in wire baskets above the sink near nurses' station

Cleaning Requirements:

- ☐ Notify Environmental services to clean unit
- ☐ Verify each patient room is clean
- ☐ Turn off the lights and close doors of each patient room
- ☐ Turn off the lights in Physician Dictation Room, Supply Rooms, etc

Turn off power on the following:

- ☐ Computer monitors
- ☐ Pharmacy fax machine
- ☐ Telemetry monitoring screens
- ☐ Copier and printer to be turned off after 2 hours and final sweep for PHI (shared copier may be left on.
- ☐ Forward phones to designated unit if applicable
- ☐ Close fire doors to unit and ensure they are locked
- ☐ Turn off the lights on the unit.
- ☐ Place unit keys in the ANM Office

***Fax completed form to the Regulatory Compliance Specialist at 760-806-4645**

Opening of Nursing Unit Checklist - Sample

Location: _____ Date: _____ Person(s) Completing: _____

- ☐ Confirm the need to open beds are available after all transfers and /or discharges are complete
- ☐ Complete Narcotic check on medication Pyxis (inventory)

Notify the Following: (These task may be delegated to an Unit Secretary)

- | | |
|--|---|
| <input type="checkbox"/> Administrative Supervisor (AS) | <input type="checkbox"/> Private Branch Exchange (PBX) |
| <input type="checkbox"/> Staffing Office | <input type="checkbox"/> Notify the Monitor Technician (MT) |
| <input type="checkbox"/> Pharmacy (to turn on Pyxis access) | <input type="checkbox"/> Environmental Services |
| <input type="checkbox"/> Information Technology (IT) /AS (nights/weekends) | <input type="checkbox"/> Food & Nutrition |
| (Notify to turn on printers) | <input type="checkbox"/> Medical Records |
| <input type="checkbox"/> Facilities Management | |
| <input type="checkbox"/> Security | |

Equipment Checks - Return equipment to operating locations and plug them into a power source:

- ☐ Crash Cart – Mark off the days the unit was closed on Crash Cart Checklist as "Unit Closed"
- ☐ Unlock supplies and equipment.
- ☐ Nurse Locators
- ☐ Patient Charts
- ☐ Check the expiration date on food left in the refrigerator as applicable

Verify Patient PHI information is secured - Check the unit for the following:

- ☐ Check all drawers and cabinets to ensure there is no unsecured PHI or logs with patient information
- ☐ Patient census - discard in the Shred Bin
- ☐ SBAR and hand-off forms with patient information - discard in the Shred Bin
- ☐ TASK list - discard in the Shred Bin
- ☐ Check Physician's dictation room (including copier) for any PHI
- ☐ Check all printers for PHI
- ☐ Check all patient rooms for PHI
- ☐ Check all supply rooms for PHI

Telemetry boxes and lead wires:

- ☐ Count Telemetry Transmitters (boxes) and lead wires. # of Telemetry boxes = _____ # of Lead wires = _____
- ☐ Place new batteries in Telemetry boxes for assigned beds
- ☐ Store clean Telemetry boxes and lead wires in wire baskets above the sink near nurses' station

Cleaning Requirements:

- ☐ Notify Environmental services to clean unit as needed
- ☐ Verify each patient room is clean
- ☐ Turn on the lights and open doors of each patient room
- ☐ Turn on the lights in Physician Dictation Room

Turn on power on the following:

- ☐ Computer monitors
- ☐ Pharmacy fax machine
- ☐ Telemetry monitoring screens
- ☐ Copier and printer wait sufficient time for cued jobs to print and secure PHI
- ☐ Cancel forward on phones as if applicable, confirm telephones are working
- ☐ Open fire doors to unit
- ☐ Turn on the lights on the unit.

***Fax completed form to the Regulatory Compliance Specialist at 760-806-4645**

PATIENT CARE SERVICES

ISSUE DATE: 10/08 **SUBJECT:** Black Box Warnings, Drugs With

REVISION DATE: 12/09, 5/13, 07/17 **POLICY NUMBER:** ~~IV.I.1~~

Department Approval:	03/1711/21
Clinical Policies & Procedures Committee Approval:	05/1712/21
Nursing Leadership Executive Committee Approval:	05/1701/22
Medical Staff Department/Division Approval:	n/a
Pharmacy & Therapeutics Committee Approval:	05/1702/22
Medical Executive Committee Approval:	06/1703/22
Administration Approval:	04/22
Professional Affairs Committee:	07/17 n/a
Board of Directors Approval:	07/17

A. PURPOSE:

1. Tri-City Healthcare District (TCHD), as part of their selection process for admission of a medication to the formulary, will determine if the medication contains a Food and Drug Administration (FDA) "Black Box Warning" and determine the appropriate action and/or limitation required for the use of the drug within the organization.

B. DEFINITIONS:

1. Black Box Warnings are specific product summaries of potential safety precautions and warnings of serious adverse reactions including potentially life-threatening effects. These warnings and information are required by the FDA. Black Box Warnings can be found in the package insert. The FDA can require a pharmaceutical company to label a prescription medication with a Black Box Warning, the strongest warning the FDA can require.

C. POLICY:

1. The Pharmacy Department will develop guidelines and protocols that are approved by the Pharmacy & Therapeutics (P&T) Committee to ensure medications are controlled and distributed properly.
2. TCHD will develop a system for medications with Black Box Warnings including but not limited to the following:
 - a. Checklist or written guidelines for use
 - b. Pre-printed orders/electronic orders
 - c. Dose limitations
 - d. Packaging adjustments (warning labels, special packaging)
 - e. A system of double checks in prescribing, dispensing and administration processes
3. All adverse events associated with Box warning medications will be reported separately to the P&T Committee. The P&T Committee will review, trend and take appropriate action to minimize any future adverse events with Black Box Warning medications.

D. PROCEDURE:

1. Identification
 - a. Medications approved for use in the hospital will be annually reviewed for Black Box Warnings.
 - b. TCHD shall maintain a list of the medications with Black Box Warnings that are most pertinent to the hospital patient population.

- c. Computer systems will alert the physician/pharmacist at the time of order entry if a drug contains a Black Box Warning with special precautions.
 - d. Labeling of dispensed products will notify the end user of Box warnings with special precautions.
2. Guidelines, Protocols and Limitations
- a. From a list of formulary drugs with Black Box Warnings, the P&T Committee will establish a subset of high priority drugs for focused attention. Analysis will be based on the severity risk level of the Black Box Warning, adverse reactions history and frequency of utilization.
 - b. The P&T Committee will assess the need to develop actions, guidelines or protocols for appropriate use of these medications. These guidelines and/or protocols will address appropriate actions to be considered by physicians, nurses and pharmacists in each medication management sub process. Actions may include:
 - i. Prescribing
 - 1) Maximum/Minimum dosing range
 - 2) Evidence based justification for use of the medication
 - 3) Preprinted or special physician order forms or electronic orders
 - a) Dose limitations
 - b) Dosing orders written with dosing criteria/calculations (example: mg/m²) in addition to final dose
 - 4) Written and/or approved by designated medical staff members competent in the use of the medication
 - 5) Appropriate monitoring orders
 - a) Laboratory test
 - b) Vital signs
 - ii. Dispensing
 - 1) Warning label identifying "Black Box warning alert" in dispensing area
 - 2) Drug/drug interaction review
 - 3) Pharmacist documented intervention with prescribing physician to confirm order and/or clinical discussion
 - 4) Auxiliary labeling
 - 5) Special packaging
 - 6) Special transport procedures
 - iii. Administration
 - 1) Warnings appropriate during administration of the drug
 - 2) Education of administering personnel regarding detection and monitoring of an adverse event
 - iv. Monitoring
 - 1) Monitoring parameters
 - 2) Reporting mechanisms for adverse events
 - 3) Specific action to be taken if an adverse event occurs
 - v. Education
 - 1) Information on any new Black Box Warnings and action needed is updated in the computer, Pyxis systems and taken before the P&T committee to approve specific actions, guidelines or protocols.
 - vi. Non-formulary Drugs with Black Box Warnings
 - 1) TCHD policy for non-formulary requests will be followed.
 - 2) All orders for non-formulary medications will be reviewed for Black Box warnings.
 - vii. Patient's Own Medications
 - 1) **See Patient Care Services Policy: Medications Brought In By the Patient** ~~TCHD policy for patient's own medication will be followed.~~

- 2) As part of the review process all drugs will be reviewed for Black Box warnings.
- viii. Non-formulary Samples
 - 1) Sample medications will not be permitted.
 - 2) TCHD Sample Policy will be followed.
- 3. Nursing shall review any additional interventions per alert to Black Box Warning drugs via Pyxis and/or the Cerner eMAR prior to administration. Additional information may be obtained, but is not limited to, the following:
 - a. Cerner reference text
 - b. Micromedex
 - c. TCHD Drug Formulary
 - d. Pharmacist

E. **RELATED DOCUMENTS:**

- 1. Black Box Warning List
- 4-2. **Patient Care Services Policy: Medications Brought In By the Patient**

F. **REFERENCES:**

- 1. The Joint Commission Standard MM.01.01.03; MM.02.01.01
- 2. Healthcare Facilities Accreditation Program (HFAP) 25.01.19; 25.01.11
- 3. Centers for Medicare and Medicaid Services CMS Interpretation Guidelines CoP §482.25(a)(1)
- 4. Hospital Formulary System Policy

Formulary Agents With Black Box Warnings

Drug Name	Black Box Warning
Abacavir	Serious hypersensitivity reactions, lactic acidosis, and severe hepatomegaly with steatosis (including fatal cases) have been reported. Risk for experiencing a hypersensitivity reaction to abacavir is increased in patients carrying the HLA-B*5701 allele. Abacavir is contraindicated in patients with a prior hypersensitivity reaction to abacavir and in HLA-B*5701-positive patients. Screening for the HLA-B*5701 allele is required prior to abacavir initiation and when reinitiating therapy in patients with an unknown HLA-B*5701 status who have previously tolerated abacavir. Discontinue abacavir and do not restart if a hypersensitivity reaction is suspected or cannot be ruled out. Discontinue abacavir if lactic acidosis or pronounced hepatotoxicity are suspected
Acetaminophen Injection	Prevent acetaminophen injection dosing errors, which may result in accidental overdose and death, by confirming that doses in milligrams (mg) are not confused with doses in milliliters (mL); that patients under 50 kg receive weight-based doses; that infusion pumps are programmed correctly; and that the total dose of acetaminophen from all routes and from all sources does not exceed daily limits. Life-threatening cases of acute hepatic failure leading to liver transplant or death have been linked with acetaminophen use. In most cases of hepatic injury, acetaminophen doses exceeded maximum daily limits and often involved the use of more than 1 acetaminophen-containing product
Aldesleukin (Proleukin)	<p>Therapy with aldesleukin should be restricted to patients with normal cardiac and pulmonary functions as defined by thallium stress testing and formal pulmonary function testing. Extreme caution should be used in patients with a normal thallium stress test and a normal pulmonary function test who have a history of cardiac or pulmonary disease.</p> <p>Aldesleukin should be administered in a hospital setting under the supervision of a qualified physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.</p> <p>Aldesleukin administration has been associated with capillary leak syndrome (CLS) which is characterized by a loss of vascular tone and extravasation of plasma proteins and fluid into the extravascular space. CLS results in hypotension and reduced organ perfusion which may be severe and can result in death. CLS may be associated with cardiac arrhythmias (supraventricular and ventricular), angina, myocardial infarction, respiratory insufficiency requiring intubation, gastrointestinal bleeding or infarction, renal insufficiency, edema, and mental status changes.</p> <p>Aldesleukin treatment is associated with impaired neutrophil function (reduced chemotaxis) and with an increased risk of disseminated infection, including sepsis and bacterial endocarditis. Consequently, preexisting bacterial infections should be adequately treated prior to initiation of aldesleukin therapy. Patients with indwelling central lines are particularly at risk for infection with gram positive microorganisms. Antibiotic prophylaxis with oxacillin, nafcillin, ciprofloxacin, or vancomycin has been associated with a reduced incidence of staphylococcal infections.</p> <p>Aldesleukin administration should be withheld in patients developing moderate to severe lethargy or somnolence; continued administration may result in coma</p>
Aliskiren (Tekturna)	<p>When pregnancy is detected, discontinue Tekturna as soon as possible.</p> <p>Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus</p>
Alprostadil Intravenous	Apnea, which generally occurs during the first hour of infusion and most often in neonates weighing less than 2 kg at birth, develops in approximately 10% to 12% of neonates with congenital heart defects treated with Prostin VR Pediatric(R) IV solution. Monitor respiratory status throughout treatment and use only where ventilatory assistance is immediately available
Amiloride (Midamor)	Like other potassium-conserving agents, amiloride may cause hyperkalemia (serum potassium levels greater than 5.5 mEq per liter) which, if uncorrected, is potentially fatal. Hyperkalemia occurs commonly (about 10%) when amiloride is used without a kaliuretic diuretic. This incidence is greater in patients with renal impairment, diabetes mellitus (with or without recognized renal insufficiency), and in the elderly. When amiloride hydrochloride is used concomitantly with a thiazide diuretic in patients without these complications, the risk of hyperkalemia is reduced to about 1 to 2 percent. It is thus essential to monitor serum potassium levels carefully in any patient receiving amiloride, particularly when it is first introduced, at the time of diuretic dosage adjustments, and during any illness that could affect renal function
Tobramycin Injection	Therapy has been associated with potential neurotoxicity, ototoxicity, and nephrotoxicity. Patients with impaired renal function, advanced age, dehydration, and those who receive high dosage or prolonged therapy are at an increased risk of toxicity. Monitor renal and auditory function during therapy and discontinue therapy or adjust dose if there is evidence of ototoxicity or nephrotoxicity. Aminoglycoside-induced ototoxicity is usually irreversible. Serum concentrations of aminoglycosides should be monitored periodically to assure adequate levels and to avoid potentially toxic levels. Concurrent use of other potentially neurotoxic or nephrotoxic agents, or potent diuretics should be avoided. Tobramycin should be used with caution in premature and neonatal infants because of their renal immaturity and the resulting prolongation of serum half-life of the drug. Aminoglycosides can cause fetal harm when administered to a pregnant woman
Amiodarone (Cordarone)	<p>Cordarone is intended for use only in patients with the indicated life-threatening arrhythmias because its use is accompanied by substantial toxicity.</p> <p>Cordarone has several potentially fatal toxicities, the most important of which is pulmonary toxicity (hypersensitivity pneumonitis or interstitial/alveolar pneumonitis) that has resulted in clinically manifest disease at rates as high as 10 to 17% in some series of patients with ventricular arrhythmias given doses around 400 mg/day, and as abnormal diffusion capacity without symptoms in a much higher percentage of patients. Pulmonary toxicity has been fatal about 10% of the time. Liver injury is common with Cordarone, but is usually mild and evidenced only by abnormal liver enzymes. Overt liver disease can occur, however, and has been fatal in a few cases. Like other antiarrhythmics, Cordarone can exacerbate the arrhythmia, e.g., by making the arrhythmia less well tolerated or more difficult to reverse. This has occurred in 2 to 5% of patients in various series, and significant heart block or sinus bradycardia has been seen in 2 to 5%. All of these events should be manageable in the proper clinical</p>

Drug Name	Black Box Warning
	<p>setting in most cases. Although the frequency of such proarrhythmic events does not appear greater with Cordarone than with many other agents used in this population, the effects are prolonged when they occur.</p> <p>Even in patients at high risk of arrhythmic death, in whom the toxicity of Cordarone is an acceptable risk, Cordarone poses major management problems that could be life-threatening in a population at risk of sudden death, so that every effort should be made to utilize alternative agents first.</p> <p>The difficulty of using Cordarone effectively and safely itself poses a significant risk to patients. Patients with the indicated arrhythmias must be hospitalized while the loading dose of Cordarone is given, and a response generally requires at least one week, usually two or more. Because absorption and elimination are variable, maintenance-dose selection is difficult, and it is not unusual to require dosage decrease or discontinuation of treatment. In a retrospective survey of 192 patients with ventricular tachyarrhythmias, 84 required dose reduction and 18 required at least temporary discontinuation because of adverse effects, and several series have reported 15 to 20% overall frequencies of discontinuation due to adverse reactions. The time at which a previously controlled life-threatening arrhythmia will recur after discontinuation or dose adjustment is unpredictable, ranging from weeks to months. The patient is obviously at great risk during this time and may need prolonged hospitalization. Attempts to substitute other antiarrhythmic agents when Cordarone must be stopped will be made difficult by the gradually, but unpredictably, changing amiodarone body burden. A similar problem exists when Cordarone is not effective; it still poses the risk of an interaction with whatever subsequent treatment is tried.</p>
Adderall XR	Amphetamines have a high potential for abuse and administration for prolonged periods of time may lead to drug dependence. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse reactions
Amphotericin B	Use primarily for the treatment of patients with progressive and potentially life-threatening fungal infections. It should not be used to treat noninvasive forms of fungal disease such as oral thrush, vaginal candidiasis and esophageal candidiasis in patients with normal neutrophil counts. Amphotericin B intravenous should not be given at doses greater than 1.5 mg/kg. Exercise caution to prevent inadvertent overdose, which can result in potentially fatal cardiac or cardiopulmonary arrest. Verify the product name and dosage if dose exceeds 1.5 mg/kg
Valsartan	When pregnancy is detected, discontinue valsartan as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus
Duloxetine	Antidepressants increased the risk of suicidal thinking and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a reduction in risk with antidepressant use in patients aged 65 or older. In patients of all ages who are started on antidepressant therapy monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber
Aripiprazole	<p>Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death; aripiprazole extended-release suspension for IM injection is not approved for the treatment of patients with dementia-related psychosis</p> <p>Aripiprazole is not indicated for treatment of dementia-related psychosis due to an increased risk of death seen in the elderly. Increased risk of suicidal thoughts and behavior with antidepressant use in children, adolescents, and young adults under the age of 24 years. Closely monitor patients of all ages for emerging suicidal thoughts and behaviors</p>
Haloperidol	Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Although the causes of death in clinical trials were varied, most of the deaths appeared to be either cardiovascular (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. Observational studies suggest that antipsychotic drugs may increase mortality. It is unclear from these studies to what extent the mortality findings may be attributed to the antipsychotic drug as opposed to patient characteristics. Haloperidol is not approved for the treatment of patients with dementia-related psychosis
Apixaban	Premature discontinuation of apixaban or any oral anticoagulant increases the risk of thrombotic events. Consider an alternative anticoagulant if apixaban treatment is discontinued for any reason other than pathological bleeding or treatment completion. In patients undergoing neuraxial anesthesia or spinal puncture, epidural or spinal hematoma risk is increased and could result in long-term or permanent paralysis. The optimal timing between dosing apixaban and neuraxial procedures is unknown. Monitor patients for signs and symptoms of neurologic impairment and treat urgently. Consider the benefits and risks of neuraxial intervention in patients who are or need to be anticoagulated
Arsenic Trioxide	<p>Acute Promyelocytic Leukemia (APL) differentiation syndrome, cardiac conduction abnormalities, and electrolyte monitoring</p> <p>APL Differentiation Syndrome: Patients with APL treated with arsenic trioxide have experienced symptoms similar to a syndrome called retinoic-acid-APL or APL differentiation syndrome, characterized by fever, dyspnea, weight gain, pulmonary infiltrates and pleural or pericardial effusions, with or without leukocytosis. This syndrome can be fatal. High-dose steroids have been administered at the first suspicion of the APL differentiation syndrome and appear to mitigate signs and symptoms. At the first signs that could suggest the syndrome (unexplained fever, dyspnea and/or weight gain, abnormal chest auscultatory findings or radiographic abnormalities), immediately initiate high-dose steroids (dexamethasone 10 mg intravenously twice daily), irrespective of the leukocyte count, and continue for at least 3 days or longer until signs and symptoms have abated. The majority of patients do not require arsenic trioxide therapy during treatment of the APL differentiation syndrome.</p> <p>Cardiac Conduction Abnormalities: Before initiating therapy, perform a 12-lead ECG, assess serum electrolytes and creatinine, correct preexisting electrolyte abnormalities, and consider discontinuing drugs known to prolong QT interval. Arsenic trioxide can cause QT interval prolongation and complete atrioventricular block. QT prolongation can lead to torsades de pointes-type ventricular arrhythmia, which can be fatal. The risk of torsades de pointes is related to the extent of QT prolongation, concomitant administration of QT prolonging drugs, a history of torsades de pointes, preexisting QT prolongation, congestive heart failure, administration of potassium-wasting diuretics, or other conditions that result in hypokalemia or hypomagnesemia. One patient (also receiving amphotericin B) had torsades de pointes during</p>

Drug Name	Black Box Warning
	induction therapy for relapsed APL with arsenic trioxide
Atomoxetine	Atomoxetine increased the risk of suicidal ideation in short-term studies in children or adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD). Anyone considering the use of atomoxetine in a child or adolescent must balance this risk with the clinical need. Comorbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behavior. Patients who are started on therapy should be monitored closely for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Atomoxetine is approved for ADHD in pediatric and adult patients. Atomoxetine is not approved for major depressive disorder. Pooled analyses of short-term (6 to 18 weeks) placebo-controlled trials of atomoxetine in children and adolescents (a total of 12 trials involving over 2200 patients, including 11 trials in ADHD and 1 trial in enuresis) have revealed a greater risk of suicidal ideation early during treatment in those receiving atomoxetine compared to placebo. The average risk of suicidal ideation in patients receiving atomoxetine was 0.4% (5/1357 patients), compared to none in placebo-treated patients (851 patients). No suicides occurred in these trials
Azathioprine (Imuran)	Chronic immunosuppression with azathioprine, a purine antimetabolite, increases risk of malignancy in humans. Reports of malignancy include post-transplant lymphoma and hepatosplenic T-cell lymphoma (HSTCL) in patients with inflammatory bowel disease. Physicians using this drug should be very familiar with this risk as well as with the mutagenic potential to both men and women and with possible hematologic toxicities. Physicians should inform patients of the risk of malignancy with azathioprine
Ativan Lorazepam	Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve use where alternative treatments are inadequate. Limit the dosage and duration, and monitor signs and symptoms
Bleomycin	Pulmonary fibrosis is the most severe toxicity for bleomycin and its most frequent presentation is pneumonitis occasionally progressing to pulmonary fibrosis. Its occurrence is higher in elderly patients and in those receiving greater than 400 units total dose, but pulmonary toxicity has been observed in young patients and those treated with low doses. A severe idiosyncratic reaction consisting of hypotension, mental confusion, fever, chills, and wheezing has been reported in lymphoma patients treated with bleomycin
Botox	The effects of onabotulinumtoxin A and all botulinum toxin products may spread from the area of injection to produce symptoms hours to weeks after injection consistent with botulinum toxin effects. Swallowing and breathing difficulties can be life threatening, and there have been reports of death. Children treated for spasticity likely have the greatest risk, but symptoms can also occur in adults. Cases of spread of effect have occurred at doses comparable to those used to treat cervical dystonia and upper limb spasticity and at lower doses
Bupivacaine	The 0.75% concentration of bupivacaine injection is not recommended for obstetrical anesthesia. Cardiac arrest with difficult resuscitation or death during use of bupivacaine for epidural anesthesia in obstetrical patients has been reported. The 0.75% concentration should be reserved for surgical procedures where a high degree of muscle relaxation and prolonged effect are necessary
Buprenorphine buccal film	Buprenorphine has the potential for addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing, and monitor for development of respiratory depression and sedation of these behaviors or conditions. Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. Chewing, swallowing, snorting, or injecting buprenorphine extracted from the buccal film will result in uncontrolled delivery which may lead to overdose and death. Accidental exposure to buprenorphine, especially in children, can result in fatal overdose of buprenorphine. Prolonged use of buprenorphine during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available. Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for patients with inadequate alternative treatment options. Limit dosages and durations to the minimum required and follow patients for signs and symptoms
Bupropion	There is an increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants. Monitor for worsening and emergence of suicidal thoughts and behaviors. Serious neuropsychiatric events have been reported in patients taking buPROPion for smoking cessation. Observe all patients for neuropsychiatric effects, even if they are not using buPROPion for smoking cessation
Busulfan	Do not use oral busulfan unless a diagnosis of chronic myelogenous leukemia (CML) has been adequately established and the responsible health care provider is knowledgeable in assessing response to chemotherapy. Busulfan is a potent cytotoxic drug that causes severe and prolonged myelosuppression at the recommended dosage. Reduce or discontinue the dosage of oral busulfan immediately at the first sign of any unusual depression of bone marrow function as reflected by an abnormal decrease in any of the formed elements of the blood. Perform a bone marrow examination if the bone marrow status is uncertain. Hematopoietic progenitor cell transplantation is required to prevent potentially fatal complications from prolonged myelosuppression due to IV busulfan.
Cabazitaxel	Neutropenic deaths have been reported. In order to monitor the occurrence of neutropenia, frequent blood cell counts should be performed on all patients receiving cabazitaxel. Cabazitaxel is contraindicated in patients with neutrophil counts of 1500 cells/mm ³ or less. Severe hypersensitivity reactions can occur and may include generalized rash/erythema, hypotension and bronchospasm. Severe hypersensitivity reactions require immediate discontinuation of the cabazitaxel infusion and administration of appropriate therapy. Patients should receive premedication. Cabazitaxel is contraindicated in patients who have a history of severe hypersensitivity reactions to cabazitaxel or to drugs formulated with polysorbate 80
Capecitabine	Patients receiving concomitant capecitabine and oral coumarin-derivative anticoagulant therapy should have their anticoagulant response (INR or prothrombin time) monitored frequently in order to adjust the anticoagulant dose accordingly. A clinically important capecitabine-warfarin drug interaction was demonstrated in a clinical pharmacology trial. Altered coagulation parameters and/or bleeding, including death, have been reported in patients taking capecitabine concomitantly with coumarin-

Drug Name	Black Box Warning
	derivative anticoagulants such as warfarin or phenprocoumon. Postmarketing reports have shown clinically significant increases in prothrombin time (PT) and INR in patients who were stabilized on anticoagulants at the time capecitabine was introduced. These events occurred within several days and up to several months after initiating capecitabine therapy and, in a few cases, within 1 month after stopping capecitabine. Age greater than 60 and a diagnosis of cancer independently predispose patients to an increased risk of coagulopathy
Capreomycin	Use capreomycin in patients with renal insufficiency or preexisting auditory impairment with great caution, and the risk of additional auditory impairment or renal injury should be weighed against the benefits to be derived from therapy. Simultaneous administration of other parenteral antituberculosis agents which have similar and sometimes irreversible toxic effects, particularly on auditory and renal function, is not recommended. Use with nonantituberculosis drugs having ototoxic or nephrotoxic potential should be undertaken only with great caution. The safety of capreomycin in pregnancy and in pediatric patients has not been established
Carbamazepine	<p>Serious Dermatologic Reactions and HLA-B*1502 Allele: Serious and sometimes fatal dermatologic reactions, including toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS), have been reported during treatment with carbamazepine. These syndromes may be accompanied by mucous membrane ulcers, fever, or painful rash. These reactions are estimated to occur in 1 to 6 per 10,000 new users in countries with mainly Caucasian populations, but the risk in some Asian countries is estimated to be about 10 times higher. There is a strong association between the risk of developing SJS/TEN and the presence of HLA-B*1502, an inherited allelic variant of the HLA-B gene. Patients with ancestry in genetically at-risk populations should be screened for the presences of HLA-B*1502 prior to initiating treatment with carbamazepine. Patients testing positive for the allele should not be treated with carbamazepine unless the benefit clearly outweighs the risk. Discontinue if you suspect that the patient has a serious dermatologic reaction.</p> <p>Aplastic Anemia and Agranulocytosis: Aplastic anemia and agranulocytosis have been reported in association with the use of carbamazepine. Data from a population-based case-control study demonstrate that the risk of developing these reactions is 5 to 8 times greater than in the general population. However, the overall risk of these reactions in the untreated general population is low, approximately six patients per one million population per year for agranulocytosis and two patients per one million population per year for aplastic anemia.</p> <p>Although reports of transient or persistent decreased platelet or white blood cell counts are not uncommon in association with the use of carbamazepine, data are not available to estimate accurately their incidence or outcome. However, the vast majority of the cases of leukopenia have not progressed to the more serious conditions of aplastic anemia or agranulocytosis.</p> <p>Because of the very low incidence of agranulocytosis and aplastic anemia, the vast majority of minor hematologic changes observed in monitoring of patients on carbamazepine are unlikely to signal the occurrence of either abnormality. Nonetheless, complete pretreatment hematological testing should be obtained as a baseline. If a patient in the course of treatment exhibits low or decreased white blood cell or platelet counts, the patient should be monitored closely. Discontinuation of the drug should be considered if any evidence of significant bone marrow depression develops</p>
Carbidopa	Bone marrow suppression with carboplatin is dose-related and may be severe, resulting in infection and/or bleeding. Anemia may be cumulative and may require transfusion support. Vomiting is another frequent drug-related side effect. Anaphylactic-like reactions to carboplatin have been reported and may occur within minutes of carboplatin administration
Carmustine	<p>Carmustine for injection should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents.</p> <p>Bone marrow suppression, notably thrombocytopenia and leukopenia, which may contribute to bleeding and overwhelming infections in an already compromised patient, is the most common and severe of the toxic effects of carmustine. Since the major toxicity is delayed bone marrow suppression, blood counts should be monitored weekly for at least 6 weeks after a dose. At the recommended dosage, courses of carmustine should not be given more frequently than every 6 weeks. The bone marrow toxicity of carmustine is cumulative and therefore dosage adjustment must be considered on the basis of nadir blood counts from prior dose.</p> <p>Pulmonary toxicity from carmustine appears to be dose related. Patients receiving greater than 1400 mg/m² cumulative dose are at significantly higher risk than those receiving less. Delayed pulmonary toxicity can occur years after treatment, and can result in death, particularly in patients treated in childhood</p>
Certalizumab	<p>Patients treated with certolizumab pegol are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Certolizumab pegol should be discontinued if a patient develops a serious infection or sepsis.</p> <p>Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor blockers, of which certolizumab pegol is a member. Certolizumab pegol is not indicated for use in pediatric patients</p>
Cetuximab	<p>Infusion reactions: Serious infusion reactions occurred with the administration of cetuximab in approximately 3% of patients in clinical trials, with fatal outcome reported in less than 1 in 1000. Immediately interrupt and discontinue cetuximab infusion for serious infusion reactions.</p> <p>Cardiopulmonary arrest: Cardiopulmonary arrest and/or sudden death occurred in 2% of patients with squamous cell carcinoma of the head and neck treated with cetuximab and radiation therapy in Study 1 and in 3% of patients with squamous cell carcinoma of the head and neck treated with European Union (EU)-approved cetuximab in combination with platinum-based therapy with 5-fluorouracil in Study 2. Closely monitor serum electrolytes, including serum magnesium, potassium, and calcium, during and after cetuximab administration</p>
Chlorambucil	Chlorambucil can severely suppress bone marrow function. Chlorambucil is a carcinogen in humans. Chlorambucil is probably mutagenic and teratogenic in humans.

Drug Name	Black Box Warning
	Chlorambucil produces human infertility
Chloramphenicol	Serious and fatal blood dyscrasias (aplastic anemia, hypoplastic anemia, thrombocytopenia, and granulocytopenia) are known to occur after the administration of chloramphenicol. In addition, there have been reports of aplastic anemia attributed to chloramphenicol which later terminated in leukemia. Blood dyscrasias have occurred after both short-term and prolonged therapy with this drug. Chloramphenicol must not be used when less potentially dangerous agents will be effective. It must not be used in the treatment of trivial infections or where it is not indicated, as in colds, influenza, infections of the throat; or as a prophylactic agent to prevent bacterial infections
Cilostazol	Contraindicated in patients with heart failure of any severity. Cilostazol and several of its metabolites are inhibitors of phosphodiesterase III. Several drugs with the pharmacologic effect have caused decreased survival compared to placebo patients with class III-IV heart failure
Cisplatin	Administer under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents. Cumulative renal toxicity associated with cisplatin is severe and other major dose-related toxicities include myelosuppression, nausea, and vomiting. Ototoxicity, which may be more pronounced in children, is significant. Anaphylactic-like reactions to cisplatin such as facial edema, bronchoconstriction, tachycardia, and hypotension have been reported and may occur within minutes of cisplatin administration. Exercise caution to prevent inadvertent cisplatin overdose as doses greater than 100 mg/m(2)/cycle once every 3 to 4 weeks are rarely used. Avoid inadvertent cisplatin overdose due to confusion with carboplatin or prescribing practices that fail to differentiate daily doses from total dose per cycle
Cladribine	<p>Cladribine injection should be administered under the supervision of a qualified physician experienced in the use of antineoplastic therapy. Suppression of bone marrow function should be anticipated. This is usually reversible and appears to be dose dependent. Serious neurological toxicity (including irreversible paraparesis and quadriplegia) has been reported in patients who received cladribine injection by continuous infusion at high doses (4 to 9 times the recommended dose for hairy cell leukemia). Neurologic toxicity appears to demonstrate a dose relationship; however, severe neurological toxicity has been reported rarely following treatment with standard cladribine dosing regimens.</p> <p>Acute nephrotoxicity has been observed with high doses of cladribine (4 to 9 times the recommended dose for hairy cell leukemia), especially when given concomitantly with other nephrotoxic agents/therapies</p>
Clindamycin	<p>Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin hydrochloride, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of C. difficile.</p> <p>Because clindamycin hydrochloride therapy has been associated with severe colitis which may end fatally, it should be reserved for serious infections where less toxic antimicrobial agents are inappropriate. It should not be used in patients with nonbacterial infections such as most upper respiratory tract infections.</p>
Clopidogrel	Diminished antiplatelet effect in patients with two loss-of-function alleles of the CYP2C19 gene. The effectiveness of clopidogrel hydrogen sulfate results from its antiplatelet activity, which is dependent on its conversion to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19. Clopidogrel hydrogen sulfate at recommended doses forms less of the active metabolite and so has a reduced effect on platelet activity in patients who are homozygous for nonfunctional alleles of the CYP2C19 gene, (termed "CYP2C19 poor metabolizers"). Tests are available to identify patients who are CYP2C19 poor metabolizers. Consider use of another platelet P2Y12 inhibitor in patients identified as CYP2C19 poor metabolizers
Clozapine	<p>Clozapine treatment has caused severe neutropenia, defined as an absolute neutrophil count (ANC) less than 500/mcL. Severe neutropenia can lead to serious infection and death. Prior to initiating treatment with clozapine a baseline ANC must be at least 1500/mcL for the general population; and must be at least 1000/mcL for patients with documented Benign Ethnic Neutropenia (BEN). During treatment, patients must have regular ANC monitoring. Advise patients to immediately report symptoms consistent with severe neutropenia or infection (eg, fever, weakness, lethargy, or sore throat). Because of the risk of severe neutropenia, clozapine is available only through a restricted program under a Risk Evaluation Mitigation Strategy (REMS) called the Clozapine REMS Program .</p> <p>Orthostatic hypotension, bradycardia, syncope, and cardiac arrest have occurred with clozapine treatment. The risk is highest during the initial titration period, particularly with rapid dose escalation. These reactions can occur with the first dose, with doses as low as 12.5 mg per day. Initiate treatment at 12.5 mg once or twice daily; titrate slowly; and use divided dosages. Use clozapine cautiously in patients with cardiovascular or cerebrovascular disease or conditions predisposing to hypotension (eg, dehydration, use of antihypertensive medications).</p> <p>Seizures have occurred with clozapine treatment. The risk is dose-related. Initiate treatment at 12.5 mg, titrate gradually, and use divided dosing. Use caution when administering clozapine to patients with a history of seizures or other predisposing risk factors for seizure (CNS pathology, medications that lower the seizure threshold, alcohol abuse). Caution patients about engaging in any activity where sudden loss of consciousness could cause serious risk to themselves or others.</p> <p>Fatal myocarditis and cardiomyopathy have occurred with clozapine treatment. Discontinue clozapine and obtain a cardiac evaluation upon suspicion of these reactions. Generally, patients with clozapine-related myocarditis or cardiomyopathy should not be rechallenged with clozapine. Consider the possibility of myocarditis or cardiomyopathy if chest pain, tachycardia, palpitations, dyspnea, fever, flu-like symptoms, hypotension, or ECG changes occur.</p> <p>Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Clozapine is not approved for use in patients with dementia-related psychosis</p>
Codeine	Codeine sulfate has the potential for addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing, and monitor for development of these behaviors or conditions. Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. Accidental ingestion of codeine sulfate, especially in children, can result in a fatal overdose of codeine. Prolonged use of codeine during pregnancy can

Drug Name	Black Box Warning
	<p>result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available. Respiratory depression and death have occurred in children who received codeine following tonsillectomy and/or adenoidectomy and had evidence of being ultra-rapid metabolizers of codeine due to a CYP2D6 polymorphism. Use of CYP3A4 inducers, 3A4 inhibitors, or 2D6 inhibitors with codeine sulfate requires careful consideration of the effects on the parent drug, codeine, and the active metabolite, morphine. Concomitant use with benzodiazepines and other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for patients with inadequate alternative treatment options. Limit dosages and durations to the minimum required and follow patients for signs and symptoms of respiratory depression and</p>
Cyclosporine	<p>Only physicians experienced in management of systemic immunosuppressive therapy for the indicated disease should prescribe cycloSPORINE, modified. Increased susceptibility to infection and the possible development of lymphoma may result from immunosuppression. Hypertension and nephrotoxicity can occur at recommended dosages, and the risk increases with increasing dose and duration of cycloSPORINE therapy. Monitor blood levels and renal function to avoid toxicity. CycloSPORINE, modified (Neoral(R) or Gengraf(R)) and cycloSPORINE (Sandimmune(R)) are not bioequivalent and cannot be used interchangeably without physician supervision. Psoriasis patients previously treated with PUVA and to a lesser extent, methotrexate or other immunosuppressive agents, UV-B, coal tar, or radiation therapy, are at an increased risk of developing skin malignancies when taking cycloSPORINE</p>
Cytarabine, Liposomal	<p>Only physicians experienced in cancer chemotherapy should use Cytarabine Injection.</p> <p>For induction therapy, patients should be treated in a facility with laboratory and supportive resources sufficient to monitor drug tolerance and protect and maintain a patient compromised by drug toxicity. The main toxic effect of cytarabine is bone marrow suppression with leukopenia, thrombocytopenia, and anemia. Less serious toxicity includes nausea, vomiting, diarrhea and abdominal pain, oral ulceration, and hepatic dysfunction.</p> <p>The physician must judge possible benefit to the patient against known toxic effects of this drug in considering the advisability of therapy with Cytarabine Injection.</p>
Dabigatran	<p>PREMATURE DISCONTINUATION OF PRADAXA INCREASES THE RISK OF THROMBOTIC EVENTS: Premature discontinuation of any oral anticoagulant, including PRADAXA, increases the risk of thrombotic events. To reduce this risk, consider coverage with another anticoagulant if PRADAXA is discontinued for a reason other than pathological bleeding or completion of a course of therapy</p> <p>SPINAL/EPIDURAL HEMATOMA: Epidural or spinal hematomas may occur in patients treated with PRADAXA who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Monitor patients frequently for signs and symptoms of neurological impairment and if observed, treat urgently. Consider the benefits and risks before neuraxial intervention in patients who are or who need to be anticoagulated</p>
Dacarbazine	<p>Hemopoietic depression is the most common toxicity with dacarbazine for injection. Hepatic necrosis has also been reported. Studies have demonstrated this agent to have a carcinogenic and teratogenic effect when used in animals.</p>
Daclizumab	<p>Daclizumab can cause severe liver injury including life-threatening events, liver failure, and autoimmune hepatitis. In clinical trials, 1 patient died due to autoimmune hepatitis. Liver injury, including autoimmune hepatitis, can occur at any time during treatment with daclizumab, with cases reported up to 4 months after the last dose of daclizumab.</p> <p>Daclizumab is contraindicated in patients with preexisting hepatic disease or hepatic impairment. Prior to starting daclizumab, obtain serum transaminases (ALT and AST) and bilirubin levels. Test transaminase levels and total bilirubin monthly and assess before the next dose of daclizumab. Follow transaminase levels and total bilirubin monthly for 6 months after the last dose of daclizumab. In case of elevation in transaminases or total bilirubin, treatment interruption or discontinuation may be required.</p> <p>In addition to autoimmune hepatitis, immune-mediated disorders such as skin reactions, lymphadenopathy, and noninfectious colitis can occur in patients treated with daclizumab. Overall, serious immune-mediated conditions were observed in 5% of patients treated with daclizumab.</p> <p>If a patient develops a serious immune-mediated disorder, consider stopping daclizumab and refer the patient to a specialist to ensure comprehensive diagnostic evaluation and appropriate treatment. Some patients required systemic corticosteroids or other immunosuppressant treatment for autoimmune hepatitis or other immune-mediated disorders and continued this treatment after the last dose of daclizumab. Because of the risks of hepatic injury, including autoimmune hepatitis, and other immune-mediated disorders, daclizumab is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ZINBRYTA(TM) REMS Program</p>
Dactinomycin	<p>Dactinomycin for injection should be administered only under the supervision of a physician who is experienced in the use of cancer chemotherapeutic agents.</p> <p>This drug is highly toxic and both powder and solution must be handled and administered with care. Inhalation of dust or vapors and contact with skin or mucous membranes, especially those of the eyes, must be avoided. Avoid exposure during pregnancy. Due to the toxic properties of dactinomycin (e.g., corrosivity, carcinogenicity, mutagenicity, teratogenicity), special handling procedures should be reviewed prior to handling and followed diligently. Dactinomycin is extremely corrosive to soft tissue. If extravasation occurs during intravenous use, severe damage to soft tissues will occur. In at least one instance, this has led to contracture of the arms</p>
Danazol	<p>Use of danazol in pregnancy is contraindicated. A sensitive test capable of determining early pregnancy is recommended immediately prior to start of therapy. A nonhormonal method of contraception should be used during therapy. Androgenic effects on the female fetus exposed in utero have been reported. Thromboembolism, thrombotic and thrombophlebotic events have been reported. Experience with long-term therapy is limited. Physician should be alert to the possibility of potentially silent peliosis hepatis and benign hepatic adenoma with long-term use. Determine the lowest dose that will provide adequate protection. Attempt to decrease or withdraw</p>

Drug Name	Black Box Warning
	therapy if initiated during exacerbation of hereditary angioneurotic edema due to trauma, stress, or other cause. Several cases of benign intracranial hypertension have been reported. Screen for papilledema and advise to discontinue immediately if symptoms are present
Dantrolene	Potential for hepatotoxicity, and should not be used in conditions other than those recommended. Symptomatic hepatitis (fatal and non-fatal) has been reported at various dose levels of the drug. The incidence reported in patients taking up to 400 mg/day is much lower than in those taking doses of 800 mg or more per day. Even sporadic short courses of these higher dose levels within a treatment regimen markedly increased the risk of serious hepatic injury. Liver dysfunction as evidenced by blood chemical abnormalities alone (liver enzyme elevations) has been observed in patients exposed to Dantrium for varying periods of time. Overt hepatitis has occurred at varying intervals after initiation of therapy, but has been most frequently observed between the third and twelfth month of therapy. The risk of hepatic injury appears to be greater in females, in patients over 35 years of age, and in patients taking other medication(s) in addition to Dantrium (dantrolene sodium). Spontaneous reports suggest a higher proportion of hepatic events with fatal outcome in elderly patients receiving Dantrium. However, the majority of these cases were complicated with confounding factors such as intercurrent illnesses and/or concomitant potentially hepatotoxic medications. Dantrium should be used only in conjunction with appropriate monitoring of hepatic function including frequent determination of SGOT or SGPT. If no observable benefit is derived from the administration of Dantrium after a total of 45 days, therapy should be discontinued. The lowest possible effective dose for the individual patient should be prescribed.
Daunorubicin, liposomal	Cardiac function should be monitored regularly because of the potential risk for cardiac toxicity and congestive heart failure. Cardiac monitoring is advised, especially in those patients who received prior anthracyclines, have preexisting cardiac disease, or had prior radiotherapy encompassing the heart. Severe myelosuppression may occur and dosage should be reduced in patients with impaired hepatic function. A triad of back pain, flushing, and chest tightness has been reported that generally occurs during the first 5 minutes of the infusion, subsides with interruption of the infusion, and does not recur if the infusion is then resumed at a slower rate
Daunorubicin, Conventional	Must be given into a rapidly flowing IV infusion and must never be given by the IM or subQ route, as severe local tissue necrosis will occur if there is extravasation during administration. Myocardial toxicity manifested in its most severe form by potentially fatal congestive heart failure may occur either during therapy or months to years after termination of therapy. The incidence of myocardial toxicity increases after a total cumulative dose exceeding 400 to 550 mg/m ² in adults, 300 mg/m ² in children more than 2 years of age, or 10 mg/kg in children less than 2 years of age. Severe myelosuppression occurs when used in therapeutic doses; this may lead to infection or hemorrhage. Dosage should be reduced in patients with impaired hepatic or renal function
Disopyramide	<p>In the National Heart, Lung and Blood Institute's Cardiac Arrhythmia Suppression Trial (CAST), a long-term, multicenter, randomized, double-blind study in patients with asymptomatic non-life-threatening ventricular arrhythmias who had had a myocardial infarction more than 6 days but less than 2 years previously, an excessive mortality or nonfatal cardiac arrest rate (7.7%) was seen in patients treated with encainide or flecainide compared with that seen in patients assigned to carefully matched placebo-treated groups (3.0%). The average duration of treatment with encainide or flecainide in this study was 10 months</p> <p>The applicability of the CAST results to other populations (eg, those without recent myocardial infarction) is uncertain. Considering the known proarrhythmic properties of disopyramide phosphate and the lack of evidence of improved survival for any antiarrhythmic drug in patients without life-threatening arrhythmias, the use of disopyramide phosphate as well as other antiarrhythmic agents should be reserved for patients with life-threatening ventricular arrhythmias</p>
Disulfiram	Disulfiram should never be administered to a patient when he is in a state of alcohol intoxication, or without his full knowledge. The physician should instruct relatives accordingly
Docetaxel	<p>The incidence of treatment-related mortality associated with Docetaxel therapy is increased in patients with abnormal liver function, in patients receiving higher doses, and in patients with non-small cell lung carcinoma and a history of prior treatment with platinum-based chemotherapy who receive Docetaxel as a single agent at a dose of 100 mg/m².</p> <p>Docetaxel should not be given to patients with bilirubin greater than upper limit of normal (ULN), or to patients with AST and/or ALT greater than 1.5 x ULN concomitant with alkaline phosphatase greater than 2.5 x ULN. Patients with elevations of bilirubin or abnormalities of transaminase concurrent with alkaline phosphatase are at an increase risk for the development of grade 4 neutropenia, febrile neutropenia, infections, severe thrombocytopenia, severe stomatitis, severe skin toxicity, and toxic death. Patients with isolated elevations of transaminase greater than 1.5 x ULN also had a higher rate of febrile neutropenia grade 4 but did not have an increased risk of toxic death. Bilirubin, AST or ALT, and alkaline phosphatase values should be obtained prior to each cycle of Docetaxel therapy. Docetaxel therapy should not be given to patients with neutrophil counts of less than 1500 cells/mm³. In order to monitor the occurrence of neutropenia, which may be severe and result in infection, frequent blood counts should be performed on all patients receiving Docetaxel.</p> <p>Severe hypersensitivity reactions characterized by generalized rash/erythema, hypotension and/or bronchospasm, or very rarely fatal anaphylaxis, have been reported in patients who received a 3-day dexamethasone premedication. Hypersensitivity reactions require immediate discontinuation of the Docetaxel infusion and administration of appropriate therapy. Docetaxel must not be given to patients who have a history of severe hypersensitivity reactions to Docetaxel or to other drugs formulated with polysorbate 80.</p> <p>Severe fluid retention occurred in 6.5% (6/92) of patients despite use of a 3-day dexamethasone premedication regimen. It was characterized by one or more of the following events: poorly tolerated peripheral edema, generalized edema, pleural effusion, requiring urgent drainage, dyspnea at rest, cardiac tamponade, or pronounced abdominal distension (due to ascites)</p>
Dopamine	To prevent sloughing and necrosis in areas in which extravasation has taken place, the area should be infiltrated as soon as possible with 10 mL to 15 mL of saline solution containing from 5 mg to 10 mg of phentolamine mesylate for injection, an adrenergic blocking agent. A syringe with fine hypodermic needle should be used, and the solution liberally infiltrated throughout the ischemic area. Sympathetic blockade with phentolamine causes immediate and conspicuous local hyperemic changes if the area is infiltrated within 12 hours. Therefore, phentolamine should be given as soon as possible after the extravasation is noted

Drug Name	Black Box Warning
Doxorubicin Liposome Injection	<p>DOXOrubicin hydrochloride (HCl) liposome injection can cause myocardial damage, including congestive heart failure, as the total cumulative dose of DOXOrubicin HCl liposome injection approaches 550 mg/m². In a clinical study of 250 patients with advanced cancer who were treated with DOXOrubicin HCl liposome injection, the risk of cardiotoxicity was 11% when the cumulative anthracycline dose was between 450-550 mg/m². Prior use of other anthracyclines or anthracenediones should be included in calculations of total cumulative dosage. The risk of cardiomyopathy may be increased at lower cumulative doses in patients with prior mediastinal irradiation.</p> <p>Acute infusion-related reactions consisting of, but not limited to, flushing, shortness of breath, facial swelling, headache, chills, back pain, tightness in the chest or throat, and/or hypotension occurred in 11% of patients with solid tumors treated with DOXOrubicin hydrochloride liposome injection. Serious, life-threatening and fatal infusion reactions have been reported</p>
Doxorubicin Adriamycin	<p>Myocardial damage can occur with DOXOrubicin hydrochloride with incidences from 1% to 20% for cumulative doses from 300 to 500 mg/m² when DOXOrubicin hydrochloride is administered every 3 weeks. The risk of cardiomyopathy is further increased with concomitant cardiotoxic therapy. Assess left ventricular ejection fraction (LVEF) before and regularly during and after treatment with DOXOrubicin hydrochloride. Secondary acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) occur at a higher incidence in patients treated with anthracyclines, including DOXOrubicin hydrochloride. Extravasation of DOXOrubicin hydrochloride can result in severe local tissue injury and necrosis requiring wide excision and skin grafting. Immediately terminate the drug, and apply ice to the affected area. Severe myelosuppression resulting in serious infection, septic shock, requirement for transfusions, hospitalization, and death may occur</p>
Dronedarone	<p>Contraindicated in patients with symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure. MULTAQ doubles the risk of death in these patients.</p> <p>Contraindicated in patients in atrial fibrillation (AF) who will not or cannot be cardioverted into normal sinus rhythm. In patients with permanent AF, MULTAQ doubles the risk of death, stroke, and hospitalization for heart failure.</p>
Droperidol	<p>Cases of QT prolongation and/or torsade de pointes, some fatal, have been reported in patients receiving droperidol at doses at or below recommended doses. All patients should undergo a 12-lead ECG prior to administration of droperidol to determine if a prolonged QT interval (i.e., QTc greater than 440 msec for males or 450 msec for females) is present. Do not administer droperidol if there is a prolonged QT interval. Droperidol is contraindicated in patients with known or suspected QT prolongation, including patients with congenital long QT syndrome. Administer droperidol with extreme caution to patients who may be at risk for development of prolonged QT syndrome, are over 65 years old, abuse alcohol, or when used concomitantly with benzodiazepines, volatile anesthetics, and IV opiates. ECG monitoring should be performed prior to treatment and continued for 2 to 3 hours after completing treatment to monitor for arrhythmias.</p>
Edetate Disodium	<p>The use of this drug in any particular patient is recommended only when the severity of the clinical condition justifies the aggressive measures associated with this type of therapy</p>
Emtricitabine/ Tenofovir disoproxil	<p>Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues, including tenofovir disoproxil fumarate, a component of emtricitabine/tenofovir disoproxil fumarate. Not indicated for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy have not been established in patients co-infected with HBV and HIV-1. Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with HBV and HIV-1 and have discontinued emtricitabine/tenofovir; monitor hepatic function upon discontinuation of therapy. Emtricitabine/tenofovir disoproxil fumarate used for a PrEP indication is only for HIV-negative individuals; status confirmed immediately prior to initiating and periodically during use. Drug-resistant HIV-1 variants have been identified with use of emtricitabine/tenofovir disoproxil fumarate for a PrEP indication following undetected acute HIV-1 infection</p>
Epoetin alfa	<p>Erythropoiesis-stimulating agents (ESAs) increase the risks for death, myocardial infarction, stroke, and other serious cardiovascular events. In patients with chronic kidney disease (CKD), patients are at a greater risk for death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target Hb levels of 11 g/dL and above. No clinical trial has identified an Hb target level, ESA dose, or dosing strategy that does not increase these risks; use at lowest sufficient dose is recommended. In cancer patients with certain tumor types (ie, breast, non-small cell lung, head and neck, lymphoid, cervical), ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in some clinical studies. In patients with cancer, use the lowest ESA dose needed to avoid RBC transfusions and serious cardiovascular and thromboembolic reactions. Use ESAs only for treatment of anemia due to concomitant myelosuppressive chemotherapy, and discontinue following the completion of a chemotherapy course. Prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program (www.esa-apprise.com or 1-866-284-8089) to prescribe and/or dispense epoetin alfa to patients with cancer. Patients receiving myelosuppressive chemotherapy should not be treated with ESAs when the anticipated outcome is cure. Deep venous thrombosis prophylaxis should be considered when epoetin alfa is used preoperatively</p>
Estrogens with and without progestins	<p>Close clinical surveillance of all women taking estrogens is important. Estrogens increase the risk of endometrial cancer; monitor for abnormal vaginal bleeding. Estrogens with or without progestins should not be used to prevent cardiovascular disease or dementia. Increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis in postmenopausal women (50 to 79 years of age) have been reported. An increased risk of developing probable dementia in postmenopausal women 65 years of age or older has also been reported</p>
Fentanyl citrate	<p>TRANSMUCOSAL: Due to the risk of fatal respiratory depression, transmucosal fentanyl citrate is contraindicated in opioid non-tolerant patients and in management of acute or postoperative pain, including headache/migraines. Monitor for respiratory depression during treatment. Accidental ingestion of fentanyl can result in a fatal overdose, especially in children; keep out of reach of children. Use with CYP3A4 inhibitors or inducers may change fentanyl plasma levels resulting in a fatal overdose of fentanyl and monitoring is recommended. Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for patients with inadequate alternative treatment options, limit dosage and duration to the minimum required, and monitor for respiratory depression and sedation. When prescribing, do not convert patients on a mcg per mcg basis from any other fentanyl products. When dispensing, do not substitute with any other fentanyl products. Fentanyl is a Schedule II controlled substance with abuse liability similar to other opioid</p>

Drug Name	Black Box Warning
	<p>analgesics. Assess risk prior to initiation and monitor for signs of misuse, abuse, and addiction during treatment. Only available through a restricted program called the Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy (TIRF REMS) Access program. Outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors are required to enroll in the program. Prolonged use during pregnancy may result in neonatal opioid withdrawal syndrome. If prolonged use is required in a pregnant woman, advise patient of potential fetal risk and ensure appropriate treatment will be available</p> <p>INJECTION/TRANSDERMAL: Fentanyl citrate injection is a Schedule II controlled substance with abuse liability similar to other opioid analgesics. Assess risk prior to initiation and monitor for signs of misuse, abuse, and addiction during treatment. Serious, life-threatening, or fatal respiratory depression may occur. Monitor for respiratory depression, especially during initiation or following a dose increase. Use with CYP3A4 inhibitors or inducers may change fentanyl plasma levels resulting in a fatal overdose and monitoring is recommended. Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for patients with inadequate alternative treatment options, limit dosage and duration to the minimum required, and monitor for respiratory depression and sedation</p>
Flecainide	Excessive mortality or nonfatal cardiac arrest rate was seen in patients with asymptomatic non-life-threatening ventricular arrhythmias and with myocardial infarction for more than six days but less than two years previously who received flecainide, compared with patients assigned to a carefully matched placebo in the Cardiac Arrhythmia Suppression Trial (CAST). Consider the risks of Class IC agents (including flecainide) and the lack of evidence of improved survival, which is generally unacceptable in a patient without life-threatening ventricular arrhythmias, even if the patient is experiencing unpleasant, but not life-threatening, symptoms or signs. Flecainide is not recommended for use in patients with chronic atrial fibrillation. Case reports of ventricular proarrhythmic effects in patients treated with flecainide for atrial fibrillation/flutter have included increased premature ventricular contractions, ventricular tachycardia, ventricular fibrillation, and death
Floxuridine	All patients should be hospitalized for initiation of the first course of therapy with floxuridine because of the possibility of severe toxic reactions
Flucytosine	Use with extreme caution in patients with impaired renal function. Close monitoring of hematologic, renal, and hepatic status of all patients is essential
Fludarabine	<p>Fludarabine phosphate for injection should be administered under the supervision of a qualified physician experienced in the use of antineoplastic therapy. Fludarabine phosphate for injection can severely suppress bone marrow function. When used at high doses in dose-ranging studies in patients with acute leukemia, fludarabine phosphate for injection was associated with severe neurologic effects, including blindness, coma, and death. This severe central nervous system toxicity occurred in 36% of patients treated with doses approximately four times greater (96 mg/m²/day for 5 to 7 days) than the recommended dose. Similar severe central nervous system toxicity, including coma, seizures, agitation and confusion, has been reported in patients treated at doses in the range of the dose recommended for chronic lymphocytic leukemia.</p> <p>Instances of life-threatening and sometimes fatal autoimmune phenomena such as hemolytic anemia, autoimmune thrombocytopenia/thrombocytopenic purpura (ITP), Evan's syndrome, and acquired hemophilia have been reported to occur after one or more cycles of treatment with fludarabine phosphate for injection. Patients undergoing treatment with fludarabine phosphate for injection should be evaluated and closely monitored for hemolysis.</p> <p>In a clinical investigation using fludarabine phosphate for injection in combination with pentostatin (deoxycoformycin) for the treatment of refractory chronic lymphocytic leukemia (CLL), there was an unacceptably high incidence of fatal pulmonary toxicity. Therefore, the use of fludarabine phosphate for injection in combination with pentostatin is not recommended</p>
Flumazenil	The use of flumazenil has been associated with the occurrence of seizures. Seizures are most frequent in patients who have been on benzodiazepines for long-term sedation or in overdose cases where patients are showing signs of serious cyclic antidepressant overdose. Individualize the dosage of flumazenil and be prepared to manage seizures
Fluoroquinolone antibiotics	<p>Fluoroquinolones, including ciprofloxacin, are associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including tendinitis and tendon rupture, peripheral neuropathy, and CNS effects. Discontinue ciprofloxacin and avoid use of fluoroquinolones in patients with these serious adverse reactions. Reserve use of ciprofloxacin for patients with no alternative treatment options for an acute exacerbation of chronic bronchitis or acute sinusitis.</p> <p>Fluoroquinolones, including ciprofloxacin, may exacerbate muscle weakness in persons with myasthenia gravis. Avoid in patients with known history of myasthenia gravis</p>
Fluoxetine	Antidepressants increased the risk compared with placebo of suicidal thinking and behavior (suicidality) in short-term studies in children, adolescents, and young adults with major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of fluoxetine or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared with placebo in adults older than 24 years; there was a reduction in risk with antidepressants compared with placebo in adults 65 years and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Appropriately monitor and closely observe patients of all ages who are started on antidepressant therapy for clinical worsening, suicidality, or unusual changes in behavior. Advise families and caregivers of the need for close observation and communication with the prescribing health care provider. Fluoxetine is approved for use in children with MDD (aged 8 years and older) and obsessive-compulsive disorder (OCD; aged 7 years and older).
Flutamide	<p>There have been postmarketing reports of hospitalization and rarely death due to liver failure in patients taking flutamide. Evidence of hepatic injury included elevated serum transaminase levels, jaundice, hepatic encephalopathy and death related to acute hepatic failure. The hepatic injury was reversible after discontinuation of therapy in some patients. Approximately half of the reported cases occurred within the initial 3 months of treatment with flutamide.</p> <p>Serum transaminase levels should be measured prior to starting treatment with flutamide. Flutamide is not recommended in patients whose ALT values exceed twice the upper limit of normal. Serum transaminase levels should then be measured monthly for the first 4 months of therapy, and periodically thereafter. Liver function tests also</p>

Drug Name	Black Box Warning
	<p>should be obtained at the first signs and symptoms suggestive of liver dysfunction (eg, nausea, vomiting, abdominal pain, fatigue, anorexia, "flu-like" symptoms, hyperbilirubinuria, jaundice, right upper quadrant tenderness). If at any time, a patient has jaundice, or their ALT rises above 2 times the upper limit of normal, flutamide should be immediately discontinued with close follow-up of liver function tests until resolution.</p>
<p>Fluticasone/Salmeterol (Advair Diskus)</p>	<p>Long-acting beta₂-adrenergic agonists (LABA), such as salmeterol, one of the active ingredients in ADVAIR DISKUS, increase the risk of asthma-related death. A U.S. trial showed an increase in asthma-related deaths in subjects receiving salmeterol (13 deaths out of 13,176 subjects treated for 28 weeks on salmeterol versus 3 out of 13,179 subjects on placebo). Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients.</p> <p>When treating patients with asthma, only prescribe ADVAIR DISKUS for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid, or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and a LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue ADVAIR DISKUS) if possible without loss of asthma control and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use ADVAIR DISKUS for patients whose asthma is adequately controlled on low- or medium-dose inhaled corticosteroids</p>
<p>Fluvoxamine</p>	<p>Antidepressants increased the risk compared with placebo of suicidal thinking and behavior (suicidality) in short-term studies in children, adolescents, and young adults with major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of fluvoxamine in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared with placebo in adults older than 24 years; there was a reduction in risk with antidepressants compared with placebo in adults 65 years and older. Depression and certain other psychiatric disorders are associated with increases in the risk of suicide. Closely observe and appropriately monitor patients of all ages who are started on therapy for clinical worsening, suicidality, or unusual changes in behavior. Advise families and caregivers of the need for close observation and communication with the health care provider. Fluvoxamine immediate release is not approved for use in pediatric patients, except for patients with obsessive-compulsive disorder (OCD). Fluvoxamine extended release (ER) has not been evaluated in pediatric patients.</p>
<p>Fondaparinux</p>	<p>Epidural or spinal hematomas may occur in patients who are anticoagulated with low molecular weight heparins, heparinoids, or fondaparinux and are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include use of indwelling epidural catheters; concomitant use of other drugs that affect hemostasis, such as nonsteroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, or other anticoagulants; a history of traumatic or repeated epidural or spinal puncture; or a history of spinal deformity or spinal surgery. Optimal timing between the administration of fondaparinux and neuraxial procedures is not known.</p> <p>Monitor patients frequently for signs and symptoms of neurologic impairment. If neurologic compromise is noted, urgent treatment is necessary. Consider the benefit and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis</p>
<p>Formoterol</p>	<p>Long-acting beta₂-adrenergic agonists increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta₂-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of long-acting beta₂-adrenergic agonists. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from long-acting beta₂-adrenergic agonists.</p> <p>Because of this risk, use of formoterol inhalation powder for the treatment of asthma without a concomitant long-term asthma control medication, such as an inhaled corticosteroid, is contraindicated. Use formoterol only as additional therapy for patients with asthma who are currently taking but are inadequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (eg, discontinue formoterol) if possible without loss of asthma control, and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use formoterol for patients whose asthma is adequately controlled on low- or medium-dose inhaled corticosteroids. The safety and efficacy of formoterol inhalation solution in patients with asthma have not been established.</p>
<p>Foscarnet</p>	<p>Renal impairment is the major toxicity of foscarnet. Frequent monitoring of serum creatinine, with dose adjustment for changes in renal function, and adequate hydration with administration of foscarnet is imperative.</p> <p>Seizures, related to alterations in plasma minerals and electrolytes, have been associated with foscarnet treatment. Therefore, patients must be carefully monitored for such changes and their potential sequelae. Mineral and electrolyte supplementation may be required.</p> <p>Foscarnet is indicated for use only in immunocompromised patients with cytomegalovirus (CMV) retinitis and mucocutaneous acyclovir-resistant herpes simplex virus (HSV) infections.</p>
<p>Fosphenytoin</p>	<p>The rate of fosphenytoin intravenous (IV) administration should not exceed 150 mg phenytoin sodium equivalent (PE)/min because of the risk of severe hypotension and cardiac arrhythmias. Careful cardiac monitoring is needed during and after administering fosphenytoin IV. Although the risk of cardiovascular toxicity increases with infusion rates above the recommended infusion rate, these events have also been reported at or below the recommended infusion rate. Reduction in rate of administration or discontinuation of dosing may be needed.</p>

Drug Name	Black Box Warning
Gadolinium based contrast agents	<p>Gadolinium-based contrast agents increase the risk for nephrogenic systemic fibrosis (NSF) among patients with impaired elimination of the drugs. Avoid use of gadolinium-based contrast agents in these patients unless the diagnostic information is essential and not available with noncontrasted magnetic resonance imaging (MRI) or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle, and internal organs.</p> <p>The risk for NSF appears highest among patients with chronic, severe kidney disease (glomerular filtration rate [GFR] <30 mL/minute/1.73 m²) or acute kidney injury.</p> <p>Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (eg, >60 years, hypertension, diabetes), estimate the GFR through laboratory testing.</p> <p>For patients at highest risk for NSF, do not exceed the recommended gadobutrol dose and allow a sufficient period of time for elimination of the drug from the body prior to any readministration.</p>
Ganciclovir	<p>The clinical toxicity of ganciclovir IV includes granulocytopenia, anemia and thrombocytopenia. In animal studies ganciclovir was carcinogenic, teratogenic and caused aspermatogenesis.</p> <p>Ganciclovir IV is indicated for use only in the treatment of cytomegalovirus (CMV) retinitis in immunocompromised patients and for the prevention of CMV disease in transplant patients at risk for CMV disease</p> <p>In animal studies ganciclovir was carcinogenic, teratogenic and caused aspermatogenesis</p>
Hydrocodone-containing antitussives	<p>Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Avoid use of opioid cough medications in patients taking benzodiazepines, other CNS depressants, or alcohol.</p>
Hydromorphone	<p>Hydromorphone exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing hydromorphone and monitor all patients regularly for the development of these behaviors or conditions.</p> <p>Serious, life-threatening, or fatal respiratory depression may occur with use of hydromorphone. Monitor for respiratory depression, especially during initiation of hydromorphone or following a dose increase. Instruct patients to swallow hydromorphone ER tablets whole; crushing, chewing, or dissolving hydromorphone ER can cause rapid release and absorption of a potentially fatal dose of hydromorphone.</p> <p>Accidental ingestion of even one dose of hydromorphone, especially by children, can result in a fatal overdose of hydromorphone.</p> <p>Prolonged use of hydromorphone during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.</p> <p>Risk of medication errors:</p> <p>Injection: High-potency hydromorphone (10 mg/mL) is a more concentrated solution of hydromorphone than hydromorphone 1, 2, or 4 mg/mL, and is for use in opioid-tolerant patients only. Do not confuse high-potency hydromorphone with standard parenteral formulations of hydromorphone or other opioids, as overdose and death could result.</p> <p>Oral solution: Ensure accuracy when prescribing, dispensing, and administering hydromorphone oral solution. Dosing errors due to confusion between mg and mL can result in accidental overdose and death.</p> <p>Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of hydromorphone and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.</p>
Hydroxyethyl starch solutions	<p>In critically ill adult patients, including patients with sepsis, use of hydroxyethyl starch (HES) products, including Hespan(R), increases the risk of mortality and renal replacement therapy. Do not use HES products, including Hespan(R), in critically ill adult patients, including patients with sepsis</p>
Hydroxyurea	<p>Hydroxyurea may cause severe myelosuppression. Monitor blood counts at baseline and throughout treatment. Interrupt treatment and reduce dose as necessary.</p> <p>Hydroxyurea is carcinogenic. Advise sun protection and monitor patients for malignancies.</p>
Ibritumomab tiuxetan	<p>Deaths have occurred within 24 hours of rituximab infusion, an essential component of the ibritumomab tiuxetan therapeutic regimen. These fatalities were associated with acute respiratory distress syndrome, cardiogenic shock, hypoxia, myocardial infarction (MI), pulmonary infiltrates, or ventricular fibrillation. Most (80%) fatalities occurred with the first rituximab infusion. Discontinue rituximab and Y-90 ibritumomab tiuxetan infusions in patients who develop severe infusion reactions.</p> <p>Y-90 ibritumomab tiuxetan administration results in severe and prolonged cytopenias in most patients. Do not administer the ibritumomab tiuxetan therapeutic regimen to patients with 25% or greater lymphoma marrow involvement and/or impaired bone marrow reserve.</p> <p>Severe cutaneous and mucocutaneous reactions, some with fatal outcome, have been reported with the ibritumomab tiuxetan therapeutic regimen. Discontinue rituximab and Y-90 ibritumomab tiuxetan infusions in patients experiencing severe cutaneous or mucocutaneous reactions.</p>

Drug Name	Black Box Warning
	The dose of Y-90 ibritumomab tiuxetan should not exceed 32 mCi (1,184 MBq).
Idarubicin	<p>Idarubicin HCl should be given slowly into a freely flowing intravenous infusion; it must never be given intramuscularly or subcutaneously. Severe local tissue necrosis can occur if there is extravasation during administration.</p> <p>As is the case with other anthracyclines, the use of idarubicin HCl can cause myocardial toxicity leading to heart failure. Cardiac toxicity is more common in patients who have received prior anthracyclines or who have preexisting cardiac disease.</p> <p>As is usual with antileukemic agents, severe myelosuppression occurs when idarubicin HCl is used at effective therapeutic doses.</p> <p>It is recommended that idarubicin HCl be administered only under the supervision of a physician who is experienced in leukemia chemotherapy and in facilities with laboratory and supportive resources adequate to monitor drug tolerance and protect and maintain a patient compromised by drug toxicity. The physician and institution must be capable of responding rapidly and completely to severe hemorrhagic conditions and/or overwhelming infection.</p> <p>Dosage should be reduced in patients with impaired hepatic function. Dosage should be reduced in patients with impaired renal function.</p>
Ifosfamide	<p>Myelosuppression can be severe and lead to fatal infections. Monitor blood counts prior to and at intervals after each treatment cycle.</p> <p>CNS toxicities can be severe and result in encephalopathy and death. Monitor for CNS toxicity and discontinue treatment for encephalopathy.</p> <p>Hemorrhagic cystitis can be severe and can be reduced by the prophylactic use of mesna.</p> <p>Nephrotoxicity can be severe and result in renal failure.</p>
Immune Globulins	<p>Thrombosis may occur with immune globulin products. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. For patients at risk of thrombosis, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.</p> <p>Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients with immune globulin intravenous (IGIV) products. Patients predisposed to renal dysfunction include those with any degree of preexisting renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. (Note: The following products do not contain sucrose: Bivigam, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam 5%, Octagam 10%, and Privigen.) For patients at risk of renal dysfunction or acute renal failure, administer immune globulin IV products at the minimum concentration dose and infusion rate practicable. Ensure adequate hydration in patients before administration.</p>
Immune globulin Rho(D)	<p>Intravascular hemolysis leading to death has been reported in Rh_o(D)-positive patients treated for immune thrombocytopenic purpura (ITP) with Rh_o(D) immune globulin.</p> <p>Intravascular hemolysis can lead to clinically compromising anemia and multisystem organ failure, including acute respiratory distress syndrome (ARDS).</p> <p>Serious complications, including severe anemia, acute renal insufficiency, renal failure, and disseminated intravascular coagulation (DIC), have also been reported.</p> <p>Closely monitor patients treated for signs and symptoms of hemolysis in a health care setting for at least 8 hours after administration. Perform a dipstick urinalysis at baseline, 2 and 4 hours after administration, and prior to the end of the monitoring period. Alert patients to and monitor them for back pain, shaking chills, fever, and discolored urine or hematuria. Absence of these signs and/or symptoms within 8 hours does not indicate intravascular hemolysis cannot occur subsequently. If signs and/or symptoms of intravascular hemolysis are present or suspected after administration, perform posttreatment laboratory tests, including plasma hemoglobin (Hb), haptoglobin, lactate dehydrogenase (LDH), and plasma bilirubin (direct and indirect).</p>
Infliximab	<p>Patients treated with infliximab are at an increased risk of developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids. Discontinue infliximab if a patient develops a serious infection or sepsis.</p> <p>Reported infections include the following:</p> <p>Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before infliximab use and during therapy. Initiate treatment for latent infection prior to infliximab use.</p> <p>Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric antifungal therapy in patients at risk of invasive fungal infections who develop severe systemic illness.</p> <p>Bacterial, viral, and other infections caused by opportunistic pathogens, including <i>Legionella</i> and <i>Listeria</i>.</p>

Drug Name	Black Box Warning
	<p>Carefully consider the risks and benefits of treatment with infliximab prior to initiating therapy in patients with long-term or recurrent infection.</p> <p>Closely monitor patients for the development of signs and symptoms of infection during and after treatment with infliximab, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.</p> <p>Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including infliximab.</p> <p>Postmarketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including infliximab. These cases had a very aggressive disease course and have been fatal. Almost all patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF-blocker at or prior to diagnosis. The majority of reported infliximab cases have occurred in patients with Crohn disease or ulcerative colitis, and most were in adolescent and young adult males.</p>
Interferon alfa-2b	<p>Alpha interferons, including interferon alfa-2b, cause or aggravate fatal or life-threatening neuropsychiatric disorders. Monitor patients closely with periodic clinical and laboratory evaluations. Withdraw therapy from patients with persistently severe or worsening signs or symptoms of these conditions. In many but not all cases these disorders resolve after stopping interferon alfa-2b therapy.</p> <p>Alpha interferons, including interferon alfa-2b, cause or aggravate fatal or life-threatening autoimmune disorders. Monitor patients closely with periodic clinical and laboratory evaluations. Withdraw therapy from patients with persistently severe or worsening signs or symptoms of these conditions. In many but not all cases these disorders resolve after stopping interferon alfa-2b therapy.</p> <p>Alpha interferons, including interferon alfa-2b, cause or aggravate fatal or life-threatening ischemic disorders. Monitor patients closely with periodic clinical and laboratory evaluations. Withdraw therapy from patients with persistently severe or worsening signs or symptoms of these conditions. In many but not all cases these disorders resolve after stopping interferon alfa-2b therapy.</p> <p>Alpha interferons, including interferon alfa-2b, cause or aggravate fatal or life-threatening infectious disorders. Monitor patients closely with periodic clinical and laboratory evaluations. Withdraw therapy from patients with persistently severe or worsening signs or symptoms of these conditions. In many but not all cases these disorders resolve after stopping interferon alfa-2b therapy.</p>
Intravenous fat emulsion products	<p>Deaths in preterm infants after infusion of intravenous (IV) fat emulsions have been reported. Autopsy findings included intravascular fat accumulation in the lungs. Treatment of premature and low-birth-weight infants with IV fat emulsion must be based on careful benefit-risk assessment. Strict adherence to the recommended total daily dose is mandatory; hourly infusion rate should be as slow as possible. Preterm infants and low birth weight infants and small for gestational age infants have poor clearance of IV fat emulsion and increased free fatty acid plasma levels following fat emulsion infusion; therefore, serious consideration must be given to administration of less than the maximum recommended doses in these patients to decrease the likelihood of IV fat overload. Monitor the infant's ability to eliminate the infused fat from the circulation (such as triglycerides and/or plasma free fatty acid levels). The lipemia must clear between daily infusions</p>
Iodixanol	Not for intrathecal use.
Iohexol	Iohexol 140 and 350 are not for intrathecal use.
Ioversol	Not for intrathecal use.
Irinotecan	<p>Early and late forms of diarrhea may occur. Early diarrhea may be accompanied by cholinergic symptoms that may be prevented or ameliorated by atropine. Late diarrhea can be life-threatening and should be treated promptly with loperamide. Monitor patients with diarrhea and give fluid and electrolytes as needed. Institute antibiotic therapy if patients develop ileus, fever, or severe neutropenia. Interrupt irinotecan and reduce subsequent doses if severe diarrhea occurs.</p> <p>Severe myelosuppression may occur.</p>
Iron Dextran	<p>Anaphylactic-type reactions, including fatalities, have followed the parenteral administration of iron dextran injection. Have resuscitation equipment and personnel trained in the detection and treatment of anaphylactic-type reactions readily available during iron dextran administration.</p> <p>Administer a test dose of iron dextran prior to the first therapeutic dose. If no signs or symptoms of anaphylactic-type reactions follow the test dose, administer the full therapeutic iron dextran dose. During all iron dextran administrations, observe for signs or symptoms of anaphylactic-type reactions. Fatal reactions have followed the test dose of iron dextran injection. Fatal reactions have also occurred in situations in which the test dose was tolerated.</p> <p>Patients with a history of drug allergy or multiple drug allergies may be at increased risk of anaphylactic-type reactions to iron dextran.</p> <p>Use iron dextran only in patients in whom clinical and laboratory investigations have established an iron-deficient state not amenable to oral iron therapy.</p>
Isoniazid	<p>Severe and sometimes fatal hepatitis has been reported with isoniazid therapy and may occur even after many months of treatment. The risk for hepatitis increases with advancing age, concomitant alcohol use, chronic liver disease, and injection drug use. Patients given isoniazid should be carefully monitored and interviewed at monthly intervals. For persons 35 and older, in addition to monthly symptom reviews, hepatic enzymes (specifically, AST and ALT (formerly SGOT and SGPT, respectively)) should be measured prior to starting isoniazid therapy and periodically throughout treatment. An increased risk of fatal hepatitis associated with isoniazid has been reported in women, particularly black and Hispanic women. The risk may also be increased during the post partum period. More careful monitoring should be considered</p>

Drug Name	Black Box Warning
	in these groups, possibly including more frequent laboratory monitoring
Isotretinoin	<p>Isotretinoin must not be used by women and adolescents who are pregnant or who may become pregnant. There is an extremely high risk that severe birth defects can result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time. Potentially, any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.</p> <p>Birth defects that have been documented following isotretinoin exposure include abnormalities of the face, eyes, ears, skull, CNS, cardiovascular system, and thymus and parathyroid glands. Cases of intelligence quotient (IQ) scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported.</p> <p>Documented external abnormalities include skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphism; cleft palate. Documented internal abnormalities include CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases, death has occurred with some of the abnormalities previously noted.</p> <p>If pregnancy does occur during treatment of a female patient who is taking isotretinoin, isotretinoin must be discontinued immediately and she should be referred to an obstetrician-gynecologist experienced in reproductive toxicity for further evaluation and counseling.</p> <p>Because of isotretinoin's teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE. Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE program. Isotretinoin must only be dispensed by a pharmacy registered and activated with iPLEDGE, and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE.</p>
Itraconazole	<p>Do not administer itraconazole for the treatment of onychomycosis in patients with evidence of ventricular dysfunction, such as congestive heart failure (CHF) or a history of CHF. If signs or symptoms of CHF occur during administration of itraconazole oral solution, reassess continued itraconazole use. If signs or symptoms of CHF occur during administration of itraconazole capsules or tablets, discontinue administration. When itraconazole was administered intravenously (IV) to dogs and healthy human volunteers, negative inotropic effects were seen.</p> <p>Coadministration of the following drugs is contraindicated with itraconazole: methadone, disopyramide, dofetilide, dronedarone, quinidine, ergot alkaloids (eg, dihydroergotamine, ergometrine [ergonovine], ergotamine, methylethergometrine [methylethergonovine]), irinotecan, lurasidone, oral midazolam, pimozone, triazolam, felodipine, nisoldipine, ivabradine, ranolazine, eplerenone, cisapride, lovastatin, simvastatin, ticagrelor and, in subjects with varying degrees of renal or hepatic impairment, colchicine, fesoterodine, telithromycin, and solifenacin. Coadministration with itraconazole can cause elevated plasma concentrations of these drugs and may increase or prolong both the pharmacologic effects and/or adverse reactions to these drugs. For example, increased plasma concentrations of some of these drugs can lead to QT prolongation and ventricular tachyarrhythmias including occurrences of torsades de pointes, a potentially fatal arrhythmia.</p>
Ixabepilone	Ixabepilone in combination with capecitabine is contraindicated in patients with AST or ALT greater than 2.5 times the upper limit of normal (ULN) or bilirubin greater than 1 times ULN due to an increased risk of toxicity and neutropenia-related death.
Ketorolac	<p>Ketorolac is indicated for the short-term (up to 5 days in adults) management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation treatment following intravenous (IV) or intramuscular (IM) dosing of ketorolac, if necessary. The total combined duration of use of ketorolac tablets and injection should not exceed 5 days.</p> <p>Ketorolac is not indicated for use in pediatric patients and is not indicated for minor or chronic painful conditions. Increasing the dose of ketorolac beyond labeled recommendations will not provide better efficacy but will increase the risk of developing serious adverse events. :</p> <p>Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction (MI) and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.</p> <p>Ketorolac is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.</p> <p>NSAIDs cause an increased risk of serious gastrointestinal (GI) events, including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Therefore, ketorolac is contraindicated in patients with active peptic ulcer disease, recent GI bleeding or perforation, and a history of peptic ulcer disease or GI bleeding. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.</p> <p>Ketorolac is contraindicated for intrathecal or epidural administration due to its alcohol content.</p> <p>Hypersensitivity reactions, ranging from bronchospasm to anaphylactic shock, have occurred and appropriate counteractive measures must be available when administering the first dose of ketorolac injection. Ketorolac is contraindicated in patients with previously demonstrated hypersensitivity to ketorolac or allergic manifestations to aspirin or other NSAIDs.</p> <p>Ketorolac is contraindicated in patients with advanced renal impairment and in patients at risk for renal failure due to volume depletion.</p> <p>Ketorolac inhibits platelet function and is, therefore, contraindicated in patients with suspected or confirmed cerebrovascular bleeding, hemorrhagic diathesis, incomplete</p>

Drug Name	Black Box Warning
	<p>hemostasis, and those at high risk of bleeding.</p> <p>Ketorolac is contraindicated as a prophylactic analgesic before any major surgery.</p> <p>Ketorolac is contraindicated in labor and delivery because it may adversely affect fetal circulation and inhibit uterine contractions.</p> <p>Ketorolac is contraindicated in patients currently receiving aspirin or NSAIDs because of the cumulative risks of inducing serious NSAID-related adverse events.</p> <p>Adjust dosage for patients 65 years and older, weighing less than 50 kg (110 lbs), and with moderately elevated serum creatinine. Doses of ketorolac injection are not to exceed 60 mg (total dose per day) in these patients.</p>
Lamivudine/Zidovudine	<p>Zidovudine, a component of lamivudine/zidovudine tablets, has been associated with hematologic toxicity, including neutropenia and severe anemia, particularly in patients with advanced HIV-1 disease.</p> <p>Prolonged use of zidovudine has been associated with symptomatic myopathy.</p> <p>Severe, acute exacerbations of hepatitis B have been reported in patients who are coinfectd with hepatitis B virus (HBV) and HIV-1 and have discontinued lamivudine, a component of lamivudine/zidovudine. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue lamivudine/zidovudine and are coinfectd with HIV-1 and HBV. If appropriate, initiation of antihepatitis B therapy may be warranted.</p> <p>Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with use of nucleoside analogues and other antiretrovirals. Discontinue lamivudine/zidovudine if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity occur.</p>
Lamotrigine	<p>Lamotrigine can cause serious rashes requiring hospitalization and discontinuation of treatment. The incidence of these rashes, which have included Stevens-Johnson syndrome, is approximately 0.3% to 0.8% in pediatric patients (2 to 17 years of age) and 0.08% to 0.3% in adults receiving lamotrigine. One rash-related death was reported in a prospectively followed cohort of 1,983 pediatric patients (2 to 16 years of age) with epilepsy taking lamotrigine immediate-release as adjunctive therapy. In worldwide postmarketing experience, rare cases of toxic epidermal necrolysis and/or rash-related death have been reported in adults and pediatric patients, but those numbers are too few to permit a precise estimate of the rate.</p> <p>The risk of serious rash caused by treatment with lamotrigine ER is not expected to differ from that with the immediate-release formulation of lamotrigine. However, the relatively limited treatment experience with lamotrigine ER makes it difficult to characterize the frequency and risk of serious rashes caused by treatment with lamotrigine ER. Lamotrigine ER is not approved for patients younger than 13 years.</p> <p>Other than age, there are as yet no factors identified that are known to predict the risk of occurrence or the severity of rash caused by lamotrigine. There are suggestions, yet to be proven, that the risk of rash may also be increased by coadministration of lamotrigine with valproate (includes valproic acid and divalproex sodium), exceeding the recommended initial dose of lamotrigine, or exceeding the recommended dose escalation for lamotrigine. However, cases have been reported in the absence of these factors.</p> <p>Nearly all cases of life-threatening rashes associated with lamotrigine have occurred within 2 to 8 weeks of treatment initiation. However, isolated cases have been reported after prolonged treatment (eg, 6 months). Accordingly, duration of therapy cannot be relied upon as a means to predict the potential risk heralded by the first appearance of a rash.</p> <p>Although benign rashes are also caused by lamotrigine, it is not possible to predict reliably which rashes will prove to be serious or life-threatening. Accordingly, lamotrigine should ordinarily be discontinued at the first sign of rash unless the rash is clearly not drug-related. Discontinuation of treatment may not prevent a rash from becoming life-threatening or permanently disabling or disfiguring.</p>
Leflunomide	<p>Leflunomide is contraindicated in pregnant women because of the potential for fetal harm. Teratogenicity and embryolethality occurred in animals administered leflunomide at doses lower than the human exposure level. Exclude pregnancy before the start of treatment with leflunomide in females of reproductive potential. Advise females of reproductive potential to use effective contraception during leflunomide treatment and during an accelerated elimination procedure after leflunomide treatment. Stop leflunomide and use an accelerated drug elimination procedure if the patient becomes pregnant.</p> <p>Severe liver injury, including fatal liver failure, has been reported in patients treated with leflunomide. Leflunomide is contraindicated in patients with severe hepatic impairment. Concomitant use of leflunomide with other potentially hepatotoxic drugs may increase the risk of liver injury. Patients with preexisting acute or chronic liver disease, or those with ALT more than twice the upper limit of normal (ULN) before initiating treatment, are at increased risk and should not be treated with leflunomide. Monitor ALT levels at least monthly for 6 months after starting leflunomide, and thereafter every 6 to 8 weeks. If leflunomide-induced liver injury is suspected, stop leflunomide treatment, start an accelerated drug elimination procedure, and monitor liver tests weekly until normalized.</p>
Lidocaine viscous 2%	<p>Postmarketing cases of seizures, cardiopulmonary arrest, and death in patients under the age of 3 years have been reported with use of lidocaine 2% viscous solution when it was not administered in strict adherence to the dosing and administration recommendations. In the setting of teething pain, lidocaine 2% viscous solution should generally not be used. For other conditions, the use of the product in patients less than 3 years should be limited to those situations where safer alternatives are not available or have been tried but failed.</p> <p>To decrease the risk of serious adverse events with use of lidocaine 2% viscous solution, instruct caregivers to strictly adhere to the prescribed dose and frequency of administration and store the prescription bottle safely out of reach of children.</p>

Drug Name	Black Box Warning
Lithium	Lithium toxicity is closely related to serum lithium levels, and can occur at doses close to therapeutic levels. Facilities for prompt and accurate serum lithium determinations should be available before initiating therapy.
Lomustine	<p>Lomustine causes myelosuppression, including fatal myelosuppression. Myelosuppression is delayed, dose-related, and cumulative, occurring 4 to 6 weeks after drug administration and persisting for 1 to 2 weeks. Thrombocytopenia is generally more severe than leukopenia. Cumulative myelosuppression from lomustine is manifested by greater severity and longer duration of cytopenias. Monitor blood counts for at least 6 weeks after each dose. Do not give lomustine more frequently than every 6 weeks.</p> <p>Prescribe, dispense, and administer only enough capsules for one dose. Fatal toxicity occurs with overdosage of lomustine. Both health care provider and pharmacist should emphasize to the patient that only one dose of lomustine is taken every 6 weeks.</p>
Low Molecular Weight Heparins	<p>Epidural or spinal hematomas may occur in patients who are anticoagulated with LMWHs or heparinoids and are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures.</p> <p>Factors that can increase the risk of developing epidural or spinal hematomas in these patients include use of indwelling epidural catheters; concomitant use of other drugs that affect hemostasis, such as nonsteroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, and other anticoagulants; a history of traumatic or repeated epidural or spinal punctures; and a history of spinal deformity or spinal surgery. Optimal timing between the administration of enoxaparin and neuraxial procedures is not known.</p> <p>Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis.</p>
Loxapine	<p>Loxapine inhalation can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest. Administer loxapine inhalation only in an enrolled health care facility that has immediate access on site to supplies and personnel trained to manage acute bronchospasm and ready access to emergency response services. Facilities must have a short-acting bronchodilator (eg, albuterol), including a nebulizer and inhalation solution, for the immediate treatment of bronchospasm. Prior to administering loxapine inhalation, screen patients regarding a current diagnosis, history, or symptoms of asthma, chronic obstructive pulmonary disease (COPD), and other lung diseases, and examine (including chest auscultation) patients for respiratory signs. Monitor for signs and symptoms of bronchospasm following treatment with loxapine inhalation.</p> <p>Because of the risk of bronchospasm, loxapine inhalation is available only through a restricted program under a risk evaluation and mitigation strategy (REMS) called the Adasuve REMS.</p> <p>Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Loxapine is not approved for the treatment of patients with dementia-related psychosis.</p>
Lurasidone	<p>Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Lurasidone is not approved for the treatment of patients with dementia-related psychosis.</p> <p>Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. Lurasidone is not approved for use in pediatric patients with depression.</p>
Mechlorethamine HCl	<p>Administer mechlorethamine injection only under the supervision of a physician who is experienced in the use of cancer chemotherapeutic agents.</p> <p>Extravasation of the drug into subcutaneous tissues results in a painful inflammation. The area usually becomes indurated and sloughing may occur. If leakage of drug is obvious, prompt infiltration of the area with sterile isotonic sodium thiosulfate (1/6 molar) and application of an ice compress for 6 to 12 hours may minimize the local reaction. For a 1/6 molar solution of sodium thiosulfate, use 4.14 g of sodium thiosulfate per 100 mL of sterile water for injection or 2.64 g of anhydrous sodium thiosulfate per 100 mL or dilute 4 mL of sodium thiosulfate injection (10%) with 6 mL of sterile water for injection.</p> <p>This drug is highly toxic, and both powder and solution must be handled and administered with care. Inhalation of dust or vapors and contact with skin or mucous membranes, especially those of the eyes, must be avoided. Due to the toxic properties of mechlorethamine (eg, corrosivity, carcinogenicity, mutagenicity, teratogenicity), review special handling procedures prior to handling and follow them diligently.</p> <p>Avoid exposure during pregnancy.</p>
Medroxyprogesterone	<p>Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease. The Women's Health Initiative (WHI) estrogen plus progestin substudy reported increased risks of deep vein thrombosis (DVT), pulmonary embolism (PE), stroke, and myocardial infarction (MI) in postmenopausal women (50 to 79 years of age) during 5.6 years of treatment with daily oral conjugated estrogens (0.625 mg) combined with medroxyprogesterone acetate (2.5 mg), relative to placebo.</p> <p>The Women's Health Initiative (WHI) estrogen plus progestin substudy demonstrated an increased risk of invasive breast cancer.</p> <p>Estrogen plus progestin therapy should not be used for the prevention of dementia. The Women's Health Initiative Memory Study (WHIMS) estrogen plus progestin ancillary study of the WHI reported an increased risk of developing probable dementia in postmenopausal women 65 years or older during 4 years of treatment with daily conjugated estrogens (0.625 mg) combined with medroxyprogesterone acetate (2.5 mg), relative to placebo. It is unknown whether this finding applies to younger postmenopausal women.</p>

Drug Name	Black Box Warning
	<p>Medroxyprogesterone contraceptive should not be used as a long-term birth control method (ie, longer than 2 years) unless other birth control methods are considered inadequate.</p> <p>Women who use medroxyprogesterone contraceptive may lose significant bone mineral density (BMD). Bone loss is greater with increasing duration of use and may not be completely reversible. It is unknown if use of medroxyprogesterone contraceptive during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk for osteoporotic fracture in later life.</p> <p>In the absence of comparable data, these risks should be assumed to be similar for other doses of conjugated estrogens (with or without medroxyprogesterone acetate) and other dosage forms of estrogens (with or without progestins). Estrogens with progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.</p>
Melphalan	<p>Severe bone marrow suppression with resulting infection or bleeding may occur. Controlled trials comparing intravenous (IV) to oral melphalan have shown more myelosuppression with the IV formulation. Monitor hematologic laboratory parameters.</p> <p>Melphalan produces chromosomal aberrations in vitro and in vivo. Melphalan should be considered potentially leukemogenic in humans.</p> <p>Hypersensitivity reactions, including anaphylaxis, have occurred in approximately 2% of patients who received the IV formulation of melphalan. Discontinue treatment with melphalan for serious hypersensitivity reactions.</p> <p>Administer melphalan under the supervision of a qualified health care provider experienced in the use of cancer chemotherapeutic agents.</p>
Metformin	<p>Lactic acidosis is a rare but serious metabolic complication that can occur because of metformin accumulation during treatment with metformin; when it occurs, it is fatal in approximately 50% of cases. Lactic acidosis may also occur in association with a number of pathophysiologic conditions, including diabetes mellitus and whenever there is significant tissue hypoperfusion and hypoxemia. Lactic acidosis is characterized by elevated blood lactate levels (5 mmol/L or more), decreased blood pH, electrolyte disturbances with an increased anion gap, and an increased lactate/pyruvate ratio. When metformin is implicated as the cause of lactic acidosis, metformin plasma levels of 5 mcg/mL or more are generally found.</p> <p>Lactic acidosis is a medical emergency that must be treated in a hospital setting. In a patient with lactic acidosis who is taking metformin, immediately discontinue the drug and promptly institute general supportive measures. Because metformin is dialyzable (with a clearance of up to 170 mL/min under good hemodynamic conditions), prompt hemodialysis is recommended to correct the acidosis and remove the accumulated metformin. Such management often results in prompt reversal of symptoms and recovery.</p>
Methadone	<p>Methadone exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing methadone, and monitor all patients regularly for the development of these behaviors and conditions.</p> <p>Serious, life-threatening, or fatal respiratory depression may occur; has been reported during initiation and conversion of patients to methadone, and even when the drug has been used as recommended and not misused or abused. Proper dosing and titration are essential and methadone should only be prescribed by health care providers who are knowledgeable in the use of methadone for detoxification and maintenance treatment of opioid addiction. Monitor for respiratory depression, especially during initiation of methadone or following a dose increase. The peak respiratory depressant effect of methadone occurs later, and persists longer than the peak analgesic effect, especially during the initial dosing period.</p> <p>QT interval prolongation and serious arrhythmia (torsades de pointes) have occurred during treatment with methadone. Most cases involve patients being treated for pain with large, multiple daily doses of methadone, although cases have been reported in patients receiving doses commonly used for maintenance treatment of opioid addiction. Closely monitor patients with risk factors for development of prolonged QT interval, a history of cardiac conduction abnormalities, and those taking medications affecting cardiac conduction for changes in cardiac rhythm during initiation and titration of methadone.</p> <p>Accidental ingestion of even one dose of methadone, especially by children, can result in a fatal overdose of methadone.</p> <p>Neonatal opioid withdrawal syndrome is an expected and treatable outcome of use of methadone during pregnancy. Neonatal opioid withdrawal syndrome may be life-threatening if not recognized and treated in the neonate. The balance between the risks of neonatal opioid withdrawal syndrome and the benefits of maternal methadone use may differ based on the risks associated with the mother's underlying condition, pain, or addiction. Advise the patient of the risk of neonatal opioid withdrawal syndrome so that appropriate planning for management of the neonate can occur.</p> <p>For detoxification and maintenance of opioid dependence, methadone should be administered in accordance with the treatment standards cited in 42 CFR Section 8, including limitations on unsupervised administration.</p> <p>When used for the treatment of opioid addiction in detoxification or maintenance programs, methadone should be dispensed only by opioid treatment programs (and agencies, or practitioners or institutions by formal agreement with the program sponsor) certified by the substance abuse and mental health services administration and approved by the designated state authority. Certified treatment programs shall dispense and use methadone in oral form only and according to the treatment requirements stipulated in the Federal Opioid Treatment Standards. Failure to abide by the requirements in these regulations may result in criminal prosecution, seizure of drug supply, revocation of program approval, and injunction precluding program operation.</p> <p>The concomitant use of methadone with all cytochrome P450 (CYP-450) 3A4, 2B6, 2C19, 2C9, or 2D6 inhibitors may result in an increase in methadone plasma concentrations, which could cause potentially fatal respiratory depression. In addition, discontinuation of concomitantly used CYP450 3A4, 2B6, 2C19, or 2C9 inducers</p>

Drug Name	Black Box Warning
	<p>may also result in an increase in methadone plasma concentration. Follow patients closely for respiratory depression and sedation, and consider dosage reduction with any changes of concomitant medications that can result in an increase in methadone levels.</p> <p>Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of methadone and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.</p>
Methohexital	<p>Use methohexital only in hospital or ambulatory care settings that provide for continuous monitoring of respiratory (eg, pulse oximetry) and cardiac function. Ensure immediate availability of resuscitative drugs and age- and size-appropriate equipment for bag/valve/mask ventilation and intubation and personnel trained in their use and skilled in airway management. For deeply sedated patients, a designated individual other than the practitioner performing the procedure should be present to continuously monitor the patient.</p>
Methotrexate	<p>Use only preservative-free methotrexate formulations and diluents for intrathecal and high-dose therapy. Do NOT use formulations or diluents containing preservatives for intrathecal and high-dose therapy because they contain benzyl alcohol.</p> <p>Because of the possibility of serious toxic reactions (which can be fatal), methotrexate should be used only in life threatening neoplastic diseases or in patients with psoriasis or rheumatoid arthritis with severe, recalcitrant, disabling disease which is not adequately responsive to other forms of therapy. Deaths have been reported with the use of methotrexate in the treatment of malignancy, psoriasis, and rheumatoid arthritis. Patients should be closely monitored for bone marrow, liver, lung, skin, and kidney toxicities. Patients should be informed by their physician of the risks involved and be under a physician's care throughout therapy.</p> <p>The use of methotrexate high-dose regimens recommended for osteosarcoma requires meticulous care. High-dose regimens of methotrexate injection for other neoplastic diseases are investigational, and a therapeutic advantage has not been established.</p> <p>Methotrexate has been reported to cause fetal death and/or congenital anomalies. Therefore, it is not recommended for women of childbearing potential unless there is clear medical evidence that the benefits can be expected to outweigh the considered risks. Pregnant women with psoriasis or rheumatoid arthritis should not receive methotrexate. Some products are contraindicated in pregnant women.</p> <p>Unexpectedly severe (sometimes fatal) bone marrow suppression, aplastic anemia, and toxicity have been reported with concomitant administration of methotrexate (usually in high dosage) along with some nonsteroidal anti-inflammatory drugs (NSAIDs).</p> <p>Methotrexate elimination is reduced in patients with impaired renal function, ascites, or pleural effusions. Such patients require especially careful monitoring for toxicity, and require dose reduction or, in some cases, discontinuation of methotrexate administration.</p> <p>Methotrexate causes hepatotoxicity, fibrosis, and cirrhosis, but generally only after prolonged use. Acutely, liver enzyme elevations are frequently seen. These are usually transient and asymptomatic, and also do not appear predictive of subsequent hepatic disease. Liver biopsy after sustained use often shows histologic changes, and fibrosis and cirrhosis have been reported; these latter lesions may not be preceded by symptoms or abnormal liver function tests in the psoriasis population. For this reason, periodic liver biopsies are usually recommended for psoriatic patients who are under long-term treatment. Persistent abnormalities in liver function tests may precede appearance of fibrosis or cirrhosis in the rheumatoid arthritis population.</p> <p>Methotrexate-induced lung disease, including acute or chronic interstitial pneumonitis, is a potentially dangerous lesion, which may occur acutely at any time during therapy and has been reported at low doses. It is not always fully reversible and fatalities have been reported. Pulmonary symptoms (especially a dry, nonproductive cough) may require interruption of treatment and careful investigation.</p> <p>Unexpectedly severe (sometimes fatal) gastrointestinal toxicity has been reported with concomitant administration of methotrexate (usually in high dosage) along with some nonsteroidal anti-inflammatory drugs (NSAIDs). Diarrhea and ulcerative stomatitis require interruption of therapy; otherwise hemorrhagic enteritis and death from intestinal perforation may occur.</p> <p>Malignant lymphomas, which may regress following withdrawal of methotrexate, may occur in patients receiving low-dose methotrexate and, thus, may not require cytotoxic treatment. Discontinue methotrexate first and, if the lymphoma does not regress, appropriate treatment should be instituted.</p> <p>Like other cytotoxic drugs, methotrexate may induce tumor lysis syndrome in patients with rapidly growing tumors. Appropriate supportive and pharmacologic measures may prevent or alleviate this complication.</p> <p>Severe, occasionally fatal skin reactions have been reported following single or multiple doses of methotrexate. Reactions have occurred within days of oral, intramuscular, intravenous, or intrathecal methotrexate administration. Recovery has been reported with discontinuation of therapy.</p> <p>Potentially fatal opportunistic infections, especially <i>Pneumocystis jirovecii</i> pneumonia, may occur with methotrexate therapy.</p> <p>Methotrexate given concomitantly with radiotherapy may increase the risk of soft tissue necrosis and osteonecrosis.</p> <p>Methotrexate should be used only by health care providers whose knowledge and experience include the use of antimetabolite therapy.</p>
Methylphenidate	<p>Methylphenidate has a high potential for abuse and dependence. Give methylphenidate cautiously to patients with a history of drug dependence or alcoholism.</p> <p>Long-term abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur.</p>

Drug Name	Black Box Warning
	especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use because severe depression may occur. Withdrawal following long-term therapeutic use may unmask symptoms of the underlying disorder that may require follow-up. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy.
Metoclopramide	<p>Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with duration of treatment and total cumulative dose.</p> <p>Discontinue metoclopramide therapy in patients who develop signs or symptoms of tardive dyskinesia. There is no known treatment for tardive dyskinesia. In some patients, symptoms lessen or resolve after metoclopramide treatment is stopped.</p> <p>Avoid treatment with metoclopramide for longer than 12 weeks in all but rare cases in which therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia.</p>
Metronidazole	Metronidazole has been shown to be carcinogenic in mice and rats. Unnecessary use of the drug should be avoided. Its use should be reserved for the conditions for which this drug is indicated.
Mexiletine	<p>In the National Heart, Lung, and Blood Institute's Cardiac Arrhythmia Suppression Trial (CAST), a long-term, multicenter, randomized, double-blind study in patients with asymptomatic non-life-threatening ventricular arrhythmias who had an myocardial infarction (MI) more than 6 days but less than 2 years previously, an excessive mortality or nonfatal cardiac arrest rate (7.7%) was seen in patients treated with encainide or flecainide compared with that seen in patients assigned to carefully matched placebo-treated groups (3%). The average duration of treatment with encainide or flecainide in this study was 10 months.</p> <p>The applicability of the CAST results to other populations (eg, those without recent MI) is uncertain. Considering the known proarrhythmic properties of mexiletine and the lack of evidence of improved survival for any antiarrhythmic drug in patients without life-threatening arrhythmias, the use of mexiletine as well as other antiarrhythmic agents should be reserved for patients with life-threatening ventricular arrhythmias.</p> <p>In postmarketing experience, abnormal liver function tests have been reported, some in the first few weeks of therapy with mexiletine. Most of these have been observed in the setting of congestive heart failure or ischemia and their relationship to mexiletine has not been established.</p>
Midazolam	<p>Midazolam has been associated with respiratory depression and respiratory arrest, especially when used for sedation in noncritical care settings; airway obstruction, desaturation, hypoxia, and apnea have also been reported, most often when used concomitantly with other CNS depressants (eg, opioids). In some cases, where this was not recognized promptly and treated effectively, death or hypoxic encephalopathy has resulted. Midazolam should be used only in hospital or ambulatory care settings, including physicians' and dentists' offices, that can provide for continuous monitoring of respiratory and cardiac function (ie, pulse oximetry). Immediate availability of resuscitative drugs and age- and size-appropriate equipment for bag/valve/mask ventilation and intubation, and personnel trained in their use and skilled in airway management should be assured. For deeply sedated pediatric patients, a dedicated individual, other than the practitioner performing the procedure, should monitor the patient throughout the procedure.</p> <p>The initial intravenous dose for sedation in adult patients may be as little as 1 mg, but should not exceed 2.5 mg in a healthy adult. Lower doses are necessary for older (over 60 years) or debilitated patients and in patients receiving concomitant narcotics or other CNS depressants. The initial dose and all subsequent doses should always be titrated slowly; administer over at least 2 minutes and allow an additional 2 or more minutes to fully evaluate the sedative effect. The use of the 1 mg/mL formulation or dilution of the 1 mg/mL or 5 mg/mL formulation is recommended to facilitate slower injection. Doses of sedative medications in pediatric patients must be calculated on a mg/kg basis, and initial doses and all subsequent doses should always be titrated slowly. The initial pediatric dose of midazolam for sedation/anxiolysis/amnesia is age, procedure, and route dependent.</p> <p>Midazolam should not be administered by rapid injection in the neonatal population. Severe hypotension and seizures have been reported following rapid IV administration, particularly with concomitant use of fentanyl.</p> <p>Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.</p>
Midodrine	Because midodrine can cause marked elevation of supine blood pressure, it should be used in patients whose lives are considerably impaired despite standard clinical care. The indication for use of midodrine in the treatment of symptomatic orthostatic hypotension is based primarily on a change in a surrogate marker of effectiveness, an increase in systolic blood pressure measured 1 minute after standing, a surrogate marker considered likely to correspond to a clinical benefit. At present, however, clinical benefits of midodrine, principally improved ability to carry out activities of daily living, have not been verified.
Minoxidil	<p>Minoxidil may produce serious adverse effects. It can cause pericardial effusion, occasionally progressing to tamponade, and it can exacerbate angina pectoris. Reserve for hypertensive patients who do not respond adequately to maximum therapeutic doses of a diuretic and 2 other antihypertensive agents.</p> <p>In experimental animals, minoxidil caused several kinds of myocardial lesions and other adverse cardiac effects.</p> <p>Administer under close supervision, usually concomitantly with therapeutic doses of a beta-adrenergic blocking agent, to prevent tachycardia and increased myocardial workload. Usually, it must be given with a diuretic, frequently one acting in the ascending limb of the loop of Henle to prevent serious fluid accumulation. When first administering minoxidil, hospitalize and monitor patients with malignant hypertension and those already receiving guanethidine to avoid too rapid or large orthostatic</p>

Drug Name	Black Box Warning
	decreases in blood pressure.
Misoprostol	<p>Misoprostol administration to women who are pregnant can cause birth defects, abortion, premature birth, or uterine rupture. Uterine rupture has been reported when misoprostol was administered in pregnant women to induce labor or to induce abortion. The risk of uterine rupture increases with advancing gestational ages and with prior uterine surgery, including cesarean delivery. Misoprostol should not be taken by pregnant women to reduce the risk of ulcers induced by NSAIDs. Patients must be advised of the abortifacient property and warned not to give the drug to others.</p> <p>Misoprostol should not be used for reducing the risk of NSAID-induced ulcers in women of childbearing potential unless the patient is at high risk of complications from gastric ulcers associated with use of the NSAID, or is at high risk of developing gastric ulceration. In such patients, misoprostol may be prescribed if the patient has had a negative serum pregnancy test within 2 weeks prior to beginning therapy; is capable of complying with effective contraceptive measures; has received both oral and written warnings of the hazards of misoprostol, the risk of possible contraception failure, and the danger to other women of childbearing potential if the drug is taken by mistake; and will begin misoprostol only on the second or third day of the next normal menstrual period.</p>
Mitomycin	<p>Mitomycin should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of therapy and complications is possible only when adequate diagnostic and treatment facilities are readily available.</p> <p>Bone marrow suppression, notably thrombocytopenia and leukopenia, which may contribute to overwhelming infections in an already compromised patient, is the most common and severe of the toxic effects of mitomycin.</p> <p>Hemolytic uremic syndrome (HUS), a serious complication of chemotherapy, consisting primarily of microangiopathic hemolytic anemia, thrombocytopenia, and irreversible renal failure has been reported in patients receiving systemic mitomycin. The syndrome may occur at any time during systemic therapy with mitomycin as a single agent or in combination with other cytotoxic drugs; however, most cases occur at doses greater than or equal to 60 mg of mitomycin. Blood product transfusion may exacerbate the symptoms associated with this syndrome. The incidence of the syndrome has not been defined.</p>
Mitoxantrone	<p>Mitoxantrone should be administered under the supervision of a health care provider experienced in the use of cytotoxic chemotherapy agents.</p> <p>Except for the treatment of acute nonlymphocytic leukemia, mitoxantrone therapy generally should not be given to patients with baseline neutrophil counts of less than 1,500 cells/mm³. In order to monitor the occurrence of bone marrow suppression (primarily neutropenia, which may be severe and result in infection), it is recommended that frequent peripheral blood cell counts be performed on all patients receiving mitoxantrone.</p> <p>Congestive heart failure (CHF), potentially fatal, may occur during therapy with mitoxantrone or months to years after termination of therapy. Cardiotoxicity risk increases with cumulative mitoxantrone dose and may occur whether or not cardiac risk factors are present. Presence or history of cardiovascular disease, radiotherapy to the mediastinal/pericardial area, previous therapy with other anthracyclines or anthracenediones, or use of other cardiotoxic drugs may increase this risk. In patients with cancer, the risk of symptomatic CHF was estimated to be 2.6% for patients receiving up to a cumulative dose of 140 mg/m². To mitigate the cardiotoxicity risk with mitoxantrone, consider the following:</p> <ul style="list-style-type: none"> • All patients should be assessed for cardiac signs and symptoms by history, physical examination, and electrocardiogram (ECG) prior to start of mitoxantrone therapy. • All patients should have baseline quantitative evaluation of left ventricular ejection fraction (LVEF) using appropriate methodology (eg, echocardiogram, multigated radionuclide angiogram [MUGA], magnetic resonance imaging [MRI]). <p>Patients with multiple sclerosis (MS) with a baseline LVEF below the lower limit of normal should not be treated with mitoxantrone.</p> <p>Patients with MS should be assessed for cardiac signs and symptoms by history, physical examination, and ECG prior to each dose.</p> <p>Patients with MS should undergo quantitative reevaluation of LVEF prior to each dose using the same methodology that was used to assess baseline LVEF. Additional doses of mitoxantrone should not be administered to MS patients who have experienced a drop in LVEF to below the lower limit of normal or a clinically significant reduction in LVEF during mitoxantrone therapy.</p> <p>Patients with MS should not receive a cumulative mitoxantrone dose higher than 140 mg/m².</p> <p>Patients with MS should undergo yearly quantitative LVEF evaluation after stopping mitoxantrone to monitor for late-occurring cardiotoxicity.</p> <p>Mitoxantrone therapy in MS patients and in patients with cancer increases the risk of developing secondary acute myeloid leukemia (AML).</p> <p>Mitoxantrone should be given slowly into a freely flowing intravenous (IV) infusion. It must never be given subcutaneously, intramuscularly (IM), or intra-arterially. Severe local tissue damage may occur if there is extravasation during administration. Not for intrathecal use. Severe injury with permanent sequelae can result from intrathecal administration.</p>
Morphine (Extended Release)	<p>Because of the risk of severe adverse effects when the epidural or intrathecal route of administration is employed, patients must be observed in a fully equipped and staffed environment for at least 24 hours after the initial dose. Single-dose Duramorph neuraxial administration may result in acute or delayed respiratory depression for up to 24 hours. Monitor patients receiving Infumorph, as appropriate, for the first several days after catheter implantation.</p> <p>Morphine exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to</p>

Drug Name	Black Box Warning
	<p>prescribing morphine and monitor all patients regularly for the development of these behaviors and conditions.</p> <p>Serious, life-threatening, or fatal respiratory depression may occur with use of morphine. Monitor for respiratory depression, especially during initiation of morphine or following a dose increase. Swallow morphine ER formulations whole. ER capsule contents may be sprinkled on applesauce and swallowed immediately without chewing. Crushing, chewing, or dissolving the tablets or contents within the capsule can cause rapid release and absorption of a potentially fatal dose of morphine. Because of delay in maximum CNS effect with IV administration (30 minutes), rapid IV administration may result in overdosing. Observe patients in a fully equipped and staffed environment for at least 24 hours after each test dose of Infunorph and, as indicated, for the first several days after surgery.</p> <p>Prolonged use of morphine during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.</p> <p>Accidental ingestion of even one dose of morphine, especially by children, can result in a fatal overdose of morphine.</p> <p>Ensure accuracy when prescribing, dispensing, and administering morphine oral solution. Dosing errors due to confusion between mg and mL, and other morphine solutions of different concentrations, can result in accidental overdose and death</p> <p>Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of morphine and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.</p>
Mycophenolate/Mycophenolic Acid	<p>Only health care providers experienced in immunosuppressive therapy and management of organ transplant patients should prescribe mycophenolate. Manage patients receiving the drug in facilities equipped and staffed with adequate laboratory and supportive medical resources. The health care provider responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.</p> <p>Immunosuppression may lead to increased susceptibility to bacterial, viral, fungal, and protozoal infections, including opportunistic infections.</p> <p>Immunosuppression may lead to increased risk of development of lymphoma and other malignancies, particularly of the skin.</p> <p>Use during pregnancy is associated with increased risks of first trimester pregnancy loss and congenital malformations. Women of reproductive potential must be counseled regarding pregnancy prevention and planning.</p>
Neomycin Oral	<p>Systemic absorption occurs following oral administration and toxic reactions may occur. Therapy has been associated with potential neurotoxicity, ototoxicity, and nephrotoxicity. Patients with impaired renal function, advanced age, dehydration, and those who receive high dosage or prolonged therapy are at an increased risk of toxicity. Monitor renal and auditory function during therapy. Aminoglycoside-induced ototoxicity is usually irreversible. Neuromuscular blockade and respiratory paralysis have also been reported following administration. Concurrent use of other potentially neurotoxic or nephrotoxic agents, or potent diuretics should be avoided</p>
Nevirapine	<p>Severe, life-threatening, in some cases fatal, hepatotoxicity and skin reactions (eg, Stevens-Johnson syndrome; toxic epidermal necrolysis; and hypersensitivity reactions characterized by rash, constitutional findings, and organ dysfunction) have been reported. Women, including pregnant women, and/or patients with higher CD4+ cell counts are at higher risk of hepatotoxicity. Permanently discontinue nevirapine following severe hepatic, skin, or hypersensitivity reactions. Monitor patients intensively during the first 18 weeks of therapy with nevirapine to detect potentially life-threatening hepatotoxicity or skin reactions. Strictly follow the 14-day lead-in period with immediate-release nevirapine 200 mg daily dosing</p>
Nimodipine	<p>Do not administer nimodipine intravenously or by other parenteral routes. Deaths and serious, life threatening adverse events have occurred when the contents of nimodipine capsules have been injected parenterally</p>
Nitroprusside sodium	<p>Sodium nitroprusside may cause precipitous decreases in blood pressure and may lead to irreversible ischemic injuries or death. Continuous blood pressure monitoring is required. Sodium nitroprusside metabolism produces dose-related cyanide and may be lethal. Limit infusions at the maximum rate (10 mcg/kg/min) to the shortest duration possible as patient's ability to buffer cyanide will be exceeded in less than 1 hour at this rate [1].</p> <p>Sodium nitroprusside is not suitable for direct injection; the reconstituted solution must be further diluted in sterile 5% dextrose injection before infusion. Sodium nitroprusside can cause precipitous decreases in blood pressure; monitor blood pressure continuously while patient is on therapy. Nitroprusside can cause cyanide toxicity which can be lethal. Infusion at the maximum dose rate (10 mcg/kg/min) should never last more than 10 minutes. Monitor acid-base balance and venous oxygen concentration while on therapy; these tests may indicate cyanide toxicity</p>
Norepinephrine Bitartrate	<p>To prevent sloughing and necrosis in areas in which extravasation has taken place, the area should be infiltrated as soon as possible with 10 mL to 15 mL of saline solution containing from 5 mg to 10 mg of phentolamine mesylate for injection USP, an adrenergic blocking agent. Phentolamine should be given as soon as possible after the extravasation is noted</p>
Oxaliplatin	<p>Anaphylactic reactions to oxaliplatin have been reported, and may occur within minutes of oxaliplatin administration. Epinephrine, corticosteroids, and antihistamines have been employed to alleviate symptoms</p>
Oxycodone	<p>Misuse and abuse may lead to overdose and death. Assess risk before subscribing and regularly monitor for signs of these behaviors and conditions. Serious and potentially fatal respiratory depression may occur. Monitor for respiratory depression, particularly when initiating or increasing dosage. Accidental ingestion of one dose or</p>

Drug Name	Black Box Warning
	<p>more can lead to fatal overdose, especially in children. Prolonged use during pregnancy can lead to potentially life-threatening neonatal opioid withdrawal syndrome. Initiation of CYP3A4 inhibitors or discontinuation of CYP3A4 inducers may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for patients with inadequate alternative treatment options. Limit dosages and durations to the minimum required and follow patients for signs and symptoms of respiratory depression and sedation</p>
Oxycodone/Acetaminophen	<p>Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product</p> <p>Serious, life-threatening, or fatal respiratory depression may occur with use of oxycodone/acetaminophen ER. Monitor for respiratory depression, especially during initiation of oxycodone/acetaminophen ER or following a dose increase. Instruct patients to swallow oxycodone/acetaminophen ER tablets whole; crushing, chewing, or dissolving oxycodone/acetaminophen ER can cause rapid release and absorption of a potentially fatal dose of oxycodone.</p> <p>Accidental ingestion of oxycodone/acetaminophen ER, especially in children, can result in a fatal overdose of oxycodone.</p> <p>Prolonged use of oxycodone/acetaminophen ER during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.</p> <p>The concomitant use of oxycodone/acetaminophen ER with all cytochrome P450 3A4 inhibitors may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse reactions and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in oxycodone plasma concentration. Monitor patients receiving oxycodone/acetaminophen ER and any CYP3A4 inhibitor or inducer.</p> <p>Oxycodone/acetaminophen ER contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product.</p> <p>Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.</p> <p>Reserve concomitant prescribing of oxycodone/acetaminophen ER and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.</p> <p>Limit dosages and durations to the minimum required.</p> <p>Follow patients for signs and symptoms of respiratory depression and sedation</p>
Oxycodone Extended Release	<p>Use caution when prescribing and administering oxycodone oral solution as dosing errors due to mg and mL could result in accidental overdose and death. Ensure the proper dose is indicated and dispensed. Oxycodone oral solution should be kept out of the reach of children. Seek emergency help immediately if accidental ingestion occurs</p> <p>Addiction, abuse, and misuse, leading to overdose and death has been reported. Before prescribing, assess the patient's risk and watch for signs of the development of these behaviors. Serious and fatal respiratory depression may occur. Monitor for respiratory depression, especially when beginning treatment or increasing dose. Advise patients to swallow tablets whole to avoid overdose. Accidental ingestion can result in a fatal overdose, especially in children. Prolonged use in pregnancy may lead to life-threatening neonatal withdrawal syndrome. If oxycodone hydrochloride must be used during pregnancy, advise the patient of the risk and ensure that treatment will be available to the infant. Initiation of CYP3A4 inhibitors or discontinuation of CYP3A4 inducers can cause a fatal oxycodone hydrochloride overdose. Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for patients with inadequate alternative treatment options. Limit dosages and durations to the minimum required and follow patients for signs and symptoms of respiratory depression and sedation</p>
Paclitaxel	<p>Anaphylaxis and severe hypersensitivity reactions characterized by dyspnea and hypotension requiring treatment, angioedema, and generalized urticaria have occurred in clinical trials. Fatal reactions have occurred in patients despite premedication, and all patients should be pretreated with corticosteroids, diphenhydramine, and H₂ antagonists. Patients who experience severe hypersensitivity reactions to paclitaxel should not be rechallenged with the drug. Paclitaxel therapy should not be given to patients with solid tumors who have baseline neutrophil counts of less than 1500 cells/mm³ and should not be given to patients with AIDS-related Kaposi's sarcoma if the baseline neutrophil count is less than 1000 cells/mm³. Monitor peripheral blood cell counts frequently</p>
Paclitaxel Albumin Bound(Protein Bound)	<p>Do not administer paclitaxel protein-bound particles therapy to patients who have baseline neutrophil counts of less than 1500 cells/mm³. In order to monitor the occurrence of bone marrow suppression, primarily neutropenia, which may be severe and result in infection, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving paclitaxel protein-bound particles.</p> <p>Note: An albumin form of paclitaxel may substantially affect a drug's functional properties relative to those of drug in solution. Do not substitute for or with other paclitaxel formulations</p>

Drug Name	Black Box Warning
Panitumumab	Dermatologic toxicities were reported in 90% of patients and were severe in 15% of patients receiving panitumumab monotherapy
Penicillinamine (Cuprimine)	Physicians planning to use penicillamine should thoroughly familiarize themselves with its toxicity, special dosage considerations, and therapeutic benefits. Patients should be warned to report promptly any symptoms suggesting toxicity
Penicillin G Benzathine	Not for intravenous use. Do not inject intravenously or admix with other intravenous solutions. There have been reports of inadvertent intravenous administration of penicillin G benzathine which has been associated with cardiorespiratory arrest and death
Penicillin G Benzathine/penicillin G procaine	Not for intravenous use. Do not inject intravenously or admix with other intravenous solutions. There have been reports of inadvertent intravenous administration of penicillin G benzathine which has been associated with cardiorespiratory arrest and death
Phytonadione Injection	Severe reactions, including fatalities, have occurred during and immediately after IV or IM injection of phytonadione. These severe reactions have resembled hypersensitivity or anaphylaxis, including shock and cardiac or respiratory arrest. Limit the use of IV and IM routes to situations where the subQ route is not feasible and the serious risk involved is considered justified
Pioglitazone	Pioglitazone hydrochloride may cause or worsen congestive heart failure. Monitor patients for signs and symptoms of heart failure after initiation or dose increases. Should such signs and symptoms of congestive heart failure develop, manage according to current standards of care and consider discontinuing therapy or a dose reduction. Pioglitazone hydrochloride is not recommended in patients with symptomatic heart failure and is contraindicated in patients with established NYHA Class III or IV heart failure
Etoposide	Severe myelosuppression with resulting infection or bleeding may occur with etoposide
Polymyxin B Injection	<p>When this drug is given intramuscularly and/or intrathecally, it should be given only to hospitalized patients, so as to provide constant supervision by a physician.</p> <p>Renal function should be carefully determined and patients with renal damage and nitrogen retention should have reduced dosage. Patients with nephrotoxicity due to polymyxin B sulfate usually show albuminuria, cellular casts, and azotemia. Diminishing urine output and a rising BUN are indications for discontinuing therapy with this drug.</p> <p>Neurotoxic reactions may be manifested by irritability, weakness, drowsiness, ataxia, perioral paresthesia, numbness of the extremities, and blurring of vision. These are usually associated with high serum levels found in patients with impaired renal function and/or nephrotoxicity.</p> <p>The concurrent or sequential use of other neurotoxic and/or nephrotoxic drugs with polymyxin B sulfate, particularly bacitracin, streptomycin, neomycin, kanamycin, gentamicin, tobramycin, amikacin, cephaloridine, paromomycin, viomycin, and colistin should be avoided.</p> <p>The neurotoxicity of polymyxin B sulfate can result in respiratory paralysis from neuromuscular blockade, especially when the drug is given soon after anesthesia and/or muscle relaxants.</p> <p>Usage in pregnancy: The safety of this drug in human pregnancy has not been established [6].</p>
Prasugrel	Prasugrel can cause significant and sometimes fatal bleeding. Do not use prasugrel in patients with active pathological bleeding or a history of transient ischemic attack or stroke. Risk factors for bleeding include body weight of less than 60 kg, propensity to bleed, and concomitant use of medications that increase the risk of bleeding (eg, warfarin, heparin, fibrinolytics, chronic use of NSAIDs). Prasugrel is not recommended in patients 75 years of age or older, except for high-risk situations (diabetes, history of prior myocardial infarction). Do not start prasugrel in patients likely to undergo urgent CABG, and discontinue at least 7 days prior to any surgery. If possible, manage bleeding without discontinuing prasugrel, as discontinuation in the first few weeks after acute coronary syndrome may increase risk for subsequent cardiovascular events
Procarbazine	Adequate clinical and laboratory facilities should be available to patients treated with procarbazine for proper monitoring of treatment [4].
Primaquine	Physicians should completely familiarize themselves with the complete contents of this leaflet before prescribing primaquine phosphate
Procarbazine	Adequate clinical and laboratory facilities should be available to patients treated with procarbazine for proper monitoring of treatment
Progesterone	Estrogens plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia. Increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis in postmenopausal women (50 to 79 years of age) have been reported with estrogen plus progestin therapy. An increased risk of developing probable dementia in postmenopausal women 65 years of age or older has also been reported. Risks should be assumed to be similar for other doses, combinations, and dosage forms of estrogens and progestins. Progestins with estrogens should be prescribed at the lowest effective doses and for the shortest duration possible
Promethazine	Promethazine hydrochloride injection should not be used in pediatric patients less than 2 years old because of the potential for fatal respiratory depression. Respiratory depression, including fatalities, have been reported with use of promethazine in pediatric patients less than 2 years old in postmarketing experience. Exercise caution when administering promethazine hydrochloride injection to pediatric patients 2 years or older. Regardless of the administration route, promethazine hydrochloride injection can cause severe chemical irritation and damage to the tissue. Adverse reactions include burning, pain, thrombophlebitis, tissue necrosis, and gangrene, requiring surgical intervention, skin graft and/or amputation in some cases. Due to the risks of IV administration, the preferred route of administration is deep IM injection. Subcutaneous injection is contraindicated

Drug Name	Black Box Warning
	<p>Promethazine hydrochloride should not be used in pediatric patients less than 2 years old because of the potential for fatal respiratory depression. Exercise caution when administering to pediatric patients 2 years or older and use at the lowest effective dose. Avoid concomitant use of other drugs with respiratory depressant effects</p> <p>Promethazine hydrochloride should not be used in pediatric patients less than 2 years old because of the potential for fatal respiratory depression. Exercise caution when administering to pediatric patients 2 years or older and use at the lowest effective dose. Avoid concomitant use of other drugs with respiratory depressant effects</p>
Propafenone	It is prudent to consider any Class 1C antiarrhythmic to have a significant proarrhythmic risk in patients with structural heart disease. Given the lack of any evidence that these drugs improve survival, antiarrhythmic agents should generally be avoided in patients with non-life-threatening ventricular arrhythmias, even if the patients are experiencing unpleasant, but not life-threatening, symptoms or signs
Propylthiouracil	Severe liver injury and acute liver failure, including fatalities, have been reported with propylthiouracil. Liver transplantation was required in some cases. Reserve propylthiouracil for patients who can not tolerate methimazole when radioactive iodine therapy or surgery are not appropriate treatment options. Propylthiouracil may be the preferred treatment when an antithyroid drug is indicated during or just prior to the first trimester of pregnancy, because of the risk of fetal abnormalities associated with methimazole
Quetiapine	Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Quetiapine fumarate is not approved for the treatment of patients with dementia-related psychosis or for patients under 10 years of age. There is an increased risk of suicidal thoughts and behavior in children, adolescents and young adults taking antidepressants. Monitor patients closely for clinical worsening and emergence of suicidal thoughts and behaviors
Quinidine Gluconate	Active antiarrhythmic therapy has resulted in increased mortality; the risk is probably greatest in patients with structural heart disease
Quinine	Quinine sulfate use for the treatment or prevention of nocturnal leg cramps may result in serious and life-threatening hematologic reactions, including thrombocytopenia and hemolytic uremic syndrome/thrombotic thrombocytopenic purpura (HUS/TTP). Chronic renal impairment associated with the development of TTP has been reported. The risk associated with quinine sulfate use in the absence of evidence of its effectiveness in the treatment or prevention of nocturnal leg cramps outweighs any potential benefit
Raloxifene	Increased risk of deep vein thrombosis and pulmonary embolism have been reported. Women with active or past history of venous thromboembolism should not take raloxifene hydrochloride. Increased risk of death due to stroke occurred in a trial in postmenopausal women with documented coronary heart disease or at increased risk for major coronary events. Consider risk-benefit balance in women at risk for stroke
Ribavirin	Ribavirin monotherapy is ineffective for treatment of chronic hepatitis C virus infection. The primary toxicity is hemolytic anemia, which may result in worsening of cardiac disease and fatal and nonfatal myocardial infarctions. Avoid use in patients with significant or unstable cardiac disease. Significant teratogenic and embryocidal effects have been demonstrated in all animal species exposed to ribavirin. Ribavirin is contraindicated in women who are pregnant and in male partners of women who are pregnant. Use 2 reliable forms of contraception and avoid pregnancy during therapy and for 6 months after completion of treatment in both female patients and in female partners of male patients who are taking ribavirin
Rituximab	Fatal infusion reactions may occur within 24 hours of rituximab infusion; approximately 80% of fatal reactions occurred with the first infusion. Monitor patients and discontinue rituximab infusion after severe reactions. Severe and potentially fatal mucocutaneous reactions can occur. Reactivation of hepatitis B virus (HBV) may occur; in some cases, it results in fulminant hepatitis, hepatic failure, or death. Screen patients for HBV infection prior to treatment. Progressive multifocal leukoencephalopathy (PML) and death can also occur
Rivaroxaban	Premature discontinuation of any oral anticoagulant, including rivaroxaban, increases the risk of thrombotic events. To reduce this risk, consider coverage with another anticoagulant if rivaroxaban is discontinued for a reason other than pathological bleeding or completion of a course of therapy. Epidural or spinal hematomas, which may result in long-term or permanent paralysis, have occurred in patients treated with rivaroxaban who are receiving neuraxial anesthesia or undergoing spinal puncture. Optimal timing between the administration of rivaroxaban and neuraxial procedures is not known. Factors that can increase the risk of developing hematomas include: use of indwelling epidural catheters; concomitant use of drugs affecting hemostasis, such as NSAIDs, platelet inhibitors, or other anticoagulants; or a history of traumatic or repeated epidural or spinal punctures, spinal deformity, or spinal surgery. Monitor patients frequently for neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Consider risks/benefits before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis
Sirolimus	Increased susceptibility to infection and the possible development of lymphoma and other malignancies may result from immunosuppression. Only physicians experienced in immunosuppressive therapy and management of renal transplant patients should prescribe sirolimus for prophylaxis of organ rejection in patients receiving renal transplants, and they should have complete information requisite for the followup of the patient. The use of sirolimus in combination with cyclosporine or tacrolimus was associated with excess mortality, graft loss, and hepatic artery thrombosis in studies in de novo liver transplant patients. Cases of bronchial anastomotic dehiscence, most fatal, have been reported in de novo lung transplant patients when sirolimus was used as part of an immunosuppressive regimen. The safety and efficacy of sirolimus as immunosuppressive therapy have not been established in liver or lung transplant patients, and such use is not recommended
Sotalol	To minimize the risk of induced arrhythmia, patients initiated or reinitiated on IV sotalol or converted from IV to oral therapy should be placed in a facility that can provide continuous cardiac monitoring and calculations of creatinine clearance. Do not initiate sotalol therapy if the baseline QTc is longer than 450 milliseconds. If the QT interval prolongs to 500 milliseconds or greater, reduce dose, reduce rate of infusion, or discontinue drug. Adjust dosing interval based on creatinine clearance
Spironolactone	Spironolactone has been shown to be tumorigenic in chronic toxicity studies in rats. Use only as indicated and avoid unnecessary use

Drug Name	Black Box Warning
Stavudine	Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported. Fatal lactic acidosis has been reported in pregnant women who received the combination of stavudine and didanosine with other antiretroviral agents. The combination of stavudine and didanosine should be used with caution during pregnancy and is recommended only if the potential benefit clearly outweighs the potential risk. Fatal and nonfatal pancreatitis have occurred during therapy when stavudine was part of a combination regimen that included didanosine
Streptomycin	The risk of severe neurotoxic reactions (eg, disturbance of vestibular and cochlear function, optic nerve dysfunction, peripheral neuritis, arachnoiditis, and encephalopathy) is sharply increased in patients with impaired renal function or prerenal azotemia. The incidence of irreversible vestibular damage is particularly high in patients treated with streptomycin. Careful monitoring of renal function and dose reduction may be warranted. Avoid the concurrent or sequential use of other neurotoxic or nephrotoxic drugs with streptomycin. Neurotoxicity can result in respiratory paralysis from neuromuscular blockage, especially when the drug is given soon after the use of anesthesia or muscle relaxants. Parenteral streptomycin should be reserved for patients with adequate laboratory and audiometric testing available during therapy
Streptozocin	Renal toxicity from streptozocin is dose-related and cumulative and may be severe or fatal. Other major toxicities are nausea and vomiting which may be severe and at times treatment-limiting. In addition, liver dysfunction, diarrhea, and hematological changes have been observed in some patients. Streptozocin is mutagenic, and when administered parenterally, it has been found to be tumorigenic or carcinogenic in some rodents
Succinylcholine	Acute rhabdomyolysis with hyperkalemia followed by ventricular dysrhythmias, cardiac arrest, and death have been rarely reported in seemingly healthy children (usually, but not exclusively, males, and most frequently 8 years of age or younger) who were subsequently found to have undiagnosed skeletal muscle myopathy (most frequently Duchenne's muscular dystrophy) after administration of succinylcholine chloride. This syndrome often presents as peaked T-waves and sudden cardiac arrest within minutes after the administration of the drug. Treatment for hyperkalemia should be immediately instituted for infants or children who appear healthy but develop cardiac arrest, not felt to be due to inadequate ventilation, oxygenation, or anesthetic overdose after administration of succinylcholine chloride. Routine resuscitative measures are likely to be unsuccessful; extraordinary and prolonged resuscitative efforts may be required. If there are signs present for malignant hyperthermia, appropriate treatment should be instituted concurrently. It is recommended that succinylcholine chloride use in children be restricted to emergency intubation or instances where immediate securing of the airway is necessary
Tacrolimus	Increased susceptibility to infection and the possible development of lymphoma and other malignancies may result from immunosuppression. Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should prescribe, and they should have complete information requisite for the follow-up of the patient [5].
Tamoxifen	Serious and life-threatening uterine malignancies, stroke, and pulmonary embolism have been associated with tamoxifen use in the risk reduction setting (women with Ductal Carcinoma in Situ (DCIS) and women at high risk for breast cancer). Some of these adverse events were fatal. Health care providers should discuss the potential benefits versus the potential risks of these serious events with women at high risk of breast cancer and women with DCIS considering tamoxifen to reduce their risk of developing breast cancer. The benefits of tamoxifen outweigh its risks in women already diagnosed with breast cancer
Tenofovir Disoproxil Fum	Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including tenofovir disoproxil fumarate. Severe acute exacerbations of hepatitis have been reported in patients infected with hepatitis B virus (HBV) who have discontinued anti-hepatitis B therapy, including tenofovir disoproxil fumarate. Closely monitor hepatic function in these patients for several months following the discontinuation of emtricitabine and resume anti-HBV therapy if warranted
Terbutaline	Terbutaline sulfate has not been approved and should not be used for prolonged tocolysis (beyond 48 to 72 hours). In particular, terbutaline sulfate should not be used for maintenance tocolysis in the outpatient or home setting. Serious adverse reactions, including death, have been reported after administration of terbutaline sulfate to pregnant women. In the mother, these adverse reactions include increased heart rate, transient hyperglycemia, hypokalemia, cardiac arrhythmias, pulmonary edema and myocardial ischemia. Increased fetal heart rate and neonatal hypoglycemia may occur as a result of maternal administration
Testosterone Gel	Virilization has been reported in children who were secondarily exposed to testosterone gel. Children should avoid contact with unwashed or unclothed application sites in men using testosterone gel. Healthcare providers should advise patients to strictly adhere to recommended instructions for use
Thalidomide	Thalidomide can cause severe birth defects or embryofetal death, even with 1 dose, if taken during pregnancy. Thalidomide distribution is restricted through the THALOMID REMS(TM) program (formerly known as the S.T.E.P.S.(R) program). The use of thalidomide in multiple myeloma patients results in an increased risk of VTE, such as DVT and pulmonary embolism. Coadministration of dexamethasone increases this risk. Monitor for thromboembolism and consider thromboprophylaxis for individualized cases
Thiotepa	Thiotepa may cause severe marrow suppression, and high doses may cause marrow ablation with resulting infection or bleeding. Monitor hematologic laboratory parameters. Hematopoietic progenitor (stem) cell transplantation (HSCT) is required to prevent potentially fatal complications of the prolonged myelosuppression after high doses of thiotepa. Thiotepa should be considered potentially carcinogenic in humans
Thyroid hormone, Liothyronine	In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects
Tramadol, Ultram	Tramadol hydrochloride has the potential for addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing, and monitor for development of these behaviors or conditions. Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or

Drug Name	Black Box Warning
	following a dose increase. Accidental ingestion of tramadol hydrochloride, especially in children, can result in fatal overdose of tramadol hydrochloride. Prolonged use of tramadol hydrochloride during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available. Concomitant use or discontinuation of concomitantly used cytochrome P450 3A4 and cytochrome P450 2D6 inhibitors may effect the plasma levels of tramadol and its active metabolite M1 and lead to fatal respiratory depression, profound sedation, opioid toxicity, and/or opioid withdrawal. Monitor patients carefully when tramadol hydrochloride and cytochrome P450 3A4 and cytochrome P450 2D6 inhibitors are concurrently used. Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for patients with inadequate alternative treatment options. Limit dosages and durations to the minimum required and follow patients for signs and symptoms of respiratory depression and sedation
Trastuzumab	Trastuzumab can result in subclinical and clinical cardiac failure, with the greatest risk and severity upon concurrent administration with anthracyclines. Evaluate cardiac function prior to and during treatment. Discontinue trastuzumab in patients receiving adjuvant therapy and withhold trastuzumab for a clinically significant decrease in left ventricular function. Serious and fatal infusion reactions and pulmonary toxicity may occur during or within 24 hours after administration. Discontinue trastuzumab if signs of anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome are noted. Exposure during pregnancy can result in oligohydramnios, in some cases complicated by pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception
Valproic acid	Hepatotoxicity (some cases fatal), usually occurring during the first 6 months of treatment, has been reported in patients receiving valproate and its derivatives. Children younger than 2 years and patients with hereditary mitochondrial disease are at a considerably increased risk of developing fatal hepatotoxicity. Use is contraindicated in patients with known mitochondrial disorders caused by mitochondrial DNA polymerase gamma (POLG) mutations and in children younger than 2 years in which mitochondrial disorder is clinically suspected. Failure of other anticonvulsants is the only indication for valproate use in patients older than 2 years with hereditary mitochondrial disease. Perform POLG mutation screening as clinically indicated. Monitor patients closely and perform liver function tests prior to therapy and at frequent intervals thereafter, especially during the first 6 months. Valproate can impair cognitive development with prenatal exposure and produce major congenital malformations, particularly neural tube defects (eg, spina bifida). Valproate should not be administered to a woman of childbearing potential unless the drug is essential to the management of her medical condition. Life-threatening pancreatitis has been reported in both children and adults receiving valproate. Cases have occurred shortly after initiation as well as several years after use. If pancreatitis is diagnosed, valproate should ordinarily be discontinued
Vecuronium	This drug should be administered by adequately trained individuals familiar with its actions, characteristics, and hazards
Vinblastine	For intravenous use only; fatal if given by other routes. To reduce the potential for fatal medication errors due to incorrect route of administration proper dilution, product labeling and packaging is necessary. Intravenous needle or catheter must be properly positioned before any vinBLASTine is injected, as leakage into the surrounding tissue may cause considerable irritation. If extravasation occurs, the injection should be discontinued immediately, and any remaining portion of the dose should then be introduced into another vein
Vincristine	For intravenous use only; fatal if given by other routes. To reduce the potential for fatal medication errors due to incorrect route of administration proper dilution, product labeling and packaging is necessary. Intravenous needle or catheter must be properly positioned before any vinCRISTine is injected, as leakage into the surrounding tissue may cause considerable irritation. If extravasation occurs, the injection should be discontinued immediately, and any remaining portion of the dose should then be introduced into another vein. Local injection of hyaluronidase and the application of moderate heat to the area of leakage help disperse the drug and are thought to minimize discomfort and the possibility of cellulitis
Vinorelbine	Myelosuppression: Severe myelosuppression resulting in serious infection, septic shock, hospitalization and death may occur. Decrease the dose or withhold vinorelbine in accord with recommended dose modifications
Warfarin	Warfarin can cause major or fatal bleeding. Regular monitoring of INR should be performed on all treated patients. Drugs, dietary changes, and other factors affect INR levels achieved with warfarin sodium therapy. Instruct patients about prevention measures to minimize risk of bleeding and to report signs and symptoms of bleeding [5].
Zidovudine	Zidovudine has been associated with hematologic toxicity, including neutropenia and severe anemia, particularly in patients with advanced HIV disease. Prolonged use of zidovudine has been associated with symptomatic myopathy. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported. Suspend treatment if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity occur [10].

PATIENT CARE SERVICES

ISSUE DATE: 12/15

SUBJECT: Clinical Alarm Management

REVISION DATE(S): 12/15, 08/18

Patient Care Services Content Expert Department Approval: 05/1806/21
Clinical Policies & Procedures Committee Approval: 06/1802/22
Nursing Leadership Executive Committee Approval: 07/1803/22
Medical Staff Department/Division Approval: n/a
Pharmacy & Therapeutics Committee Approval: n/a
Medical Executive Committee Approval: 07/1803/22
Administration Approval: 08/1804/22
Professional Affairs Committee Approval: n/a
Board of Directors Approval: 08/18

A. DEFINITION(S):

1. Clinical alarms: Alarms on equipment or devices used for physical or physiological monitoring to protect the patient.
2. Alarm fatigue: Desensitization of clinicians due to exposure to excessive alarms.
3. Nuisance Alarms — ~~A~~Non-actionable alarms which do not require medical intervention.

B. POLICY:

1. This policy ensures the effectiveness of clinical alarm systems by providing regular preventative maintenance and testing of alarm systems; assuring that alarms are activated with appropriate settings and are sufficiently audible with respect to the distances and competing noise within the unit; and defines the roles and responsibilities for alarm management.
2. Patients requiring medical equipment with clinical alarms will be placed in the appropriate patient care settings. Refer to Patient Care Services Policy: Admission Criteria-.
3. Alarm signals and parameter management: Failure to hear or respond to critical alarms may lead to unintended patient harm.
 - a. Alarms on clinical monitoring and intervention systems will be maintained in the “on” position and sufficiently audible to staff.
 - i. Alarms will be turned on by the clinician initiating the clinical monitoring.
 - ii. Alarms may not be turned off. Alarms will be “on” as long as the equipment is being used for the patient.
 - 1) Alarms may be suspended during direct patient care (e.g., bathing).
 - 2) All alarms must be resumed prior to the caregiver leaving the room.
 - 3) Alarms will not be set to such extremes that they fail to detect significant changes in a patient's condition.
 - b. Alarm parameters:
 - i. Alarm parameters should be initially set at the manufacturers default settings or to area/unit specific criteria.
 - ii. Parameters may be adjusted by a licensed clinician (within their scope of practice) based on the patient's clinical condition to reduce nuisance alarms and alarm fatigue.
 - 1) The licensed clinician may set alarms within closer parameters, but never any less than the documented standard **unless ordered by the physician.**

- iii. Staff at the beginning of each shift or when care is initiated will ensure alarms are on and review the patient's alarm parameters, including alarm volume.
 - iv. Patient and/or family education regarding clinical alarms and parameters will be done by the RN/clinician as needed throughout the shift to decrease alarm induced anxiety and increase patient involvement in their care.
- 4. Responsible personnel
 - a. ~~The Patient Safety Committee~~~~Clinical Alarm Management Team~~ and Medical Executive Committee (MEC) are responsible for establishing alarm management guidelines based on manufacturer's recommendations and published best practices.
 - b. Directors and managers, or designee, are responsible for assessing staff competency and for providing training in the operation of medical and monitoring equipment to include the use of alarm systems.
 - c. Registered nurses (RN) are responsible for setting and validating clinical alarms.
 - d. A Monitor Technician (MT) will notify an RN or Advanced Care Technician (ACT) immediately when a patient's cardiac rhythm is not visible on the central monitor station.
 - i. The MT shall not change default cardiac settings or make parameter adjustments unless directed by the RN.
 - e. Respiratory therapists are responsible for setting and validating ventilator equipment, alarm limits, function, and audibility.
 - f. Licensed ancillary staff members (i.e. radiology technologists, MRI/CT specialists, Nuclear Medicine technologists) may within their scope of practice be responsible for setting and validating alarm limits, function, and audibility.
 - g. Clinical engineering (biomedical) is responsible for preventative maintenance.
 - h. All clinical staff shall respond promptly to any alarm intended to protect the patient receiving care.
 - i. Other personnel are responsible for alerting the appropriate clinician of a clinical alarm, but not adjusting unless within the scope of their training.
 - j. ~~All staff employees~~ are responsible ~~to~~ for identifying the source of an alarm and notifying the appropriate clinical staff for evaluation and intervention.
- 5. Alarm audibility:
 - a. The volume level of clinical alarms must be sufficiently audible with respect to distances and competing noise to be heard by the responsible clinicians in the immediate patient care area. The layout of the unit may impact the ability to hear certain alarms and require one or more of the following actions:
 - i. Alarm volume to be adjusted upward at certain times of the day based upon the noise level and activity in the patient care area.
 - ii. ~~The patient's~~ room/physical location may be moved to ensure audibility of the alarms.
 - iii. An area for charting may be set up closer to ~~the patient's~~ rooms to ensure audibility of alarms (zone charting).
 - iv. Doors to patient's rooms kept open, or partially open with the exception of select patient situations (i.e. isolation precautions, fire alarms, or specific patient/family requests).
 - v. In the event that the door to the patient room is closed, alarm audibility will be validated by the RN outside the closed door.
 - b. Critically ill patients ~~should~~**must** have cardiac monitors and/or ventilators visible from outside the patient room.
 - i. If the door to the patient's room is required to be closed, the curtain in the room will be kept partially open to allow for adequate visibility of the patient and the monitoring device.
- 6. Maintenance and testing of alarm systems
 - a. Engineering is responsible for the preventative maintenance of all medical equipment and alarm devices. ~~Refer to Engineering Policy: Equipment Management Plan~~
 - b. Clinical Engineering will maintain a current inventory of all medical equipment.

- c. Alarm malfunctions and apparent malfunctions must be reported to Biomedical Engineering via **TCMC's** the online work order system ~~found on the TCMC Intranet.~~
- i. Equipment with malfunctioning or apparent malfunctioning alarms must be taken out of service and evaluated by Biomedical Engineering personnel. . Refer to policy 8610-396: Incident report –Quality Review Report (QRR).

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

1. NICU Procedure: Pulse Oximetry
2. NICU Policy: Standards of Care
3. Patient Care Services Policy: Admission Criteria
4. Patient Care Services Policy: Pulse Oximetry
5. Patient Care Services Standardized Procedure: Standards of Care, Adult
6. Pulmonary Procedure: Mechanical Ventilation (Initial Set Up Protocol, Management and Troubleshooting)
7. Telemetry Unit Specific Policy: Management of Telemetry Patient 6150-108
8. Telemetry Unit Specific Procedure: Monitoring Telemetry Patients Using the DASH 3000
9. Women & Newborn Services Standardized Procedure: Standards of Care, Intrapartum
10. Women & Newborn Services Policy: Standards of Care, Newborn
11. Women & Newborn Services Policy: Standards of Care, Postpartum

D. **REFERENCE(S):**

1. **Bach, T.A., L. & Turk, E. (2018, July). Managing Alarm Systems for Quality and Safety in the Hospital Setting. MJ Open Quality 2018; 7(3): doi:10.1136/bmjog-2017-000202. Retrieved from the <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6069923/>**
- ~~4-2.~~ **The Joint Commission Perspectives;: Special Report: Suicide Prevention in Health Care Settings. November 2017** ~~July 2013~~, Vol.373, Issue 711.
- ~~2-3.~~ **ECRI Institute: Strategies to Improve Alarm Safety, 2014**

PATIENT CARE SERVICES

ISSUE DATE: 02/19

SUBJECT: Discharge Planning, Homeless
Patient Policy

REVISION DATE(S):

Patient Care Services Content Expert Approval:	12/18/21
Clinical Policies & Procedures Committee Approval:	12/18/22
Nursing Leadership Executive Committee Approval:	12/18/22
Utilization Review Committee Approval:	12/18/22
Medical Executive Committee Approval:	04/19/22
Administration Approval:	04/19/22
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	02/19

A. DEFINITION(S):

1. A homeless patient is an individual who:
 - a. Lacks a fixed and regular nighttime residence, or
 - b. Has a primary nighttime residence that is a supervised publicly- or privately-operated shelter designed to provide temporary living accommodations, or
 - c. Is residing in a public or private place that was not designed to provide temporary living accommodations or to be used as a sleeping accommodation for human beings.
2. Residence: the location identified to the hospital by the patient as his or her principal dwelling place.

B. POLICY:

1. The purpose of this policy is to help prepare the homeless patient for return to the community by connecting him or her with available community resources, treatment, shelter, and other supportive services.
2. Nondiscrimination policy: Housing status will not be used to discriminate against a patient or prevent medically necessary care or hospital admission.
3. This policy applies to patients discharged from Tri-City Medical Center.
4. All information about discharge will be provided to the homeless patient in culturally competent manner.
5. A homeless patient log will be available via the electronic health record.

C. PROCEDURE:

1. Patient Access Registrar will screen the patient to determine if homeless criteria are met.
 - a. The Patient Access Registrar will document the patient's answer or refusal to state by entering into the electronic health record.
2. The social worker, case manager, nurse and/or attending physician assigned to the patient will do further assessment to determine if the patient is homeless.
3. The social worker, case manager, and/or nurse will prepare an individual discharge plan for each homeless patient.
 - a. Discharge planning will be guided by the best interests of the homeless patient, his or her physical and mental condition, and his or her preferences for placement.
4. A post-discharge destination will be identified for each homeless patient, which may be:
 - a. A social services agency, nonprofit social services provider, or governmental services provider that has agreed to accept the patient.
 - i. The social worker, case manager, and/or nurse must document the name of person at the receiving agency or shelter who agreed to accept the patient.

- ii. The social worker, case manager, and/or nurse must send the receiving entity electronic information (depart) about the patient's post-discharge health and behavioral health needs.
 - b. The homeless patient's residence.
 - c. An alternative destination, as indicated by the homeless patient.
- 5. The hospital will not "cause the transfer" of a homeless patient to another county for the purpose of receiving supportive services from a social services agency, health care service provider, or nonprofit social services provider in the other county, unless the hospital has received prior authorization from the receiving entity to accept the specific patient.
- 6. Each homeless patient will be offered the following services prior to discharge:
 - a. The patient will be offered a physical exam and the physician will determine the patient's stability for discharge.
 - b. The patient will be given referrals for any needed follow-up care, both medical and behavioral, as determined by the treating physician. Referrals will include: the provider's name, address and phone number to make an appointment, other information as needed. If follow-up behavioral health care is recommended, the psych liaison will contact the patient's health plan or primary care provider or other provider (including entry into coordinated entry system), if applicable.
 - c. The patient will be offered a meal. This will be an inpatient tray or "to-go-meal" (bagged lunch).
 - d. If the patient's clothing is not weather-appropriate, the patient will be offered weather-appropriate clothing. Clothing available through social work, and also in specified patient care areas.
 - e. The patient will be provided discharge medications as determined by the treating physician via prescription (will need to provide medication supply when outpatient pharmacy is licensed during business hours).
 - f. The hospital will offer homeless patients when appropriate or refer homeless patients for infectious disease screening.
 - i. Infection Control is mandated to report all reportable diseases and conditions based on Title 17 to CDPH.
 - ii. All patients are "screened" for infectious diseases and reportable conditions based on signs and symptoms, lab tests, and risk factors.
 - g. The patient will be offered vaccinations appropriate to his or her presenting medical condition, as determined by the treating physician.
 - h. Hospital personnel will offer the patient transportation to his or her chosen discharge destination, if that destination is within 30 miles or 30 minutes of the hospital via appropriate transportation for the patient's condition.
 - i. The patient will be screened for, and helped to enroll in, any affordable health insurance coverage for which he or she is eligible by the hospital approved MediCAL screener.
 - j. Document homeless patient discharge plan in electronic health record.
- 7. A written plan for coordinating services and referrals for homeless patients is available including the following:
 - a. County behavioral health agencies
 - b. Healthcare and social services in San Diego County
 - c. Other healthcare providers
 - d. Nonprofit social services providers.
- 8. The plan will include a list of homeless shelters including:
 - a. Their hours of operation
 - b. Admission procedures/requirements
 - c. Population served
 - d. General scope of medical and behavioral health services available
 - e. Contact information for intake coordinator
 - f. Referral procedures
 - g. Training protocols for discharge planning staff.

D. **REFERENCE(S):**

1. California Hospital Discharge Planning for Homeless Patients: Understanding the law on preparing to return homeless patients to the community
2. SB 1152, Hernandez. Hospital patient discharge process: homeless patients.

PATIENT CARE SERVICES

ISSUE DATE: 12/01

SUBJECT: Emergency Cart (Crash Cart),
Cardiopulmonary Arrest

REVISION DATE: 06/03, 10/04, 11/06, 10/07, 06/08,
08/09, 08/12, 07/16, 03/19

Patient Care Services Content Expert Approval:	04/18/21
Clinical Policies & Procedures Committee Approval:	04/19/21
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Pharmacy & Therapeutics Committee:	n/a
Medical Executive Committee Approval:	02/19/22
Administration Approval:	03/19/22
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	03/19

A. POLICY:

1. Emergency Carts (crash carts) shall be checked at least daily for integrity and expiring products by a licensed healthcare provider or designee on the unit. This is documented by date, shift, and signatures in a logbook kept on top of the cart.
 - a. The licensed healthcare provider or designee checking cart will ensure missing items are replaced immediately. If items cannot be replaced in a timely manner, the cart should be replaced by the Sterile Processing Department (SPD).
 - b. A crash cart may be left on a unit that is closed if properly secured.
 - i. The crash cart does not require checking until the unit is re-opened.
 - 1) The licensed healthcare provider or designee will write "Unit Closed" in the logbook for the dates when the unit was closed.
2. Crash carts shall be stored in a visible or secure location.
3. SPD shall immediately replace any cart used during a Code Blue, Code Caleb or Code Pink with an Emergency Cart that has been checked for integrity and expiring products.
 - a. The replacement cart shall be deemed ready for use upon arrival to the unit.
 - b. After a code, one (1) lock is used to lock the cart before it is returned to SPD for cleaning.
 - c. The used crash cart shall remain locked and monitored until it is returned to SPD.
4. The Code Blue Committee shall make recommendations for content changes based on code evaluations and recommendations from the American Heart Association.

B. PROCEDURE FOR CHECKING CODE BLUE, CODE PINK AND CODE CALEB CRASH CARTS:

1. All documentation of cart checks is completed on the department specific Emergency Equipment/Supplies Checklist. All fields must be completed and the document signed.
 - a. Check the integrity of all locks/tags. If any lock/tag is broken, call SPD to replace the cart.
 - i. Adult cart document:
 - 1) Lock number on the locking bar on the crash cart.
 - ii. Pediatric cart document:
 - 1) Medication drawer expiration date and lock number
 - 2) IV drawer expiration date and lock number
 - 3) Red Airway Bag expiration date and lock number

- iii. Neonatal cart document:
 - 1) Medication drawer expiration date and lock number
 - 2) IV drawer expiration date and lock number
- b. Check the medication sticker and document medication expiration date. Ensure the sticker number matches the lock number. Notify Pharmacy of any lock number discrepancies.
 - i. Notify Pharmacy of expired medications.
- c. Check non-medication supply sticker(s) and document the expiration dates.
- d. Check IV solution sticker and document expiration date.
 - i. Notify SPD if any supplies are expired.
- e. Presence and function of suction equipment (except for neonatal cart).
 - i. Suction unit shall be checked unplugged for adequate function.
 - ii. Battery level of suction unit will be checked while unit is unplugged to ensure adequate charge.
- f. Presence of Resuscitation Code Record and Evaluation/Debriefing form on clipboard appropriate to type of cart (adult, pediatric, neonatal).
- g. Resuscitation algorithms appropriate for type of cart (adult, pediatric, neonatal).
- h. The inventory lists are available on the attached to side of cart.
 - i. The list is maintained and updated by SPD.
- i. One pack of ECG electrodes.
- j. Presence of resuscitation bag (Ambu) and supplies appropriate for type of cart (adult, pediatric, neonatal).
 - i. Check the mask to ensure the seal is sufficiently inflated.
- k. Presence of oxygen tank (except for neonatal cart).
 - i. Replace tank if gauge reads 1000 p.s.i. or less.
- l. Presence of extension cord/multi-outlet cord.
- m. Presence of backboard (except for neonatal cart).
- n. For Pediatric/Broselow Cart only:
 - i. Scissors
 - ii. Two (2) Alaris Pumps
- 2. For units with Automatic External Defibrillators (AED):
 - a. Check unit for flashing hourglass
 - i. If hourglass is not visible or not flashing, notify Clinical Engineering immediately.
 - b. Ensure two (2) packs of AED pads appropriate for type of cart (except for neonatal cart), Ensure pads are not expired.
 - c. Note: HouseWide AED's are checked daily by Security Staff.
- 3. For units with defibrillators, check defibrillator for proper functioning per Patient Care Services Procedure: Defibrillator Checks.
 - a. Ensure defibrillator pads appropriate for type of cart (except for neonatal cart), Ensure pads are not expired.

C. **FORM(S):**

- 1. Tri-City Medical Center Crash Cart Checklists – Age Specific

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

- 1. Patient Care Services (PCS) Policy: Rapid Response Team
- 2. PCS Procedure: Defibrillator Checks
- 3. PCS Procedure: Malignant Hyperthermia Management
- 4. Women & Newborn Services Procedure: Obstetrical (OB) Hemorrhage

UNIT: _____

TRI-CITY MEDICAL CENTER ADULT CRASH CART CHECKLIST MONTH/YEAR: _____

Legend: ✓ = Present/Checked R = Replaced	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
YELLOW LOCK # (check mark if unchanged from previous day)																															
YELLOW LOCK # MATCHES ORANGE STICKER #																															
MEDICATION DRAWER EXP DATE																															
CART (STERILE SUPPLIES) EXP. DATE																															
IV SOLUTION DRAWER EXP DATE																															
SUCTION UNIT TESTED (test unplugged, ensure battery is charged)																															
CARDIOPULMONARY ARREST RECORDS & EVALS																															
RESUSCITATION ALGORITHMS																															
CART INVENTORY LISTS																															
AMBU BAG																															
O₂ TANKS (PSI >1000)																															
EXTENSION/OUTLET CORD																															
BACKBOARD																															
REMOVE EXTRANEOUS SUPPLIES FROM TOP OF CART																															
AED																															
AED FLASHING BLACK HOURGLASS																															
AED PADS x2 (CHECK EXP. DATE)																															
DEFIBRILLATOR																															
DEFIB TESTED/BATTERY CHECKED																															
ECG ELECTRODES (Check exp. date)																															
GEL DEFIB PADS (Check exp. date)																															
MULTIFUNCTION PADS x2 (Check exp. date)																															
TIME UPDATED TWICE MONTHLY																															
SIGNATURE OF PERSON CHECKING CART, AED AND/OR DEFIBRILLATOR																															
SIGNATURE OF PERSON COMPLETING SECOND DEFIBRILLATOR CHECK (IF APPLICABLE)																															
NOTE: Episodic unit (i.e. procedural areas) shall check defibrillators once a day when unit is open																															

PATIENT CARE SERVICES

ISSUE DATE: 08/01 **SUBJECT:** Medication Administration

REVISION DATE(S): 06/02, 01/03, 06/03, 12/03, 02/04,
03/05, 03/06, 04/07, 03/08, 09/08,
04/09, 03/10, 01/11, 07/11, 04/12,
02/14, 12/15, 07/17, 03/19

Patient Care Services Content Expert Approval:	07/1811/21
Clinical Policies & Procedures Committee Approval:	11/1812/21
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Pharmacy & Therapeutics Committee Approval:	01/1902/22
Medical Executive Committee Approval:	02/1903/22
Administration Approval:	03/1904/22
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	03/19

A. DEFINITION(S):

1. Titrating Orders – orders in which the dose is either increased or decreased in response to the patient's clinical status. See Patient Care Services (PCS) Titrating Medications Policy.
2. Taper Orders – orders in which the dose is decreased by a specified amount with each dosing interval.
3. Indefinite Hold Medication Order – order for discontinuation of the medication (refer to PCS Automatic Stop Orders Policy).
4. Barcode medication administrator (BCMA) device [point of care (POC)] Solution designed to support positive patient identification using bar code technology. It is based on Cerner Millennium® Mobile technology and is deployed using hand-held devices with integrated bar code scanners.
5. Scheduled medications include all maintenance doses administered according to Tri-City Medical Center (TCMC) medication administration timeframes (e.g., QID, TID, BID, daily, weekly, monthly, and annually). Scheduled medications do not include:
 - a. STAT AND Now doses
 - b. First doses and loading doses
 - c. One-time doses
 - d. Specifically timed doses (e.g., antibiotic for surgical patient to be given a specified amount of time before incision, drug desensitization protocols)
 - e. On-call doses (e.g., pre-procedure sedation)
 - f. Time-sequenced or concomitant medications (e.g., chemotherapy and rescue agents, n-acetylcysteine and iodinated contrast media)
 - g. Drugs administered at specific times to ensure accurate peak/trough/serum drug levels.
 - h. Investigation drugs in clinical trials
 - i. PRN medications
6. STAT-medications to be given as soon as possible and within 30 minutes of availability of the medications.
7. Time-critical scheduled medications are those where early or delayed administration of maintenance doses of greater than 30 minutes before or after the scheduled dose may cause harm or result in substantial sub-optimal therapy of pharmacological effect. Examples of time-critical medications/medication types may include, but are not limited to:
 - a. Antibiotics

- b. Anticoagulants
 - c. Insulin
 - d. Anticonvulsants
 - e. Immunosuppressive agents
 - f. Pain medication
 - g. Medications prescribed for administration within a specified period of time of the medication order
 - h. Medications that must be administered apart from other medications for optimal therapeutic effect (i.e. ciprofloxacin and multivitamin)
 - i. Medications prescribed more frequently than every 4 hours
8. Non-time-critical scheduled medications are those where early or delayed administration within a specified range of 1 hour should not cause harm or result in substantial sub-optimal therapy or pharmacological effect.
9. Controlled Substance: is a drug, compound, mixture, preparation or substance included in Schedule II, III, IV, or V.

B. POLICY:

1. Medication Order Process

- a. Medications shall be administered only upon the order of medical staff members or allied health professionals who have been granted clinical privileges to write such orders under the guidelines of their respective scopes of practice.
 - i. Medications shall be administered according to the guidelines set forth in Administering Medication per Scope of Practice.
 - ii. See PCS Physician/Provider Orders Policy for information on ordering medication including telephone/verbal orders and PRN medications.
- b. Medication orders shall be reviewed by pharmacists before administration by a licensed healthcare ~~personnel~~ provider, unless a physician is overseeing administration of the medication, i.e. "Non-Profile" Pyxis areas.
 - i. See Pharmacy Unlabeled Uses of FDA Approved Medications Policy for information on additional information on unlabeled use of medications
- c. Registered Nurses (RN) shall verify all new medication orders for accuracy using Nurse Review each time an order is added to the Electronic Medication Administration Record (eMAR) by the pharmacist per PCS Physician/Provider Orders Policy. The paper MAR is to be used ONLY if the eMAR is unavailable to staff.
 - i. Respiratory Care Practitioners may conduct medication review for all nebulized and inhaled medications if the RN has not completed Nurse Review and one of the above medications is due for administration.
 - ii. Under the supervision of a physician, physician assistant, or other appropriate licensed person, medical assistants in an outpatient setting may administer medications, except controlled substances, in several ways to a patient, including simple injections, ingestion or pre-measured medications.
 - iii. Medical assistants who receive the appropriate training are allowed to administer injections of scheduled drugs only if the dosage is verified and the injection is intramuscular, intradermal or subcutaneous. The supervising physician or physician assistant must be on the premises as required in section 2069 of the Business and Professions Code, except as provided in subdivision (a) of that section. However, this does not include the administration of any anesthetic agent.
- d. A nurse may obtain medications not yet reviewed by a Pharmacist through the Pyxis override function only if need is deemed urgent or emergent.
 - i. Urgent indications include those in which significant patient harm could result from a delay secondary to a pharmacist's review of the order.
 - ii. Emergent indications include situations in which life, limb, or eyesight is threatened.

- iii. In each individual case, the need for the override must outweigh the risk of omitting the pharmacist's review of the order.
 - e. If orders are received with more than one set of ranges (dose and frequency), then the healthcare professional must clarify the order with the physician.
 - i. If clarification is not obtained before the dose is needed, the RN shall implement range orders at the smallest ordered dose and the longest time interval between doses, if repeated dosing would be required. However, if the patient assessment indicates a clinical need for more aggressive intervention, then the individual implementing the range-dosed medication may initiate treatment at a higher dosage or administer the medication at the more frequent time interval within the parameters of the order.
 - ii. Adjustments within the dose range are based on:
 - 1) Patient assessment
 - 2) Prior dose administered
 - 3) Time interval between doses
 - 4) Effectiveness of prior doses
 - f. The RN shall assess the patient and if therapy is not meeting clinical needs or desired response, the physician shall be contacted for dosage and/or frequency adjustment.
 - g. All continuous infusions of controlled substances shall have the medication in a secured device (for example lock box or locked infusion pump).
- 2. Medication Administration Process
 - a. The Electronic Medication Administration Record (eMAR) or paper MAR shall be evaluated at the beginning of each shift and PRN to:
 - i. Verify medications to be administered during the shift.
 - ii. Review and document review of allergies in the medical record.
 - iii. Conduct Nurse Review (RN Sign-off) on any medications that have not yet been reviewed (identified with the icon of Eyeglasses) per PCS Physician/Provider Orders Policy.
 - b. Once BCMA application on hand-held devices is implemented, the departments shall use BCMA for medication administration.
 - c. Medications brought from home may be administered only on the order of a physician per PCS Medication Brought in by Patient Policy.
 - i. A pharmacist shall positively identify the medication, print and initial a patient-specific medication label, and affix it to the medication container.
 - ~~d. Prior to administration of heparin, the amount ordered and prepared shall be verified by a 2nd RN or licensed practitioner per PCS Medication High Risk/High Alert Policy.~~
 - ~~i. Identification of the patient shall take place in the patient's room~~
 - ~~ii. Behavioral Health Unit will not be required to validate in patient's room due to safety issues~~
 - ~~iii. Document first and last name and title of second practitioner who verified the medication via BCMA device or electronic medical record.~~
 - e-d. Prior to administration of intravenous insulin, heparin, 10% magnesium sulfate, tissue plasminogen activator (tPA) and patient controlled analgesia (PCA), or any medication given through an epidural, the amount ordered, amount prepared, initial infusion rate, and any changes in infusion rate shall be verified by a second RN or licensed practitioner per PCS Medication High Risk/High Alert Policy.
 - i. Validation process shall take place in the patient's room.
 - ii. Document initiation and dose changes on eMAR/paper MAR. Document first and last name and title of second practitioner who verified under the comments section.
 - 1) Document epidural/PCA assessment in IView.
 - f.e. For maximum amounts of solution to be administered intramuscularly in one site see Intramuscular Administration Amount per Site.

- g-f.** Medication shall be administered immediately by the licensed healthcare ~~personnel~~ provider withdrawing the medication from an ampule or vial. If not administered immediately by the licensed staff, syringe must be labeled appropriately.

 - i.** Non-controlled - medications shall be withdrawn from a single dose vial at bedside.
 - ii.** Controlled Medication – requiring waste upon removal shall be performed according to PCS Controlled Substance (Narcotics) Management Policy and PCS Wasting Narcotics via Pyxis Machine Procedure.
- ~~**h.** Medication from ampules shall be prepared and labeled appropriately prior to entering patient room.~~
- i-g.** Medication from multi-dose vials shall be prepared and labeled appropriately prior to entering patient room or operating room.

 - i.** Only vials clearly labeled by the manufacturer for multiple dose use can be used more than once.
 - ii.** Limit use of a multi-dose vials to a single patient whenever possible.
 - iii.** Multi-dose medications used for more than one patient are stored and accessed away from the immediate areas where direct patient contact occurs.
 - iv.** If a multi-dose vial is taken into a patient room/operating room, it can only be used for that patient and must be discarded after use.
 - v.** When multiple dose vials are used more than once, use a new needle and new syringe for each entry.
 - vi.** Disinfect the vial's rubber septum before piercing by wiping (using friction) with an approved antiseptic swab. Allow the septum to dry before inserting a needle or other device into the vial.
 - vii.** All multi-dose vials once opened or punctured, shall be labeled with an expiration date of 28 days or the manufacturer's date or package insert recommendations, whichever is shorter.
- j-h.** Label all medications, medication containers (i.e., syringes, medicine cups, basins), or other solutions on and off the sterile field in perioperative and other procedural settings. Refer to PCS Labeling Medication On and Off the Sterile Field Procedure.
- k-i.** Never administer medications from the same syringe to more than one patient, even if the needle is changed or you are injecting through an intervening length of IV tubing.
- l-j.** Do not enter a medication vial, bag, or bottle with a used syringe or needle.
- ~~**m-k.**~~ A medication may only be diluted in the neonatal and pediatric population unless specified by the manufacturer.
- ~~**n-l.**~~ Never use medications packaged as single-dose or single-use for more than one patient. This includes ampules, insulin pens, bags, and bottles of intravenous solutions, and sterile water bottles.

 - i.** Use a single-dose/single-use vial for a single patient during the course of a single procedure
 - ii.** Discard the vial after this single use, used vials should never be returned to stock on clinical units, drug carts, anesthesia carts etc.
 - iii.** If a single dose/single use vial must be entered more than once during a single procedure for a single patient to achieve safe and accurate titration of dosage, use a new needle and new syringe for each entry
 - iv.** Select the smallest vial necessary when making treatment decisions to reduce waste
- o-m.** Always use aseptic technique when preparing and administering injections.
- p-n.** For patients age 13 years and younger, the maximum IV solution volume for administration is 500 mL.
- q-o.** Educate the patient/family/significant other according to comprehension level. Education should include:

 - i.** Drug name
 - ii.** Dose

- iii. Purpose
 - iv. Ask if they have any questions/concerns about taking the medication especially new or first time medications.
 - v. Side effects of medications.
 - 1) Adverse drug reactions or side effects may occur with the first dose or any subsequent dose.
 - vi. Licensed healthcare ~~personnel~~ providers shall provide teaching materials (drug leaflets, handbooks, videos, lectures, demonstration, and equipment) to all patients (parents, significant others) to prepare them for successful self-medication.
 - vii. Document all teaching ~~in the electronic health record (EHR) on the Education—All Topics Form.~~
 - r.p. Discuss any unresolved, significant patient/family concerns about the medication with the patient's physician, prescriber (if different from the physician), and/or relevant staff involved with the patient's care, treatment, and services. Document in the ~~EHR~~ medical record.
 - s-q. The licensed healthcare ~~personnel~~ provider shall accurately document medication at the time of administration.
 - t-r. Scheduled medications shall be administered within 1 hour prior to the order time and 1 hour after the order time.
 - u-s. If a medication cannot be given at the time ordered, the appropriate reason shall be documented on the eMAR/paper MAR.
 - v-t. When administering medications from a standardized procedure, the **Registered Nurse (RN)** ~~health care provider~~ shall enter the order electronically
 - i. Exception: Orders generated by screening in Cerner
 - w-u. If a medication is not administered or used, it shall be returned, wasted within 1 hour or at the end of procedure per Patient Care Services Controlled Substance (Narcotics) Management Policy.
3. Self Administration/Non-Staff
- a. Persons who administer medications, but are not staff members (including the patient if self-administering), must demonstrate ability to safely administer medication before being allowed to self-administer medications. This includes understanding medication name, type, reason for use, how to administer medication (including process, time, frequency route and dose) and anticipated action/side effects of medication administered
 - i. If they cannot demonstrate the ability to safely administer medications:
 - 1) They will not be able to self-administer until the ability is demonstrated.
 - 2) Licensed healthcare ~~personnel~~ providers will provide teaching using Tri-City Medical Center approved drug leaflets, handbooks, videos, lectures, demonstration, and equipment to all patients (parents, significant others) to prepare them for successful self-medication.
 - 3) Discharge planning shall include a follow-up plan as needed.
4. Monitoring Effects of Medications on Patients
- a. Effects of medications on patients are monitored to assess the effectiveness of medication therapy and to minimize the occurrence of adverse events.
 - i. Each patient's response to medication administered is monitored according to his or her clinical needs.
 - ii. Ongoing patient medication monitoring will use a collaborative approach between patient care providers, physician, pharmacists and the patient, family or caregiver.
 - b. Monitoring will address the patient's response to the prescribed medication and actual or potential medication-related problems.
 - c. The results of patient medication monitoring will be used to improve the patient's medication regimen and/or other clinical care and treatment processes.

- i. The physician/Allied Health Professional will be notified if the medication therapy is not achieving the desired effect.
5. Medication Handling, Storage, and Disposal
 - a. All medications received from the pharmacy shall be placed in approved storage areas as soon as possible, not to exceed 30 minutes from the time of receipt.
 - b. Any medication removed from the medication storage area:
 - i. Shall remain with the individual at all times and shall not be left unattended including flushes and vials.
 - ii. Shall not be left on or in any area exceeding 80°F. This includes the pockets of the healthcare ~~personnel~~ provider.
 - iii. No medications shall be left at the bedside.
 - 1) Exception: Appropriately labeled topical ointments, creams, or pads as approved by the Pharmacy and Therapeutics Committee and ordered for bedside storage by the physician/Allied Health Professional
 - 2) Exception: In areas with designated storage area, medications shall be kept secured.
 - c. Access to medications and syringes are limited to appropriate staff via locked or computerized controlled access.
 - d. In all inpatient areas, insulin pens, creams, inhalers, eye drops and other medications that are not stored in the Pyxis medication station must be kept in patient-specific bins in a locked cabinet in the medication area.
 - i. The primary nurse will be responsible for transferring these medications when a patient is transferred to another unit or room.
 - ii. The primary nurse will be responsible for returning un-used medications or disposing of opened medications when a patient is discharged from the hospital.
 - iii. The primary nurse must clean the medication bin with a sani-wipe after patient transferred or discharged.
 - e. A device holder will be used when administering a medication from a pre-filled syringe.
 - f. Any intravenous solutions spiked outside of a laminar flow hood must be initiated/administration started within 1 hour of being spiked.
 - g. Nursing personnel shall only compound or admix when not feasible for pharmacy to do so (i.e. emergency or product stability is short). Refer to Patient Care Services procedure Admixture, Intravenous). Medication preparation is performed by using aseptic technique as appropriate in a clean, uncluttered, functionally separate area, to minimize the possibility of contamination.
 - h. Unused/Intact Medication removed from the Medication Pyxis and not administered shall be returned to the Pyxis "Return Bin" with the exception of refrigerated and some designated controlled substance medication.
 - i. For non-controlled medications that are too large, place into the red external "Return to Pharmacy" bin.
 - ii. For controlled substances that are too large to be returned to the Medication Pyxis, contact pharmacy for assistance.
 - i. At discharge, unused intact medications shall be returned to the pharmacy.
 - j. For proper disposal of pharmaceutical waste,
 - i. See Administrative Policy #276 Handling of Pharmaceutical Waste, Expired Medications, and Expired IV Solutions.
 - ii. See the Patient Care Services procedure Hazardous Drugs for hazardous drug disposal and waste.
 - k. Patient specific medications maybe delivered by TCMC personnel as designated per Pharmacy.
6. Medication Error/Near Miss Reporting – see Administrative Policy: ~~Event~~ Incident Reporting–
Quality Review Report (QRR) ~~RL Solutions Policy Number 8610-396~~

C. **PROCEDURE:**

1. For Departments Using BCMA:
 - a. Prior to administering a medication, the licensed healthcare ~~personnel~~provider shall:
 - i. Verify correct patient
 - 1) Use two patient identifiers (see PCS Identification, Patient Policy)
 - ii. Verify medications due per eMAR
 - 1) Verify RN review completed, no eyeglasses icon, in all areas (except ED)
 - 2) Review allergies to make sure all information is current and correct before administration of any medications
 - 3) Review for any contraindication(s) for administering medication
 - a. Prepare medications for one patient at a time with the patient's current, updated eMAR for accuracy.
 - i. Verify correct dose, route and time
 - ii. Verify expiration date on medication package
 - iii. Visually inspect medication integrity (i.e., discoloration, particulates, turbidity when a medication should be clear) or torn packaging may be signs of medication deterioration
 - iv. Take all medication in their original packages into patient room to be scanned. When any medication is removed from package for mixing, crushing, or splitting, the package must be taken into patient room.
 - 1) Medications shall be crushed and administered separately.
 - 2) Crusher shall be cleaned after each crush if medication cups are not used inside of crusher.
 - 3) Pill splitter shall be cleaned after each use
 - b. Retrieve hand-held device from the unit specific secure hand-held device storage area.
 - c. Scan the "Aztec" barcode on the patient ID band to ensure the right patient record is opened on the BCMA application.
 - d. If a patient ID band does not scan, the licensed healthcare ~~personnel~~provider may replace the patient ID band, or manually search for the patient on the hand-held device using the patient identifiers on the patient ID band. Scan each medication with the hand-held device to ensure additional medication "rights" for mistake free medication are identified.
 - i. Verify correct:
 - 1) Patient
 - 2) Dose
 - 3) Time
 - 4) Medication
 - 5) Route/ Rate (if applicable)
 - 6) Documentation
 - 7) Reason
 - e. Assess and resolve any warning message(s).
2. Educate the patient/family/significant other and address any unresolved concerns about the medication.
 - a. Name of the drug, the dose, and the purpose according to the patient's ability to comprehend.
 - b. Side effects of medications.
 - i. Adverse drug reactions or side effects may occur with the first dose or any subsequent dose.
 - c. Licensed healthcare ~~personnel~~providers shall provide teaching materials (drug leaflets, handbooks, videos, lectures, demonstration, and equipment) to all patients (parents, significant others) to prepare them for successful self-medication.
 - d. Document all teaching in the ~~EHR~~on the ~~Education~~ — All Topics Form.
3. Administer medications after the medications are scanned and all "rights" are assured to be accurate.

- a. STAT or one-time medications shall be given as soon as they are available and the exact time given shall be documented.
 - b. The licensed health care ~~personnel~~ ~~provider~~ administering oral medication shall remain with the patient until the medication is successfully administered.
4. Sign the medications on the hand-held device after the medication is given and/or successfully administered. Comments may be added as required.
 - a. The BCMA application will automatically update the Cerner system (eMAR) with the data entered.

D. FOR DEPARTMENTS NOT USING BCMA:

1. Prior to administering a medication, the licensed healthcare ~~personnel~~ ~~provider~~ shall:
 - a. Verify correct patient
 - i. Use two patient identifiers (see PCS Identification, Patient Policy)
 - b. Verify medications due per eMAR
 - i. Verify RN review completed, no eyeglasses icon, in all areas (except ED)
 - ii. Review allergies and/or contraindication(s) for administering medication
2. Prepare medications for one patient at a time with the patient's current, updated eMAR for accuracy.
 - a. Verify correct dose, route and time
 - b. Verify expiration date on medication package
 - c. Visually inspect medication integrity (i.e., discoloration, particulates, and turbidity when a medication should be clear) or torn packaging may be a sign the medication deterioration
 - d. Medication may be withdrawn from vial at bedside and shall be administered immediately. If medicine is prepared in the Medication room – the syringe must be labeled appropriately.
 - e. The medication "rights" are identified before the medication is administered. Verify the following are correct:
 - i. Patient
 - ii. Dose
 - iii. Time
 - iv. Medication
 - v. Route/ Rate (if applicable)
 - vi. Documentation
 - vii. Reason
 - f. Medications shall be crushed and administered separately. Crusher shall be cleaned after each crush if medication cups are not used inside the device.
3. Educate the patient/family/significant other and address any unresolved concerns about the medication.
 - a. Name of the drug, the dose, and the purpose according to the patient's ability to comprehend.
 - b. Side effects of medications.
 - i. Adverse drug reactions or side effects may occur with the first dose or any subsequent dose.
 - c. Licensed healthcare ~~personnel~~ ~~providers~~ shall provide teaching materials (drug leaflets, handbooks, videos, lectures, demonstration, and equipment) to all patients (parents, significant others) to prepare them for successful self-medication.
 - d. Document all teaching in the ~~EHR~~ ~~on the Education – All Topics Form~~.
4. Administer medications after all "rights" are assured
5. The licensed health care ~~personnel~~ ~~provider~~ administering oral medication must remain with the patient until the medication is successfully administered.
6. The licensed healthcare ~~personnel~~ ~~provider~~ shall then accurately document medication administration in the eMAR or paper MAR as soon as possible after the dose is given.

E. OUTPATIENTS:

1. Any medication brought to the hospital by a patient who is to receive outpatient testing is the sole responsibility of the patient.
2. The hospital shall not administer nor handle any medications brought into the facility by patients for outpatient testing.

F. CHEMOTHERAPY ADMINISTRATION:

1. Chemotherapeutic agents shall be administered by TCMC chemotherapy credentialed RNs per the Oncology Chemotherapy Administration.
2. Notify pharmacy and oncology unit if chemotherapeutic agents are to be administered in areas other than dedicated chemotherapy area.

G. HAZARDOUS DRUGS, HANDLING OF:

1. See PCS Hazardous Drugs Procedure

H. RELATED DOCUMENT(S):

1. Administrative Policy: Incident Report - Quality Review Report (QRR) RL Solutions – 8610-396
2. Administering Medication per Scope of Practice
3. How Fast Can I Give That? IV Push Rate
4. Intramuscular Administration Amount per Site
5. Intravenous (IV) Medication Administration by Location
6. Medication Administration Time Frames
7. PCS Procedure: Chemotherapy Administration
8. PCS Procedure: Admixture, Intravenous
9. PCS Policy: Automatic Stop Orders
10. PCS Policy: Controlled Substance (Narcotics) Management
11. PCS Procedure: Hazardous Drugs
12. PCS Policy: Identification, Patient
13. PCS Procedure: Labeling Medication On and Off the Sterile Field
14. PCS Policy: Medication Brought in by Patient
15. PCS Policy: Medication, High Risk/High Alert
16. PCS Policy: Physician/Provider Orders
17. PCS Policy: Titrating Medications
18. PCS Procedure: Wasting Narcotics via Pyxis Machine
19. Pharmacy Policy: Unlabeled Uses of FDA-Approved Medications

I. EXTERNAL LINK(S):

1. Elsevier Medication Administration: Intravenous Bolus

Administering Medication per Scope of Practice

X indicates who may administer	IV	IV PUSH	IVPB	PO	SQ	IM	SL	Intra-dermal	Topical	Inhalant Aerosol
RN	X	X	X	X	X	X	X	X	X	X
LVN I/Licensed Psychiatric Technician				X	X	X	X	X	X	X
LVN II (IV-certified) May only administer electrolytes, vitamins, nutrients, blood, and blood products	X			X	X	X	X	X	X	X
Respiratory Care Practitioners								X		X
Physical Therapist									X	
Licensed Physical Therapy Assistant									X	
Radiologic Technologists under physician guidance*	X			X						
Nuclear Med Technician*	X									
EKG/Echo Tech under direct supervision of physician as part of EKG/Echo procedure							X			
Medical Technicians								X		
Student RCP under supervision										X
Medical Assistants				X	X	X	X	X	X	

*Only RN's may administer IV medications via PICC and central lines.

How Fast Can I Give That? IV Push Rate

Medication	Rate of Admin	Medication	Rate of Admin	Medication	Rate of Admin
acetaZOLAMIDE	3 minutes	esmolol	30-60 seconds		≤ 125mg: 3-15 minutes 250mg: 15-30 minutes >500mg: 30-60 minutes
adenosine*	1 to 2 seconds	etomidate	30-60 seconds	methylPREDNISolone	
alteplase	Stroke 1 minute	famotidine*	2 minutes	metoclopramide*	≤ 10mg: 1-2 minutes
aminophylline*	30-60 seconds	fentaNYL*	1-2 minutes	metoprolol	2-5mg/minute
amiodarone	Pulseless VT or VF: Rapid IV push	flumazenil	30 seconds	midazolam*	RSI: 30 seconds Other: 2-5 minutes
atropine*	Rapid IV push	fosphenytoin	150mg PE/minute	morphine*	2-5 minutes
aztreonam	3-5 minutes	furosemide*	40mg/minute	nalbuphine	2-3 minutes
benztropine	1 minute	glucagon	1 minute	naloxone*	30 seconds
bumetanide	Rapid IV push	glycopyrrolate	2 minutes	octreotide	3 minutes
calcitriol	Rapid IV push	haloperidol	5mg/minute	ondansetron	2-5 minutes
calcium chloride*	2-5 minutes or 100mg/min	heparin	5000 units/minute	pantoprazole	2 minutes
calcium gluconate*	2-5 minutes or 200mg/min	hydrALAZINE	5mg/minute	phenobarbital*	50mg/minute
ceFAZolin*	3-5 minutes	hydrocortisone *	For Doses<500mg: 30 seconds	phenytoin	50mg/minute
cefoTEtan	3-5 minutes	HYDROmorphone	2-5 minutes	prochlorperazine	5mg/minute
ceftAZidime*	3-5 minutes	insulin regular/ lispro	50 units/minute	rocuronium	Rapid IV injection
cefTRIAxone*	2-4 minutes	ketamine	1 minute	sodium bicarbonate*	Cardiac arrest: Rapid IV push Other: 3-5 minutes
cisatracurium*	5-10 seconds	ketorolac	15 seconds	succinylcholine	10-30 seconds
cosyntropin	2 minutes	labetalol	10mg/minute	vecuronium	Rapid IV push
desmopressin	1 minute	levothyroxine*	1 minute		
dexamethasone*	1-4 minutes	lidocaine*	Stable VT: 25-50mg/minute VF or Pulseless VT: Rapid IV bolus	verapamil	2.5mg/minute
dextrose 50%	200mg/kg/min	lorazepam*	2mg/minute		
digoxine immune fab (Digifab)	IV bolus if cardiac arrest imminent	magnesium sulfate	Eclampsia/seizure: 3-4 minutes Cardiac Emergency: Rapid IV push		
diltiazem	2 minutes	meperidine	2-5 minutes		
diphenhydrAMINE	25mg/minute	methocarbamol	3mL/minute		
enalaprilat	5 minutes	methohexital	1mL/5 seconds		
EPINEPHrine*	Rapid IV push	methylergonovine	1 minute		

*For NICU administration refer to Neofax guidelines

Intramuscular Administration Amount per Site

Age group (years)	Needle Length-max	Needle gauge	Volume-Max	Site(s)
Infant (0-1.5)	5/8 inch	25-27	0.5-1 mL: infant less than 1500 gm, maximum 0.5 mL	<ul style="list-style-type: none"> Vastus lateralis Rectus femoris
Toddler/ Preschool (1.5-3)	1 inch	22-23	1 mL	<ul style="list-style-type: none"> Vastus lateralis Rectus femoris Dorsogluteal (for children who has been walking for at least one year)
Preschool (3-6)	1 inch	22-23	Deltoid: 0.5 mL All other sites: 1.5 mL	<ul style="list-style-type: none"> Vastus lateralis Rectus femoris Dorsogluteal Ventrogluteal (for children who have been walking for several years) Deltoid (for children over 4 – 5 years of age due to small muscle mass)
School Age (6-15)	1-1 ½ inch	22-23	Deltoid: 0.5 mL All other sites: 1.5-2.0 mL	<ul style="list-style-type: none"> Vastus lateralis Rectus femoris Dorsogluteal Ventrogluteal Deltoid
Adolescent (up to 21)	1-1 ½ inch	22-23	Deltoid: 1 mL All other sites: 2-2.5 mL	<ul style="list-style-type: none"> Vastus lateralis Rectus femoris Dorsogluteal Ventrogluteal Deltoid
Adults	1-1 ½ inch	22-27(for aqueous solutions) 18-25 (for viscous or oil-based medications)	3 mL	

INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION					
		X = Approved for Level of Care Indicated			
Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
Abciximab (ReoPro)	Antiplatelet	X	X		May be used post cath for limited duration in Zone 2 areas. Must use 0.22 micron filter.
Acetaminophen (Ofirmev)	Analgesic	X	X	X	
AcetaZOLAMIDE(Diamox)	Diuretic	X	X	X	
Adenosine (Adenocard)	Antiarrhythmic agent, diagnostic agent	X	X		IV PUSH ONLY. Infusion not recommended. If given centrally, reduce dose by 50%; otherwise use peripheral site as proximal to trunk as possible (not lower arm, hand, lower leg, or foot). Continuous ECG monitoring required. May be given as IV push in any unit pursuant to Rapid Response and Code Blue Standardized Procedures. Transfer to Critical Care Area as soon as possible
Albumin	Blood Product Derivative	X	X	X	
Allopurinol (Aloprim, Zyloprim)	Xanthine Oxidase Inhibitor	X	X	X	
Alteplase Tissue Plasminogen Activator (t-PA, Activase)	Thrombolytic	X	X	X	Infusion in Zone 1 only. CathFlo (2mL syringe) may be used to declot ports in any area. May be given IV push in any unit during Code Blue situations per MD order.
Aminocaproic acid (Amicar)	Hemostatic Agent	X			Do not administer as an IV push
Amiodarone (Cordarone)	Antiarrhythmic agent	X	X (Fixed Rate, no titration by Nurse)		** Central line preferred, must use 0.22 micron filter. IV Push during cardiac arrest only per ACLS. May be administered in any unit pursuant to Rapid Response and Code Blue Standardized Procedures. Transfer to Critical Care Area as soon as possible.

ZONE 1 = OR, ICU, CCL, IR, ED, PACU

ZONE 2 = 2E/2W, 3P, 4E/4W, PCU

ZONE 3 = 1N, 2P, 4P 1S – Rehab, L&D, Post-Partum

Revised 06.2019

Patient Care Services Policy: Medication Administration

INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION					
		X = Approved for Level of Care Indicated			
Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
Antibiotics (i.e. penicillin G, ampicillin/sulbactam, piperacillin/tazobactam, ceftriaxone, ceftazidime, levofloxacin, trimethoprim/sulfamethoxazole, clindamycin, aztreonam, amikacin)		X	X	X	Administration of some antibiotics may be preferred via central line. Contact pharmacy for more information.
Antifungals (i.e. amphotericin, fluconazole, voriconazole, micafungin)		X	X	X	
Antivirals (i.e. acyclovir, ganciclovir, Foscarnet)		X	X	X	**Central line preferred
Argatroban	Anticoagulant, Direct Thrombin inhibitor	X	X	X	
Atropine	Anticholinergic	X	X		May be used by GI lab RN's for salivation reduction and anti-spasmodic effect of the esophagus, stomach, and pylorus. May be given in any unit pursuant to Rapid Response and Code Blue Standardized Procedures.
Azathioprine (Imuran)	Immunosuppressant	X	X	X	Use Hazardous Medications handling precautions
Bivalirudin (Angiomax)	Anticoagulant, Direct Thrombin inhibitor	X	X		PCI and Cardiac Surgery only; not for inpatient use. May be used post cath for limited duration in ZONES 1 and 2.
Blood Factors (i.e. Factor VIII (Alphanate), Recombinant Factor VIII (Benefix), Recombinant VIIa (NovoSeven), Factor XI (Alphanine), Prothrombin Complex Concentrate (PCC, Profilnine SD)		X	X	X	Alphanine (Factor IX) and Prothrombin Complex Concentrate (PCC or Profilnine SD) are NOT interchangeable. Prothrombin Complex Concentrate contains Factors II, IX, and X).
Bumetanide (Bumex)	Loop Diuretic	X	X (Fixed Rate only, no titration by nurse)	X (IV Push Only)	
Buprenorphine (Buprenex)	Opioid	X	X	X	
Butorphenol (Stadol)	Opioid	X	X	X	
Caffeine sodium benzoate	Central Nervous System Stimulant	X	X	X	
Calcitriol (Rocaltrol)	Vitamin D Analog	X	X	X	May be administered as a bolus into the venous line at the end of dialysis by dialysis nurses

ZONE 1 = OR, ICU, CCL, IR, ED, PACU

ZONE 2 = 2E/2W, 3P, 4E/4W, PCU

ZONE 3 = 1N, 2P, 4P 1S – Rehab, L&D, Post-Partum

INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION

X = Approved for Level of Care Indicated

Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
Calcium Chloride	Electrolyte	X	X	X	Central line preferred. Infusion preferred. May be given IV push over 5-10 minutes during emergencies and/or Code Blue Only.
Calcium Gluconate	Electrolyte	X	X	X	If used to treat magnesium toxicity in L&D/Postpartum, patient must be on a cardiac monitor.
Chemotherapeutic agents (i.e. bleomycin, CARBOplatin (Paraplatin), CISplatin (Platinol), Cytarabine, conventional cyclophosphamide (Cytoxan), dacarbazine, DOCEtaxel (Taxotere), Doxorubicin (Adriamycin), DOXOrubicin liposomal (Doxil), epirubicin, etoposide (Toposar), Fluorouracil (Adrucil), gemcitabine (Gemzar), idarubicin, ifosfamide (Ifex), Irinotecan (Camptosar), methotrexate, Oxaliplatin (Eloxatin), PACLitaxel (Taxol), vinBLASTine, vincristine (Oncovin)		X	X	X	Chemotherapy for all floors to be delivered to 2P, EXCEPT chemo for Progressive Care Unit patients, IR and OR patients. Chemo will be delivered directly to those areas. See Chemotherapy Administration P&P. Handling precautions- dispose of as hazardous chemical waste.
ChlorproMAZINE (Thorazine)	Antipsychotic	X	X	X	Slow IV infusion (Max rate 1 mg/minute) for hiccups only. IM injection is preferred for all other indications. Do not administer an IV push
Clevidipine (Cleviprex)	Antihypertensive agent, Calcium Channel Blocker	X			Use within 12 hours of puncturing vial
Conivaptan (Vaprisol)	Vasopressin antagonist	X	X		**Central line preferred. Monitor serum sodium at least every 8 hours. Change infusion site every 24 hours if peripheral line used
Conjugated Estrogens (Premarin IV)	Estrogen Derivative	X	X	X	Use Hazardous Medications handling precautions
Cosyntropin	Corticosteroid, Diagnostic agent	X	X	X	
CycloSPORINE (sandIMMUNE)	Immunosuppressant	X	X		Requires close observation for at least during the first 30 minutes of infusion and monitored frequently thereafter. Anaphylaxis has been reported with IV use, reserve for patients who cannot take oral form. Use Hazardous Medications handling precautions

ZONE 1 = OR, ICU, CCL, IR, ED, PACU

ZONE 2 = 2E/2W, 3P, 4E/4W, PCU

ZONE 3 = 1N, 2P, 4P 1S – Rehab, L&D, Post-Partum

INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION					
		X = Approved for Level of Care Indicated			
Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
Dantrolene (Dantrium, Revonto, Ryanodex)	Skeletal Muscle Relaxant	X		X (L&D Only)	
Deferoxamine (Desferal)	Antidote	X			
Desmopressin (DDAVP)	Vasopressin analog	X	X	X	
Dexamethasone (Decadron)	Corticosteroid	X	X	X	
Dexmedetomidine (Precedex)	Sedative	X			
Diazepam (Valium)	Benzodiazepine	X	X	X	IV Push Only. Continuous infusion is not recommended. GI lab RN may give IV push under direct supervision of a physician
Digoxin (Lanoxin)	Cardiac glycoside	X	X	X	
Digoxib immune fab (DigiFab)	Antidote	X	X		Slow IV infusion over 30 minutes. If cardiac arrest imminent, may give via IV push. Stopping the infusion and restarting at a slower rate may help if an infusion-related reaction occurs.
Dihydroergotamine (DHE 45)	Antimigraine	X	X	X	
Diltiazem (Cardizem)	Calcium Channel Blocker	X	X (Fixed Rate only, no titration by Nurse)		May be given in any unit pursuant to Rapid Response and Code Blue Standardized Procedures. Transfer to Critical Care Area as soon as possible
DiphenhydrAMINE (Benadryl)	Antihistamine	X	X	X	
DOBUTamine (Dobutrex)	Adrenergic agonist	X	X (Fixed Rate only, no titration by Nurse)		** Central line preferred

ZONE 1 = OR, ICU, CCL, IR, ED, PACU

ZONE 2 = 2E/2W, 3P, 4E/4W, PCU

ZONE 3 = 1N, 2P, 4P 1S – Rehab, L&D, Post-Partum

INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION					
		X = Approved for Level of Care Indicated			
Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
DOPamine (Intropin)	Adrenergic agonist	X	X (Fixed Rate only, no titration by Nurse)		**Central Line Preferred – may initiate using peripheral vein during emergent situations until central access is obtained May be administered in any unit pursuant to Rapid Response and Code Blue Standardized Procedures. Transfer to Critical Care Area as soon as possible
Enalaprilat (Vasotec)	ACE inhibitor	X	X	X (IVPB only)	
ePHedrine	Adrenergic agonist	X		L&D only	
Epidural infusions (i.e. bupivacaine +/- opioid)		X	X	X	
EPINEPHrine (Adrenalin)	Adrenergic agonist	X			** Central Line Preferred – may initiate using peripheral vein during emergent situations until central access is obtained May be administered in any unit pursuant to Rapid Response and Code Blue Standardized Procedures. Transfer to Critical Care Area as soon as possible
Eptifibatide (Integrilin)	Antiplatelet	X	X		May be used post cath for limited duration
Erythromycin	Antibiotic	X	X	X	** Central line preferred
Erythropoietin (Epogen, Procrit, EPO)	Erythropoietin Stimulating agent	X	X	X	IV push for dialysis patients only
Esmolol (Brevibloc)	Beta-blocker	X	X (Fixed Rate only, no titration by Nurse)		** Central line preferred
Ethacrynic acid (Edecrin)	Diuretic	X	X	X	IV Push only. Administer each 10mg over 1 minute not to exceed 100mg per dose.
Etomidate (Amidate)	Sedative/hypnotic	X			May be given on any patient care unit for emergency intubation purposes only. Must be administered by MD.
Famotidine (Pepcid)	Histamine blocker	X	X	X	
Fenoldopam (Corlopam)	Antihypertensive	X			

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ZONE 2 = 2E/2W, 3P, 4E/4W, PCU

ZONE 3 = 1N, 2P, 4P 1S – Rehab, L&D, Post-Partum

INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION					
		X = Approved for Level of Care Indicated			
Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
Fentanyl (Sublimaze)	Opioid analgesic	X	X (IV push only)	X (L&D Only as IV Push)	IV PUSH doses for pain: Permitted in ZONE 1, ZONE 2, and in L&D only. IV PUSH doses for procedural sedation: Permitted in ZONE 1, ZONE 2, and L&D. Nurse must meet requirements of the PCS Procedure "Sedation/Analgesia Used During Therapeutic or Diagnostic Procedures" to administer. If DEEP sedation is required ,fentanyl must be administered by a physician Fentanyl continuous infusion restricted to ZONE 1 (Exception: Comfort Care patients may receive titrated infusion in all units)
Flumazenil (Romazicon)	Antidote	X	X	X	
Folic acid	Nutritional supplement	X	X	X	
Fosphenytoin (Cerebyx)	Anticonvulsant	X	X	X	Use hazardous medication precautions
Furosemide (Lasix)	Diuretic	X	X (IV Push or as Fixed Rate Infusion. No titration by Nurse.	X (IV Push Only)	.
Glucagon	Antidote	X	X (IM/IV Only)	X (IM/IV Only)	Continuous infusion in ZONE 1 only.
Glycopyrrolate (Robinul)	Anticholinergic	X	X	X (Comfort Care Only)	
Granisetron	Antiemetic	X	X	X	
Haloperidol (Haldol)	Antipsychotic	X	X		Max single IV dose is 5mg. Refer to Haloperidol IV Administration Standardized Procedure
Heparin	Anticoagulant	X	X	X	HIGH ALERT MEDICATION. 2nd RN to verify dose and pump settings at initiation of therapy and dose changes

ZONE 1 = OR, ICU, CCL, IR, ED, PACU

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ZONE 3 = 1N, 2P, 4P 1S – Rehab, L&D, Post-Partum

INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION					
X = Approved for Level of Care Indicated					
Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
Hetastarch (Hespan)	Volume Expander	X	X	X	Crystalloids (NS or LR) preferred in critically ill patients
HydraLAZINE (Apresoline)	Vasodilator	X	X	X	
Hydrocortisone (SoluCORTEF)	Corticosteroids	X	X	X	
HYDROMORPHONE (Dilaudid)	Opioid analgesic	X	X (IV Push. Fixed Rate infusion permitted. No titration by nurse.)	X (IV push and PCA only)	PCA and IV push allowed in all patient care areas. Hydromorphone continuous infusion in ZONE 2 requires patient to be on End Tidal CO2 monitor and continuous pulse oximetry) (<i>Exception: Comfort care patients may receive titrated infusion in all units.</i>)
Ibutilide (Corvert)	Antiarrhythmic	X			Patient must be monitored with continuous ECG for a minimum of 4 hours after dose received
Immune Globulin (IVIG, i.e. Gammagard, Gamunex)		X	X	X	
Regular Insulin (Humulin R)	Insulin	X	X (No continuous infusion)	X No continuous infusion(Exception : L&D)	High Alert Medication. IV push permitted for hyperkalemia only on all units – must be followed by dextrose 50% Continuous infusion permitted only for ZONE 1 and L&D
Iron Products (Iron Dextran, Ferrlecit, Venofer)		X	X	X	
Isoproterenol (Isuprel)	Adrenergic agonist	X			May be administered in any patient care area during Code situations. Transfer to Critical Care Area as soon as possible
Ketamine (Ketalar)	Sedative/hypnotic	X			Can only be administered by MD for procedural sedation. Can be administered by RN for pain.
Ketorolac (Toradol)	NSAID	X	X	X	
Labetalol (Trandate)	Beta Blocker	X	X (IV Push Only)	X (IV Push Only)	Continuous infusions are restricted to ZONE 1 (Max cumulative dose on infusion is 300 mg/24 hours. Consider alternate BP lowering agent if not at goal)
Levetiracetam (Keppra)	Anticonvulsant	X	X	X	

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ZONE 3 = 1N, 2P, 4P 1S – Rehab, L&D, Post-Partum

INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION					
		X = Approved for Level of Care Indicated			
Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
Levothyroxine (Synthroid)	Thyroid hormone	X	X	X	
Lidocaine (Xylocaine)	Antiarrhythmic	X	X (Fixed Rate only, no titration by Nurse)		May be administered in all units pursuant to Rapid Response and Code Blue Standardized Procedures. <i>For information regarding use in potassium IVPB see General and Concentrated Electrolytes Policy</i>
LORazepam (Ativan)	Benzodiazepine	X	X (IV push. Fixed rate infusion permitted on 2E/2W if patient mechanically ventilated)	X (IV push only)	Continuous infusion on Critical Care Areas only. (Exception: Patients on 2E/2W that are mechanically ventilated may receive lorazepam at a fixed rate. Comfort care patients may receive titrated infusion in all units).
Magnesium sulfate	Electrolyte	X	X	X	
Mannitol (Osmitol)	Osmotic agent	X	X	X	Must use 0.22 micron filter.
Meperidine (Demerol)	Opioid analgesic	X	X	X	PCA and Continuous infusion not recommended
Methyldopa (Aldomet)	Antihypertensive agent	X	X	X	
Methylprednisolone (soluMEDROL)	Corticosteroid	X	X	X	
Metoclopramide (Reglan)	Antiemetic	X	X	X	
Metoprolol (Lopressor)	Beta Blocker	X	X		May be administered by a Rapid Response Nurse on any unit pursuant to MD order
Midazolam (Versed)	Benzodiazepine	X	X (IV push only unless on Comfort Care)	X (IV push for procedures only by an RN qualified to give moderate sedation)	Continuous infusion in ZONE 1 only. (<i>EXCEPTION:</i> <i>Continuous titrated infusion permitted on Telemetry units for Comfort Care patients.</i>) IV PUSH doses for procedural sedation: Permitted in all units. Nurse must meet requirements of the PCS Procedure "Sedation/Analgesia Used During Therapeutic or Diagnostic Procedures" to administer. If DEEP sedation is required ,midazolam must be administered by a physician

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ZONE 3 = 1N, 2P, 4P 1S – Rehab, L&D, Post-Partum

INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION					
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Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
Milrinone (Primacor)	Inotropic agent	X	X (Fixed Rate only, no titration by Nurse)		No titration of infusion on Tele (Fixed rate only)
Morphine	Opioid analgesic	X	X (IV Push. Fixed Rate infusion permitted. No titration by nurse.)	X (IV push and PCA only)	PCA and IV push allowed in all patient care areas. Morphine continuous infusion in ZONE 2 requires patient to be on End Tidal CO2 monitor and continuous pulse oximetry) <i>(Exception: Comfort care patients may receive titrated infusion in all units)</i>
Non-hazardous monoclonal antibodies (i.e. bevacizumab (Avastin), Cetuximab (Erbix), Trastuzumab (Herceptin), RITUXimab (Rituxan))		X	X	X	
Nalbuphine (Nubain)	Opioid analgesic	X	X	X	
Naloxone (Narcan)	Antidote	X	X	X	
Neostigmine (Prostigmine)	Antidote	X			
Neuromuscular Blocker Agents i.e. cisatracurium (Nimbex), rocuronium (Zemuron), vecuronium, succinylcholine		X			HIGH ALERT MEDICATION. Mechanically ventilated patients in ZONE 1 areas ONLY. Allowed on any patient care area for intubation purposes only. Continuous infusions require concomitant continuous sedation.. Succinylcholine IV push not for continuous infusion.
NiCARDipine (Cardene)	Calcium Channel Blocker	X	X (Fixed Rate only, no titration by Nurse)		**Central line preferred. May be administered in any unit pursuant to Rapid Response Standardized Procedures.
Nitroglycerin	Vasodilator	X	X (Fixed Rate only, no titration by Nurse)		May be administered in any unit pursuant to Rapid Response and Code Blue Standardized Procedures. Transfer to Critical Care Area as soon as possible
Nitroprusside (Nipride)	Vasodilator	X			

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ZONE 2 = 2E/2W, 3P, 4E/4W, PCU

ZONE 3 = 1N, 2P, 4P 1S – Rehab, L&D, Post-Partum

INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION					
		X = Approved for Level of Care Indicated			
Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
Norepinephrine (Levophed)	Adrenergic agonist	X			**Central Line Preferred – may initiate using peripheral vein during emergent situations until central access is obtained May be administered in any unit pursuant to Rapid Response and Code Blue Standardized Procedures. Transfer to Critical Care Area as soon as possible
Octreotide (sandoSTATIN)	Somatostatin analog	X	X	X	
Ondansetron (Zofran)	Antiemetic	X	X	X	
Oxytocin (Pitocin)	Oxytocic agent	X	X	X	Use Hazardous Medications handling precautions
Pamidronate	Bisphosphonate	X	X	X	** Central line preferred
Papaverine	Vasodilator	X			MD must be present at bedside. IV push only
Paracalcitol (Zemlar)	Vitamin D analog	X	X	X	
Pantoprazole (Protonix)	Proton pump inhibitor	X	X	X	
PentaMIDINE (Pentam)	Antibiotic	X	X	X	
PENTObarbitol (Nembutal)	Barbiturate	X			If given IM, no more than 5 mL (250 mg) should be injected at any one site IV Push – do not administer faster than 50 mg/min
PHENObarbitol (Luminal)	Barbiturate	X	X	X	Not for continuous infusion If given IM, no more than 5 mL (250 mg) should be injected at any one site
Phentolamine (Regitine)	Antidote	X	X	X	
Phenylephrine (Neosynephrine)	Adrenergic agonist	X		X (L&D only)	**Central Line Preferred – may initiate using peripheral vein during emergent situations until central access is obtained
Phenytoin sodium (Dilantin)	Anticonvulsant	X	X	X	** Central line preferred. Must use 0.22 micron filter.
Phytonadione (Vitamin K)	Antidote	X	X	X	Do not administer as IV push

ZONE 1 = OR, ICU, CCL, IR, ED, PACU

ZONE 2 = 2E/2W, 3P, 4E/4W, PCU

ZONE 3 = 1N, 2P, 4P 1S – Rehab, L&D, Post-Partum

INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION					
		X = Approved for Level of Care Indicated			
Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
Potassium Chloride	Electrolyte	X	X	X	Do not administer as IV push Maximum infusion rate of 10 mEq/hour (<i>Exceptions: Patients in ZONE 1 and ZONE 2 on continuous ECG monitoring and with a central line may receive at a rate of 20 mEq/hour. See General and Concentrated Electrolytes Policy</i>) Maximum IV fluid concentration = 40 mEq/Liter of solution with a infusion rate of 10 mEq/hour (May infuse at a rate of 20 mEq/hour in ZONE 1 and ZONE 2 if on continuous ECG monitoring)
Potassium Phosphate	Electrolyte	X	X	X	Do not administer as IV push Maximum infusion rate of phosphate 7 mmol/hr (10 mEq/hr potassium via peripheral line or central line without cardiac monitoring. Maximum infusion rate of phosphate up to 14 mmol/hr (20 mEq/hr potassium via central line with cardiac monitoring in ZONE 1 or ZONE 2. See Pharmacy Policy General and Concentrated Electrolytes)
Pralidoxime (Protopam)	Antidote	X			
ProCHLORperazine (Compazine)	Antiemetic	X	X	X	When given as IV push do not exceed rate of 5 mg/min
ProMETHAZINE (Phenergan)	Antiemetic	X	X	X	Do not administer as IV push. Must dilute in at least 25 mL NS or call pharmacy.
Propofol (Diprivan)	Sedative	X			Mechanical ventilation required for patients receiving a continuous infusion of propofol. IV push/bolus doses must be administered by a physician. In emergency situations this may be performed on any unit.
Propranolol (Inderal)	Beta Blocker	X	X		Continuous infusions are not recommended.
Protamine Sulfate	Antidote	X	X	X	IV push in ZONE 1 only
PyridOSTIGMINE bromide (Mestinon)	Antidote	X			Do not administer as an IV push
PyridOXINE (Vitamin B6)	Antidote	X	X	X	

ZONE 1 = OR, ICU, CCL, IR, ED, PACU

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INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION					
		X = Approved for Level of Care Indicated			
Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
Remifentanyl (Ultiva)	Opioid analgesic	OR only			
Quinidine gluconate	Antiarrhythmic	X			
Sodium Bicarbonate	Electrolyte	X	X	X	<p>** Central line preferred. If running continuously it is preferred that the line remain dedicated for sodium bicarbonate only.</p> <p>Refer to Pharmacy Policy General and Concentrated Electrolytes for additional information</p>
Sodium Chloride 3% (Hypertonic saline)	Electrolyte	X	X		<p>HIGH ALERT MEDICATION, DOUBLE CHECK</p> <p>Do not administer IV Push.</p> <p>**Central Line Preferred – may initiate using peripheral vein during emergent situations until central access is obtained.</p> <p>May be infused in any patient care area for emergent situations pending transfer to ZONE 1 or ZONE 2</p> <p>Refer to Pharmacy Policy General and Concentrated Electrolytes for additional information</p>
Sodium Phosphate	Electrolyte	X	X	X	<p>Do not administer as an IV Push.</p> <p>Refer to Pharmacy Policy General and Concentrated Electrolytes</p>
Tacrolimus	Immunosuppressant	X	X		<p>Do not administer as an IV push. Requires close observation for at least during the first 30 minutes of infusion and monitored frequently thereafter. Anaphylaxis has been reported with IV use, reserve for patients who cannot take oral form.</p> <p>Use hazardous medication handling precautions</p>
Thiamine	Nutritional supplement	X	X	X	
Tranexamic Acid	Hemostatic Agent	X	X	X	
Valproate (Depacon)	Anticonvulsant	X	X	X	

ZONE 1 = OR, ICU, CCL, IR, ED, PACU

ZONE 2 = 2E/2W, 3P, 4E/4W, PCU

ZONE 3 = 1N, 2P, 4P 1S – Rehab, L&D, Post-Partum

INTRAVENOUS (IV) MEDICATION ADMINISTRATION BY LOCATION

X = Approved for Level of Care Indicated					
Drug Name	Drug Class	ZONE 1 (OR, ICU, CCL, IR, ED, PACU)	ZONE 2 (2E/2W, 3P, 4E/4W, PCU)	ZONE 3 (1N, 2P, 4P, 1S- Rehab, L&D, Post-Partum)	Comments
Vasopressin (Pitressin)	Vasoconstrictor	X			<p>** Central line preferred.</p> <p>May be administered via IV push in any patient care area during emergency situations pursuant to a physician order. Transfer to Critical Care Area as soon as possible.</p> <p>Continuous infusions allowed in ZONE 1 only.</p> <p>IM or SQ administration for Diabetes Insipidus is permitted in all units.</p>
Verapamil (Calan, Isoplin)	Calcium Channel Blocker	X			May be administered via IV push in any patient care area during Code situations pursuant to a physician order.
Zoledronic acid (Reclast, Zometa)	Bisphosphonate	X	X	X	
<p>Refer to references such as Elsevier Online Skills for additional information on administration and monitoring. Alternate infusion rates may be permitted at provider discretion. List is not inclusive, if medication not on list- please contact pharmacy for more information.</p> <p>**Central Line Preferred indicates that the medication is associated with venous irritation. Certain situations may require that the medication be administered peripherally (i.e. emergency situations, waiting on central line placement, or very short duration of infusion planned). Infusion of these medications/solutions through a peripheral vein may lead to loss of vascular access or damage to the vein and/or surrounding tissue, resulting in chemical phlebitis and thrombus formation. Other factors including vein size, infusion rate, catheter dwell time, catheter size, and location also influence the risk of phlebitis. Monitor closely for signs and symptoms of infiltration and/or phlebitis if given peripherally.</p>					

Approval Process:	Dates
Department Review:	03/19
Clinical Policies and Procedures:	03/19
Nurse Executive Committee:	03/19
Pharmacy & Therapeutics Committee:	03/19
Medical Executive Committee:	06/19

ZONE 1 = OR, ICU, CCL, IR, ED, PACU
 ZONE 2 = 2E/2W, 3P, 4E/4W, PCU
 ZONE 3 = 1N, 2P, 4P 1S – Rehab, L&D, Post-Partum

Medication Administration Time Frames

Daily	-	0900
qam	-	0900
qhs	-	2100
bid	-	0900 - 2100
tid	-	0900 - 1500 - 2100
qid	-	0900 - 1300 - 1700 - 2100
q4h	-	0100 - 0500 - 0900 - 1300 - 1700 - 2100
q6h	-	0600 - 1200 - 1800 - 2400
q8h	-	0500 - 1300 - 2100
q12h	-	0900 - 2100

Specific Medications:

Warfarin - 1700

Standard capillary blood glucose checks AC and HS - 0800, 1130, 1730, and 2100

Standard capillary blood glucose checks every 6 hours - 0600, 1200, 1800, and 2400

Lithium - 2000

Digoxin - 1200

Diuretics - 0900 - 1700 (ordered BID)

Medications ordered with meals shall be given according to tray delivery times.

Respiratory medications shall be given per unit specific policy.

Bupropion, Venlafaxine, Modafinil, Methylphenidate: if ordered BID 09:00 and 14:00

In addition to the above standard administration times, the pharmacist shall designate the appropriate administration time for certain medications to optimize drug therapy. Some examples are as follows:

Proton Pump Inhibitors – BID 0600 – 2100

Statins – Daily 2100

Carafates – Q6 2400 – 0600 – 1100 – 1600

PATIENT CARE SERVICES

ISSUE DATE: 03/03

SUBJECT: Medications, High Risk/High
Alert/Look Alike Sound Alike

REVISION DATE: 06/03, 02/04, 05/05, 04/06, 04/09,
12/09, 02/14, 01/18

POLICY NUMBER: ~~IV.1.8~~

Patient Care Services Content Expert Approval/Department Review: 09/4711/21

Clinical Policies & Procedures Committee Approval: 40/4712/21

Nursing Leadership/Executive Committee Approval: 40/4701/22

Pharmacy & Therapeutics Committee: 44/4702/22

Medical Executive Committee Approval: 44/4703/22

Administration Approval: 04/22

Professional Affairs Committee Approval: 04/18 n/a

Board of Directors Approval: 01/18

A. PURPOSE:

1. To identify medications with high risk to patients and provide a process to safely deliver the highest quality pharmaceutical care with the minimum number of medication errors and the lowest potential for patient risk.

B. DEFINITION(S):

1. High Risk/High Alert medications are drugs that have a heightened risk of causing significant patient harm when they are used in error.
2. High Risk/High Alert medications have a higher risk of causing injury, either as a result of a narrow therapeutic range or due to a high incidence of reported serious errors.
3. Methods to reduce error include strategies such as:
 - a. Improving access to information about these drugs
 - b. Limiting access to High Risk/High Alert medications
 - c. Using Tallman lettering for lookalike sound alike meds
 - d. Using auxiliary labels and automated alerts on the electronic Medication Administration Record (eMAR) and Automated Dispensing Machine (ADM)
 - e. Standardizing the ordering, storage, preparation and administration of these products
 - f. Employing redundancies such as automated or independent double checks when necessary
4. New formulary medications and additional relevant safety information will be reviewed for inclusion on the High Risk/High Alert Medication list by the Medication Safety Committee and Pharmacy and Therapeutics Committee.
5. Medications that have deemed to be High Risk or High Alert include the following:
 - a. Chemotherapy agents
 - b. Therapeutic Anti-Coagulants (infusions of heparin, argatroban,)
 - c. Insulin – both continuous infusions and subcutaneous doses
 - d. Epidural/Intrathecal infusions, Patient-Controlled Analgesias (PCA)
 - e. Continuous Thrombolytic Infusions (alteplase)
 - f. Concentrated Electrolytes
 - g. Neuromuscular Blocking Agents (NMBA)
 - h. Fentanyl – patch and transmucosal products
 - i. Glycoprotein IIb/IIIa inhibitors (eptifibatide, abciximab)
 - j. Inotropic medications (dopamine, dobutamine, milrinone)

- k. Intravenous (IV) Adrenergic Agonists (epinephrine, norepinephrine, phenylephrine)
- l. 10% Magnesium Sulfate

C. **POLICY:**

- 1. High Risk/High Alert Medication Verification and ADM Alert List – medications requiring verification by a second practitioner.
 - a. Chemotherapy (refer Patient Care Services (PCS) Procedure: Chemotherapy Administration)
 - b. Therapeutic Anti-Coagulants:
 - i. Heparin (refer to PCS Policy: Therapeutic Anticoagulation Management)
 - ii. Argatroban:
 - 1) Standardized dosing nomograms and orders are in place.
 - 2) All infusions will be administered by a programmable infusion pump with "smart pump" technology.
 - 3) Independent double checking of dose ordered, dose prepared, initial infusion rate and any changes in infusion rate shall be verified and documented by another nurse.
 - c. Insulin:
 - i. Continuous Infusions:
 - 1) Standard concentration of an insulin infusion is 1 unit/mL.
 - 2) Standardized dosing protocol for insulin infusions.
 - 3) All Insulin infusions will be administered by a programmable infusion pump with "smart pump" technology.
 - 4) Independent double checking of dose ordered, dose prepared, initial infusion rate and any changes in infusion rate shall be verified and documented by a second nurse.
 - ii. ~~Subcutaneous:~~
 - 1) ~~Insulin vials opened on nursing units will have an expiration date of 28 days per the PCS Policy: Medication Administration.~~
 - 2) ~~Insulin vials are separated by type in labeled bin dividers in the refrigerators.~~
 - d. Epidural/Intrathecal/PCA Infusions:
 - i. All infusions will be administered by a programmable infusion pump with "smart pump" technology.
 - ii. Independent double checking of dose ordered, dose prepared, initial infusion rate and any changes in infusion rate shall be verified and documented by another nurse.
 - e. Continuous Thrombolytic Infusions (alteplase):
 - i. All infusions will be administered by a programmable infusion pump with "smart pump" technology.
 - ii. Independent double checking of dose ordered, dose prepared, initial infusion rate and any changes in infusion rate shall be verified and documented by another nurse.
 - iii. An ADM alert will identify this agent with the warning "1 BOTTLE Maximum for Stroke. Maximum dose of 90mg"
 - f. Concentrated Electrolytes (refer to Pharmacy: General and Concentrated Electrolyte Policy).
 - g. Neuromuscular Blocking Agents (NMBA):
 - i. NMBA continuous infusions require an independent double checking of dose ordered, dose prepared, initial infusion rate and any changes in infusion rate shall be verified and documented by another nurse.
 - ii. All infusions will be administered by a programmable infusion pump with "smart pump" technology.
 - iii. Standard concentrations for NMBA infusions are used.

- iv. Use of NMBA are limited to Operating Room (OR), Intensive Care Unit (ICU), Neonatal Intensive Care Unit (NICU) and procedural areas.
 - v. A paralytic warning label is applied to all NMBA prior to distribution.
 - vi. An ADM alert will identify these agents with a warning upon removal "Paralyzing agent high risk/high alert requires – Patient to be on mechanical ventilation or Physician in attendance" and requires nurse to indicate which condition applies prior to removal.
- 2. High Risk/High Alert Medication ADM Alert List:
 - a. ADM alert is defined as a reminder message that appears prior to obtaining a medication from the ADM machine and is designed to notify staff that the medication is High Risk/High Alert.
- 3. Look Alike Sound Alike Medications (LASA):
 - a. The LASA list will be annually updated.
 - b. LASA meds in Talyst are bar coded in and out, and bins are not labeled with drug names.
 - c. Medications in Talyst and CII Safe are not stored in any order enhancing patient safety with lookalike sound alike medications in pharmacy.
 - d. A current list of LASA can be found on the Tri-City Intranet.
 - e. Tall man lettering shall be utilized as appropriate.

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

- 1. Look Alike sound Alike (LASA) Medication List
- 2. Patient Care Services Procedure: Chemotherapy Administration
- 3. Patient Care Services Policy: Medication Administration
- 4. Patient Care Services Policy: Therapeutic Anticoagulation Management
- 5. Pharmacy Policy: General and Concentrated Electrolyte

**** MEDICATION SAFETY ALERT ****

L_{ook} **A**_{like} **S**_{ound} **A**_{like}
MEDICATION LIST

KEPPra/ketaMINE/ketoroLAC

ePHEDrine/EPINEPHrine

HYDROmorphone/morphine

hydrOXYzine/hydrALAZINE

DAUNOorubicin/DOXOorubicin/IDArubicin

oxyCONTIN/oxyCODONE

vinBLASTine/vinCRISTine

cloNIDine/clonazePAM

ceFAZolin/cefTRIAXone

NIFEdipine/niMODipine/niCARDipine

leveMIR/lanTUS/lisPRO (HumaLOG)/HumuLIN/novoLIN

levETIRAcetam/levofFLOXacin

pyridOXINE/pyridOSTIGMINE

inFLIXimab/riTUXimab

What does Tri-City do to help avoid LASA medication errors?

- Use tall man lettering – seen on Pyxis removals and eMAR
- Store medications in Talyst carousel (non-alphabetically)
- Barcoding – upon receipt in pharmacy, during Pyxis fills and at the bedside

PATIENT CARE SERVICES

ISSUE DATE: 05/19

SUBJECT: Physician/Allied Health
Professional (AHP) Orders –
Outpatient Services

REVISION DATE(S):

Patient Care Services Content Expert Approval:	04/17/11/21
Clinical Policies & Procedures Committee Approval:	03/19/12/21
Nursing Leadership Executive Committee Approval:	03/19/01/22
Pharmacy & Therapeutics Committee Approval:	03/19/02/22
Medical Executive Committee Approval:	04/19/03/22
Administration Approval:	05/19/04/22
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	05/19

A. PURPOSE:

1. To ensure outpatient orders and requisitions are written in accordance with Tri-City Healthcare District (TCHD)/Center for Medicare and Medicaid Services (CMS) guidelines.

B. POLICY:

1. TCHD Medical Staff or AHP credentialed by the Medical Staff Office may order outpatient treatment and diagnostic studies that are within their scope of practice and as permitted by applicable state law.
 - a. AHP may not order chemotherapy.
 - b. For Rehabilitation Services patients, the ordering physician must have an established relationship with the patient and be available to sign the plan of care at least every 10 visits or thirty (30) days, whichever comes first.
 - c. Only physicians/AHP granted Wound Care & Hyperbaric Medicine Medical Staff privileges may provide orders for patients being seen at the Wound Care Center.
2. Non-Physician members and Non-Members of TCHD medical staff may only order diagnostic, imaging, therapeutics, laboratory tests, and rehabilitation services within their scope of practice for outpatient services per Patient Care Services Policy: Physician/ Allied Health Professionals (AHP) Inpatient Orders.
3. A valid order must be received prior to performing any outpatient procedure, test or service.
 - a. Verbal orders are not accepted.
 - b. Telephone orders:
 - i. Are acceptable in STAT situations when the physician/Allied Health Professional (AHP) may not be in the office or is otherwise unavailable to send a copy of the order to initiate/modify any outpatient service.
 - ii. Telephone orders shall be entered directly into the electronic health record (EHR). When it is not possible to enter a telephone order, document the order immediately on the Physician's Order sheet and ensure it is signed, dated and timed by the individual who received the order.
 - 1) The complete order(s) shall be clearly read back to the physician/AHP directly from the primary source.
 - a) Orders entered directly into the EHR shall be entered using the correct Communication Type.
 - b) If orders written on the Physician's Order sheet, the Read Back

- box shall be check-marked (✓) to document orders were read back.
- 2) Orders must be signed within 48 hours for medication orders and fourteen (14) days post discharge for all other orders.
 - a) Outpatient Behavioral Health Services medication orders written on Friday may be signed on the next business day (Monday).
 - b) Arrangements must be made by the scheduling department as to when the written order will be received or when the physician/AHP will be available to authenticate the order.
 - 3) Telephone orders for antineoplastic agents are not permitted.
 - a) Exceptions: See Patient Care Services: Chemotherapy Prescribing, Processing, and Preparation Policy.
 - c. Faxed or original signed orders are acceptable provided all required elements are present and may be submitted in any of the following formats:
 - i. Prescription Forms
 - ii. Referral Forms (can be payer specific)
 - iii. Order Sheets
 - iv. Outpatient Scheduling Forms
 - v. Office Letterhead
 - vi. Office history and physical or progress notes including clear indication that an order is contained within
 - vii. TCHD approved pre-printed order forms
 - d. Medication orders must be submitted on an approved TCHD order sheet or pre-printed order form.
 - e. A physician/AHP order is not required for provision of services that are provided to the community at large or for direct access testing.
 - i. Examples: Wellness Health Fair, Cardiac Scoring, Screening mammogram
 - ii. Patients requesting screening mammograms
 - iii. Cardiac Phase 3 patients
 - iv. Pulmonary Phase 3 patients
 4. It is the responsibility of Registration or the ancillary departments scheduling the service to ensure all elements are present. These include:
 - a. Patient Name
 - b. Date of birth
 - c. Validate physician license or AHP number
 - d. Ordering physician/AHP signature (written or electronic)
 - i. Orders signed by office personnel and stamped orders will not be accepted.
 - e. Date and time of physician signature
 - f. Service to be provided
 - g. Reason for service/Medical necessity (i.e. diagnosis or condition)
 - i. Orders to "Rule out _____" are not sufficient
 - ii. A narrative description of medical necessity is preferable over ICD codes. However, if a code is provided and it is deemed to be a valid ICD code, it will be used in the absence of a narrative description.
 - h. Orders must be activated within ninety (90) days of the date of the signed/authenticated order.
 5. Invalid orders are to be brought to the attention of the ordering practitioner who will have an opportunity to clarify/complete the order to meet requirements.
 6. Upon confirmation of a compliant order the department follows through with the Scheduling of the patient for services requested in the order and/or Registration of the patient for the walk-in service.
 - a. Orders for outpatient invasive procedures and infusion therapies will be accepted based on additional patient care needs with consideration of the patient's clinical condition and

whether a licensed physician/AHP can assume responsibility for follow up treatment resulting from the order.

7. Orders will be valid for a period of ninety (90) days from date reflected on the outpatient order unless otherwise indicated.
 - a. Outpatient Behavioral Health Services orders are valid for up to twelve (12) months.
 - b. Outpatient medication orders (including but not limited to chemotherapy and infusion therapies) are valid for twelve (12) months.
 - c. Cancer surveillance treatment orders are valid up to six (6) months.
 - d. In-Custody patients:
 - i. California Department of Corrections/Rehabilitation (CDCR) orders are valid for twelve (12) months
 - ii. San Diego Sheriff Department (SDSD) orders are valid up to six (6) months
 - e. For recurring accounts there is no specific date in which the order will expire. If there is a change in the patient's condition which warrants a change in treatment, a new physician/AHP order is required.
8. Patterns of non-compliant orders will be tracked and reported to department leadership for follow-up.

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

1. Patient Care Services Policy: Chemotherapy, Prescribing, Processing, and Preparation
2. Patient Care Services Policy: Physician/ Allied Health Professionals (AHP) Inpatient Orders

PATIENT CARE SERVICES

ISSUE DATE: 10/96 **SUBJECT:** Potential Food and Drug Interactions, Patient Education

REVISION DATE(S): 06/03, 08/05, 03/08, 03/11, 12/15, 09/18

Patient Care Services Content Expert Approval:	06/1810/21
Clinical Policies & Procedures Committee Approval:	07/1811/21
Nursing Leadership Executive Council Approval:	07/1812/21
Pharmacy & Therapeutics Committee Approval:	07/1802/22
Medical Executive Committee Approval:	08/1803/22
Administration Approval:	09/1804/22
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	09/18

A. POLICY:

1. The Pyxis MedStation will prompt the nurse to assess the educational needs of the patient when one of the medications below has been added to a patient's profile and the nurse makes a withdrawal of the medication:
 - a. Warfarin (Coumadin)
2. Nursing may obtain a current Drug/Nutrient interaction education sheet from a hospital approved information resource.
3. Nursing will provide this information to the patient/family/caregiver if any of the above medications are started in the hospital and are intended for continued use at home and as deemed necessary from the patient assessment.
4. Patient education and counseling on drug/nutrient interactions may also be initiated by a physician order or another health care professional after assessment of knowledge deficits, and/or by the patient/caregiver request.
5. Nursing may make a consult request from Clinical Pharmacist and/or Clinical Dietitian for additional patient education as indicated.
6. Documentation of counseling and materials provided will be documented in the patient education section of the patient record and in the patient's discharge instructions.

**PROCEDURE: PRE, INTRA AND POST OPERATIVE ASSESSMENT OF FETAL HEART RATE AND UTERINE ACTIVITY FOR NON-OBSTETRIC PROCEDURE/SURGERY**

Purpose: To outline the nursing management and assessment practices regarding fetal heart rate and uterine activity monitoring for gravid, non-obstetric surgical patient in the pre, intra, and post-operative periods.

Supportive Data: Improvements in surgical techniques and anesthesia permit surgical interventions during pregnancy. The ideal time for surgery in the antenatal period is the second trimester (14 to 26 weeks gestation). Teratogenicity for spontaneous abortion is a potential complication of surgery during the first trimester; preterm labor is a more common potential complication of the third trimester, secondary to increased uterine to endogenous uterotonic agents (e.g. oxytocin). At a minimum pregnant women who are 24 or more weeks of gestation shall have electronic fetal heart rate and contraction monitoring performed before and after the procedure to assess fetal well-being and the absence of contractions.

Equipment:

1. Portable external fetal monitor with external ultrasound and tocodynamometer.
2. Conductive gel
3. Labor and Delivery Charge Sheet
4. Initial Fetal Monitor Strip Label

Personnel:

1. A skilled obstetric nurse who can interpret the results shall perform all external fetal heart rate and uterine activity monitoring..
2. ~~The labor and Delivery Assistant Nurse Manager (ANM)/designee/relief charge~~ **Labor and Delivery relief Charge Nurse** will work with the patient's physician, main Operating Room (OR) and Post Anesthesia Care Unit (PACU) to coordinate obstetrical monitoring.

A. PRE-OPERATIVE:

1. All pregnant patients undergoing a non-obstetric surgical procedure require an obstetric consult., including ~~unexpected-emergencies~~ when possible
 - a. ~~The consult should include review of the gestational age, pregnancy complications, any need for pre-treatments, positioning, and recommendations for fetal monitoring.~~
2. For patients who are between 14 and less than 24 weeks gestation, fetal heart tones (FHTs) shall be obtained and documented both pre- and post-operatively.
3. For patients 24 weeks and greater, obtaining an **20 – 30 minute** electronic fetal heart rate (FHR) and uterine activity monitoring strip ~~of 20 to 30 minutes~~ **is recommended** prior to the induction of anesthesia ~~is recommended~~.
4. If the surgical procedure is an emergency, obtaining FHTs is acceptable.
 - a. It is the responsibility of the **operating surgeon/clinic staff** to inform the OR scheduling staff that the patient is pregnant and ensure an obstetrical consult is identified and available.
 - a. If the patient's obstetrician is not on staff or unavailable, the surgeon should consult with the obstetrician on "unassigned call."
5. Staff responsible for scheduling surgeries and preadmission testing should notify the Labor and Delivery (L&D) charge nurse of the patient's monitoring requirements, at the earliest possible convenience so a L&D nurse can be available.
 - a. Notification should occur at least 24 hours prior to elective surgery and as soon as possible for urgent/emergency surgery.
6. L&D unit shall supply the monitoring equipment and qualified nursing staff to perform the external fetal monitoring.

Review / Revision Date	Clinical Policies & Procedures	Nursing Leadership Executive Committee	Department of OB/GYN	Operating Room Committee	Medical Executive Committee	Administration	Professional Affairs Committee	Board of Directors Approval
7/03, 2/06, 12/08, 4/09, 2/10, 04/15, 02/20	04/10, 05/15, 03/20	05/10, 05/15, 04/20	12/15, 06/21	02/16, 02/22	05/10; 02/16, 03/22	04/22	06/10; 03/16, n/a	06/10; 03/16

7. The L&D nurse shall notify the obstetrician consulted of any FHR and/or uterine activity concerns.
8. The obstetrician consulted should notify the neonatologist of an impending surgery for a patient carrying a potentially viable fetus.
9. **If required by the obstetric consult physician, the OR should be prepared for the possibility of an emergency cesarean delivery.**
 - a. Ensure , instrument tray, infant warmer and infant crash cart from L&D are available.
 - b. Notify Neonatal Intensive Care Unit(NICU) shift supervisor/or designee of impending surgery and potentially viable fetus.
 - c. Request NICU staff bring transport incubator if called to the OR for cesarean delivery.

B. INTRAOPERATIVE:

1. In select circumstances, continuous fetal monitoring may be considered, but is usually not possible.
 - a. A provider with obstetrical privileges must be available and willing to intervene during the surgical procedure for fetal indications.

C. POSTOPERATIVE:

1. For patients who are between 14 and less than 24 weeks gestation, fetal heart tones (FHTs) shall be obtained and documented post-operatively.
2. For patients 24 weeks and greater, **continuous** external FHR and uterine activity monitoring should begin in the Post-Anesthesia Care Unit (PACU) and continue until the patient has recovered from anesthesia or per provider order.
3. The L&D nurse shall observe the patient closely for contractions as increased uterine activity can occur after surgery.
 - a. Notify attending obstetric physician for ≥ 3 or more contractions in 10 minutes or ≥ 6 or more contractions in 60 minutes.
 - b. Notify the obstetrician for any FHR assessment concerns.
4. After discharge from PACU and admission to any unit, continuous or intermittent fetal monitoring may be ordered by either the obstetrician or the surgeon.

D. REFERENCES:

1. American Academy of Pediatrics & American College of Obstetricians and Gynecologists. (2012). *Guidelines for perinatal care* (7th ed.).
2. Martin, E.J. (2009). *Intrapartum management modules* (3rd ed.). Lippincott, Williams, & Wilkins.
3. Tucker, S.M., Miller, L.A., & Miller, D.A. (2009). *Fetal monitoring and assessment* (5th ed.). Mosby Elsevier.
4. American Society of Anesthesiologists (2009). Statement on Non-Obstetric Surgery During Pregnancy.
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- 4.7. **ACOG Committee Opinion No. 775. *Obstetrics & Gynecology*, vol. 133, no. 4, April 2019, pp. e285–e286. doi: 10.1097/AOG.0000000000003174.**

PATIENT CARE SERVICES

ISSUE DATE: 07/93

SUBJECT: Release of Deceased to a Family Member

REVISION DATE: 06/03, 08/07, 08/13, 03/18

POLICY NUMBER: ~~IV.P.4~~

Patient Care Services Content Expert Approval/Department Review: 44/4711/21

Clinical Policies & Procedures Committee Approval: 44/4712/21

Nursing Leadership/Executive Committee Approval: n/a03/22

Pharmacy and Therapeutics Approval: n/a

Medical Executive Committee Approval: 02/1803/22

Administration Approval: 04/22

Professional Affairs Committee Approval: 03/18 n/a

Board of Directors Approval: 03/18

A. POLICY:

1. A decedent may be released for transportation by a family member only after the family has provided the following:
 - a. Death certificate
 - b. Burial permit **before disposing of human remains**
 - c. Valid transportation
2. Death Certificate: A death certificate must be obtained (blank form from a mortuary or other facility), properly completed by the attending physician, filed with Department of Health by the family member and presented to Tri-City Healthcare District (TCHD).
3. Burial Permit: The family member must obtain and present to TCHD a burial permit from the mortuary or cemetery at the point of destination, stating that said mortuary or cemetery will accept delivery of the decedent by the family member.
4. Valid Transportation: The family member must provide proof to the Department of Health that the decedent was properly embalmed and/or placed in a hermetically sealed coffin. The decedent cannot be transported in an airplane or across state lines without proof of a hermetically sealed coffin.
5. The family member shall sign the Authority for Release of Deceased Report in place of mortuary at time of pick-up.
6. Exclusions: Justice Involved Patients.

B. FORM(S):

1. 8720-1015 Release of Deceased
2. ~~Authority for Release of Deceased Report — Sample~~

C. REFERENCE(S):

1. California Health & Safety Code § 103050 (2018).

Authority for Release of Deceased Report – Sample

Test, Fred

MRN 00000547

FIN# 6002100724

2

SSN 487-66-5555

Room # 516

Oceanside

Next of kin: Test

Patient a donor:

Attending Physician

Pronounced Time

I acknowledge

Date (Fecha)

I hereby authorize

authorization a T

To (Al):

Mortuary/Pr

(Nombre del)

Date

(Fecha)

Physician to sign

Mortuary Notified

Received from Tr

Date/Time

Returned By:

Received from Tr

Date/Time

Public Administrator Notified

Date/Time

DELETE

0

Tri-City Medical Center

Authority for Release of Deceased

00000547

Test, Fred

02/02/1954/ 62 Years/Male

TCMC/Inpatient/6002100724

PLEASE MAKE COPY OF ORIGINAL WITH FAMILY SIGNATURES FOR MORTUARY PICK UP SERVICE

Name of Deceased _____
(Last Name) (First Name)
Unit / Room _____
Expiration (Patient Pronounced) Date: _____ Time: _____
Nurse's Name _____ Signature _____

Call Lifesharing at 1-888-423-6667
Lifesharing notified: Date _____ Time _____
Donor Referral Number: _____
IS PATIENT A DONOR Yes _____ No _____
Exclusion by Lifesharing Yes _____ No _____

Reportable Death Criteria (to be reported to Medical Examiner [Coroner]):

Please review the following list and identify any reportable death criteria. Criteria # _____ If none apply, record N/A

1. Known or suspected homicide. (This would include any delayed (days to years) death resulting from any non-accidental trauma; example: A quadriplegic from a gunshot wound 10 years ago, remote head injury, suspected elder abuse.)
2. Known or suspected suicide. (This would include any delayed (days to years) death resulting from any accidental injury; example: A person with organ failure due to an intentional medication overdose.)
3. A result of an accident, injury, trauma, or mishap either old or recent. (This would include any delayed (days to years) death resulting from any accidental injury; example: A person with a brain injury from a fall or motor vehicle accident: burns or drowning, pulmonary embolism or other complication following trauma, medication, or surgical error.)
4. Indications that the death is the result of an acute alcohol and/or prescription or illegal drug overdose.
5. An infectious process, such as AIDS or hepatitis, which may pose a threat to public health.
6. A sudden unexpected adult / child / infant death.
7. A death resulting from a complication during a recently performed surgical procedure.
8. Death of an inmate/prisoner or in-custody patient.
9. Fatal events occurring at decedent's place of employment

Medical Examiner (ME) Notified: Yes _____ No _____ (858) 694-2895

Name of ME Investigator notified: _____ Date _____ Time _____ Waiver No: () - ()

In the event that one of the nine criteria listed above are fulfilled, it is the physician's responsibility to inform the family of the benefits/risk of Autopsy.

Family offered autopsy Yes _____ No _____ Autopsy to be performed: Yes _____ No _____

Physician who will complete/sign Death Certificate: Name _____ Phone No: ()

(When notifying Physician, verify that both the cause of death and etiology have been determined or case meets criteria 1-9 above.)

I acknowledge receipt of personal effects: (Please list or, if none, record "None" and obtain signature)

Acuso recibo de los efectos personales: (Favor de enumerarlos o, si no hay nada, indique "nada" y obtenga la firma)

Date (Fecha) _____ X _____
Signature of Next of Kin (Firma del Pariente más cercano) Relationship (Parentesco)

I hereby authorize Tri-City Medical Center to release the remains of:

Por medio del presente documento autorizo a Tri-City Medical Center liberar los restos de:

Patient (Paciente)	To (Al)	Mortuary/Procurement Agency (Nombre del Mortuario)	() Area Code/Phone Number (Código de Area o # de Teléfono)
Date (Fecha)	X	Signature of Next of Kin (Firma del Pariente más cercano)	() Area Code/Phone Number (Código de Area o # de Teléfono)

Mortuary Notified: Date _____ Time _____ Initials _____

Mortician's/Medical Examiner's Receipt:

Received from TRI-CITY MEDICAL CENTER the remains of (Name) _____

(Date) (Time) (Signature of Medical Examiner/Lifesharing) (Released by)

Released By: _____ Date: _____ Time: _____

Public Administrator Notified: _____ Date: _____ Time: _____ Initials _____



Tri-City Medical Center

4002 Vista Way • Oceanside • CA • 92056



8720-1015

(Rev. 2/10)


**AUTHORITY FOR RELEASE OF DECEASED
(AUTORIZACION PARA LIBERAR LOS
RESTOS DEL DIFUNTO)**

White: Medical Record

Yellow: Admin Coordinator

Pink: Mortuary

Affix Patient Label

 Tri-City Medical Center	Patient Care Services
PROCEDURE:	SPONGE, SHARPS & INSTRUMENT COUNTS, PREVENTION OF RETAINED SURGICAL ITEMS
Purpose:	To outline nursing responsibilities and accountability regarding sponges sharps, and instrument counts in the surgical/procedural areas.
Supportive Data:	Sponges, sharps, and instrument counts are performed during surgery/invasive procedures to provide for safe patient care and prevent retained surgical items. Counts for sponges/soft goods, sharps, and instruments are performed to account for all items used on the surgical field and to lessen the potential for injury to the patient as a result of a retained surgical item. All items are to be counted except those used for storage or disposal of items.
Equipment:	White Board, White Board Marker, Count Sheet(s), Sponge holders

A. POLICY:

1. Sponges, sharps, and miscellaneous item counts are required on all procedures except eyes and cystoscopies.
2. All counts shall be conducted both audibly and visually.
 - a. Counted items shall be visualized by both the scrub person and circulator/designee.
 - b. At time of permanent relief of either the scrub or circulating Registered Nurse (RN), direct visualization may not be possible; the team shall account for all items.
3. In surgery/obstetric operating room (OB-OR), one of the counting team members must be an RN.
4. A count may be initiated by any member of the perioperative team.
5. Unnecessary activity and distractions should be omitted during the counting process.
6. To the extent possible, the initial count shall be completed before the patient is brought into the Operating Room (OR).
7. Counts may be omitted in an emergency.
 - a. The emergent nature of a procedure or an unexpected change in the condition of the patient may necessitate omission of counts to preserve patient life or limb. In such cases, counts may be waived on order of the surgeon. The surgeon will document the omission of the count and rationale for the practice variation in the medical record.
 - b. If counts were omitted due to an emergency, fluoro image shall be performed and read prior to the completion of skin closure.
 - i. Document events regarding the nature of the emergency.
 - ii. Document the name of physician reading the fluoro image and the fluoro image results.
 - iii. The fluoro image must be saved in the patient's electronic health record (EHR).
 - iv. Complete an incident report.
8. If a patient is transferred to another department for completion of the procedure (i.e., transferred from OR to Interventional Radiology or transferred from Labor and Delivery to OR), a fluoro image must be performed and read for retained surgical items prior to the completion of skin closure.
9. Sponge, sharps, and miscellaneous item counts shall be written on the white board. Instrument counts shall be recorded on the instrument count sheet(s).

B. PROCEDURE:

1. Surgical counts are classified as:

Patient Care Services Content Expert	Clinical Policies & Procedures Committee	Nurse Executive Committee	Operating Room Committee	Pharmacy & Therapeutics Committee	Medical Executive Committee	Administration	Professional Affairs Committee	Board of Directors
03/03, 04/06, 08/09, 05/12, 01/13, 05/14, 04/15, 09/15, 10/17, 06/18, 08/20	06/12, 07/13, 05/14, 11/15, 02/16, 01/18, 12/18, 10/20	06/12, 02/13, 05/14, 02/16, 01/18, 12/18, 08/21	06/14, 01/16, 12/17, 07/18, 10/18, 02/22	n/a	07/12, 07/14, 09/16, 02/18, 01/19, 03/22	01/19, 04/22	08/12, 10/14, 10/16, 03/18, n/a	08/12, 11/14, 11/16, 03/18, 02/19

- a. Initial count: count before the procedure begins to establish the baseline and identify manufacturer packaging errors.
 - b. Add count: count new items added to the field after the baseline count is complete.
 - c. Relief count: count at the time of permanent relief of the scrub or RN circulator.
 - i. The relief count is performed by the incoming scrub and/or circulator who are assuming responsibility for the count as it stands at the time of relief.
 - d. Cavity ~~count~~ closure count: count before closure of a cavity (e.g., uterus, bladder, stomach, peritoneum, placement of mesh to close a space).
 - e. Closing count: count before **each layer of wound closure begins (documented as 1st count, 2nd count, etc.)**.
 - f. Final count: count after skin closure or end of procedure, when surgical items are no longer in use and all sponges (used and unused) are passed off the field, separated into sponge holders and confirmed by the surgical team.
2. Count in the following order:
 - a. Sponges
 - b. Needles
 - c. Other sharps and miscellaneous items
 - d. Instruments
 3. Count items in the following sequence:
 - a. Operative field
 - b. Mayo stand
 - c. Back table
 - d. Items off field
 4. Items passed off or dropped from the sterile field shall be retrieved by the circulating nurse, isolated from the field, and included in the final count. Countable items must never be subtracted from the count or removed from the operating room.
 5. Members of the surgical team shall account for broken or separated instruments/items within the surgical field.
 6. Multi-part items shall be counted as one unit (e.g., hypo and cap is counted as one unit), unless otherwise specified on the count sheet/whiteboard. Account for all individual pieces of multi-part items.
 7. Items added to the field need to be recorded at the time they are added.
 - a. Once the count has begun, recalled memory and/or counting packages cannot be used to reconcile a count.
 - b. The number on the whiteboard/count sheets must match the number of items on the field at the time of the count, or the count is considered incorrect.
 8. The count is to be recorded on the count board using a horizontal superscript running total format (e.g., 10¹⁰20¹⁰30¹⁰40). No additional slashes, initials, equal signs, or extraneous marks are to be made.
 9. The person adding countable items to the field is responsible for recording the items on the count board.
 - a. If items are added by anyone other than the primary RN circulator, the person adding the items shall verbally report the additions to the primary RN circulator.
 10. Inform primary surgeon of the count outcomes.
 11. Incorrect Counts:
 - a. Inform primary surgeon of count discrepancies.
 - b. The surgeon should perform a methodical wound examination, and a thorough search of all areas should be completed by the surgical scrub and circulating nurse.
 - c. Search the total room including floor, trash and linen:
 - i. If item is not found, a fluoro image of the patient must be taken prior to patient leaving the operating room.
 - ii. Complete an incident report.
 - d. Ensure sterile field remains sterile until item is found or fluoro image is read.
 - e. Inform a member of the department's leadership team/designee of count discrepancies.

12. Fluoro image interpretation for incorrect counts, emergencies, and fluoro image in lieu instrument counts:
 - a. When possible, it is highly recommended that a radiologist read the fluoro image before the skin is closed and the results of the reading, along with the name of the person who read the fluoro image, are documented.
 - b. At a minimum, the surgeon must interpret the film intraoperatively.
 - c. The fluoro image must be saved in the patient's EHR.
13. If an item is used to occlude the colpotomy during a da Vinci hysterectomy (i.e., asepto or glove), it becomes a countable item and must be accounted for at the end of the case.

C. SPONGES/SOFT GOODS COUNT:

1. Sponges (laps, baby laps, raytex) are issued in groups of ten.
2. The following counts are required for sponges/soft goods:
 - a. Initial count
 - b. Add count
 - c. Relief count
 - d. Cavity **closure** count
 - e. Closing count (**1st count, 2nd count, etc.**)
 - f. Final count
3. Initial sponge counts shall be performed in the quantity as packaged by the manufacturer in order to identify manufacturer packaging errors (i.e., laps are counted in multiples of five and raytex are counted in multiples of ten), total count in multiples of ten.
4. If a package of sponges/soft goods is found to be defective when opened (e.g., wrong number, damaged, contaminated), the package and its contents will be removed immediately from the field, placed in a plastic bag, labeled, and removed from the operating room.
5. Sponges shall be counted in order from largest sponge to smallest sponge (e.g., laps then baby laps, then raytex).
6. All sponges shall be fluoro image detectable.
 - a. Never use fluoro image detectable sponges for wound dressings.
7. Count each sponge and separate from other sponges during the count.
8. Remove all packing and wrapping materials and promptly discard in the trash.
9. All sponges must be opened and visualized during closing counts and separated into sponge holders.
 - a. At the end of skin closure, ALL sponges are passed off the field, separated, opened to full length, and placed in sponge holders.
 - b. Use a separate sponge holder for each sponge type (i.e., one for laps, one for raytex).
 - c. Only one sponge should be placed in each pocket of the sponge holder.
 - d. Load the sponge holder horizontally from the bottom row to the top row, filling first the bottom two pockets and continuing upwards. This process will make visual determination of the filled holder easier to see from the OR table so empty pockets will be clearly visible to all in the room.
 - e. Place the sponge inside the pocket with the blue tag or blue stripe visible.
 - f. Place one sponge per pocket, two sponges per row, and 10 sponges per sponge holder.
 - g. When a holder has 10 sponges, there will be no empty pockets.
 - h. The final sponge count CANNOT be considered completed until ALL sponges opened during the case are bagged and visualized by the surgical team.
 - i. The sponge holders are not disposed of until the patient leaves the OR.
10. Towels used in an open wound shall be fluoro image detectable and shall be included in the count as miscellaneous items.
 - a. Scrub person shall notify the circulating RN when a towel is placed in a wound/cavity and when it has been removed.

D. SHARPS AND MISCELLANEOUS ITEMS COUNTS:

1. The following counts are required for sharps and miscellaneous items:

- a. Initial count
 - b. Add count
 - c. Relief count
 - d. Cavity **closure** count
 - e. Closing count (**1st count, 2nd count, etc.**)
 - f. Final count
2. Packaged needles containing an incorrect number shall be removed from the room.
3. All used needles are to be placed in a puncture-proof needle counter box.
 - a. Place one needle in each numbered slot; do not double-up needles in a numbered slot.
 - b. Obtain an additional needle counter box if the initial needle counter box is full.
4. Counting number of needle packages may not be used to reconcile an incorrect needle count.

E. **INSTRUMENT COUNTS:**

1. The following counts are required for instruments:
 - a. Initial count
 - b. Add count
 - c. Relief count
 - d. Closing count (**1st count, 2nd count, etc.**)
2. The instrument count is driven by the instrument count sheet, used as a checklist. The circulating nurse/designee directs the instrument count by reading off the instrument count sheet and visualizing the counted instruments with the scrub.
 - a. All instruments shall remain within the OR during the procedure until all counts are completed and resolved.
 - i. Individual pieces of assembled instruments shall be accounted for within the instrument count (e.g., suction tips, wingnuts, blades, sheaths).
3. Instrument counts are required for cases entering the abdominal, thoracic, mediastinal, and retroperitoneal cavities.
 - a. Instrument counts are required for any procedure where the incision is large enough for an instrument (including instrumentation, such as screws) to pass through.
 - b. Instruments shall be counted at the start of all hernia repairs, laparoscopy, thoracoscopy, and robotic procedures since the possibility of converting to an open procedure or extending the incision exists.
 - i. If the procedure does not convert to an open procedure or the incision is not extended to be larger than the smallest instrument used on the case, the closing instrument count may be waived.
 - c. Closing instrument counts are required for vaginal hysterectomies and laparoscopic assisted vaginal hysterectomies. For all other vaginal procedures, the surgeon is to perform a methodical wound examination of the vaginal cavity at the conclusion of the procedure to ensure items are not retained in the vagina.
 - d. Instrument counts may be omitted in certain cases with numerous and/or complex instruments or instrumentation. A fluoro image is taken before the completion of skin closure to confirm instruments are not left in the wound. **It is ideal to take the closing fluoro image immediately prior to the start of wound closure. All instruments must be out of the wound. The latest time to take the closing fluoro image is immediately prior to the completion of skin closure.** The following cases shall use a fluoro image in lieu of instrument count:
 - i. All anterior, posterior, and lateral spine cases.
 - ii. Cervical spine cases.
 - iii. Total joint replacements (hips, knees and shoulders).
 - iv. Any orthopedic case using trays of screws, wires, or other complex instrumentation.
 - v. Any case using loaner trays or large numbers of instruments which is prohibitive of completing an accurate instrument count.
 - vi. If fluoroscopy is being used on the case, a fluoroscopic image may substitute for

- vii. a fluoro image if a permanent copy of the image can be recorded and retained. When possible, it is highly recommended that a radiologist read the fluoro image before the patient leaves the OR and the results of the reading, along with the name of the person who read the fluoro image, are documented. At a minimum, the surgeon must interpret the film intraoperatively.
- e. Reverse total shoulder replacements: the surgeon shall announce when the humeral protector is placed into the wound and when it is removed and the RN circulator shall record it on the whiteboard.

F. **DOCUMENTATION:**

1. Document verification of all counts in the OR record.
 - a. **Items counted**~~Types of counts (i.e., instruments, sharps, sponges, sharps, and instruments miscellaneous items).~~
 - b. **Type of count (i.e., Initial count, relief count, 1st closing count, 2nd closing count, cavity closure count, additional count, and final count)**~~the number of closing counts.~~
 - c. **Count method (i.e., manual)**
 - ~~e.d.~~ Names and titles of personnels performing counts.
 - ~~d.e.~~ Results of counts (i.e., correct or incorrect)
 - i. Actions taken if count discrepancies occur.
 - ii. Rationale if counts are not performed or completed.
 - f. **Surgeon notified of count results.**
 - ~~e.~~ Complete an incident report for all incorrect counts or waiver of counts in the event of an emergency.

G. **REFERENCE(S):**

- ~~1. Conner, R. (2018). Guidelines for Perioperative Practice, 2018 Edition. Denver, CO: Association of PeriOperative Registered Nurses.~~
1. **AORN, Inc. (2020). *Guidelines for Perioperative Practice*. Denver.**
2. Verna Gibbs, MD. NoThing Left Behind®: Prevention of Retained Surgical Items Multi-Stakeholder Policy (2015).

**PROCEDURE: UNIVERSAL PROTOCOL**

Purpose: To outline the requirements and the process of Universal Protocol for surgical and invasive procedures. This procedure is designed to enhance patient safety by ensuring proper identification of the patient and that the correct invasive or surgical procedure is performed on the correct side and at the correct site. Procedures that place the patient at the most risk include those that involve general anesthesia or deep sedation.

A. DEFINITIONS:

1. **Invasive Procedure:** The puncture or the incision of the skin, insertion of an instrument or insertion of foreign material into the body for diagnostic or treatment-related purposes. For purposes of this policy, excluded as invasive procedures are venipuncture, arterial puncture for lab draw, nasogastric tube placement, urethral catheter placement, and peripheral intravenous (IV) therapy.
2. **Patient Safety:** In all cases the goal of the Universal Protocol is patient safety. To that end, the ~~site marking or time out requirements and processes of Universal Protocol~~ may be deferred if the risk outweighs the benefit to the patient in a life-threatening situation.
3. **Pre-Procedural Verification:** The process of assuring all relevant and needed documents (e.g. history and physical, signed procedure consent form, ~~informed consent documented by physician,~~ physicians orders, surgery/procedure schedule, nursing assessment, pre-anesthesia assessment, labeled diagnostic and radiology test results, scans, pathology and biopsy reports, and any required blood products, implants, devices, and/or special equipment for procedure), information and equipment are available prior to the start of the procedure, correctly identified, labeled and matched to the patient's identifiers, and are reviewed and consistent with the patient's expectations and team's understanding of the intended patient, procedure, site and side. ~~Pre-procedural verification is completed before the patient leaves the pre-procedure i.e., nursing units or enters the procedure room.~~
4. **Site Marking:** For purposes of this procedure, site marking is when the physician/Allied Health Professional (AHP) who has been granted privileges to perform the procedure and will be directly involved in the procedure places his/her initials at the intended site of the procedure. Marking the site may also be done by use of a special purpose armband when it is not possible/feasible to mark the actual site.
5. **Time Out:** For purposes of this procedure, the Time Out means that after the induction of anesthesia or administration of any pre-procedure medication (as applicable), completion of prepping and draping, and just prior to the start of the procedure (injection of local anesthesia, insertion of instrument or device, and/or incision), the staff involved with the procedure cease all other noise and activities (to the extent possible without compromising patient safety) and conduct the final assessment that the correct patient, site and procedure are identified. ~~A designated member of the team initiates the time out.~~

B. POLICY:

1. The pre-operative/pre-procedure verification process occurs **at the following times (as applicable to the location the procedure is taking place)**, with the patient is-awake and aware if possible ~~(as applicable):~~
 - a. ~~At the time the surgery/procedure is scheduled~~
 - b.a. At the time of preadmission testing/assessment **(if patient has a Pre-Operative Education/Preadmission testing appointment)**
 - c. ~~At the time of admission~~
 - d.b. Before the patient leaves the unit/floor for the surgery/procedure **(inpatients only)**

Patient Care services Content Expert	Clinical Policies & Procedures Committee	Nursing Leadership	Operating Room Committee	Pharmacy & Therapeutics Committee	Medical Executive Committee	Administration	Professional Affairs Committee	Board of Directors
10/08, 01/09, 09/09, 06/10, 07/12, 03/13, 09/14, 02/17, 05/18; 09/20; 06/21	08/12, 07/13, 04/14, 10/14, 06/17, 12/18, 10/20, 08/21	08/12, 04/14, 10/14, 07/17, 12/18, 12/20, 10/21	10/14, 05/17, 10/18, 09/20, 02/22	n/a	10/12, 6/14, 11/14, 8/17, 02/19, 01/21, 03/22	03/19, 03/21, 04/22	11/12, 07/14, 01/15, 09/17, n/a	12/12, 07/14, 01/15, 09/17, 03/21

- c. In Pre-Op Hold/Pre-Procedure area (assessment performed by the Pre-Operative Hold/Pre-Procedure RN and the surgical/procedural RN circulator, as when applicable)
 - e.i. Pre-Operative/Pre-Procedure verification by the surgical/procedural RN circulator may be conducted in the procedure room prior to beginning the procedure in certain areas (i.e., Interventional Radiology [IR], Gastroenterology procedure room, Cardiac Catheterization Lab [CCL]).
 - f. ~~Prior to transporting the patient to the operating/procedural room~~
 - g. ~~Anytime the responsibility for care of the patient is transferred to another member of the surgical/procedural care team (including anesthesia providers), at the time of and during the surgery/procedure~~
- 2. A Time Out is performed for every surgery and invasive procedure, regardless of laterality, levels, structure, location, or setting within the hospital, including bedside procedures. Any discrepancy discovered during the time out must be resolved before proceeding with the invasive procedure/surgery.
- 3. Any discrepancies identified during the pre-procedure verification process shall require a "hard stop" and a "huddle" to be called at the patient's bedside to resolve the discrepancy.
 - a. Discrepancies include any difference between the patient's verbal confirmation of the surgery/procedure to be performed, the history and physical (H&P), order for consent, surgery/procedural schedule, consent and imaging studies.
 - b. Members of the huddle may include, but are not limited to:
 - i. Physician/AHP performing the procedure
 - ii. Anesthesiologist
 - iii. Radiologist/Radiology Physician's Assistant
 - iv. Circulating Registered Nurse (RN)
 - v. Scrub RN or Operating Room (OR) Technician
 - vi. RN caring for the patient in the pre-procedural area
 - vii. Primary RN
 - viii. Patient/patient representative
 - ix. OR/Pre-procedural area charge nurse
 - x. Imaging technologist
 - xi. Other healthcare provider (HCP) involved in the procedure
 - c. The following documents are reviewed in the huddle:
 - i. History & Physical (H&P)
 - ii. Order for consent
 - iii. Surgery/procedural schedule (if add on for the same day, ~~no printed schedule is required~~ **use the Add-On Booking Sheet**) as applicable to the location the procedure is taking place.
 - iv. Consent form
 - v. Imaging studies as ordered
 - d. The procedure shall not progress until all discrepancies are resolved.
 - e. The discussion resolving the discrepancy and the final result of the decision shall be documented in the medical record by one of the following:
 - i. Physician/AHP performing the procedure
 - ii. RN/Healthcare Provider
 - iii. Anesthesiologist (as applicable)

C. **SITE MARKING:**

- 1. Process:
 - a. Prior to leaving Pre-Op Hold or the pre-procedure area, the intended surgical site is marked by the physician/AHP performing the procedure. Site marking must be legible, unambiguous, used consistently throughout hospital, and visible once the patient is prepped and draped.

- i. Outpatient areas without pre-procedure areas will perform site marking in the procedure room.
 - b. Site marking is required for all surgeries and invasive procedures except:
 - i. ~~Emergency situations where any delay in initiating the surgery or invasive procedure would compromise the safety of the patient or outcome of the procedure.~~
 - ii.i. Single organ procedures without intended laterality.
 - iii.ii. Procedures that are intended to be bilateral and no laterality-based choice is involved.
 - iv.iii. Procedures with no pre-determined site of insertion (i.e. cardiac catheterization, Interventional Radiology procedures).
 - v.iv. Procedures in which the site is so clearly evident (i.e. open fracture, laceration, cast) that it cannot be confused.
 - vi.v. Procedures in which the physician/AHP performing the procedure is in continuous attendance of the patient from the point of decision to perform the procedure through the completion of the procedure.
 - vii.vi. Endoscopic procedures and Bronchoscopies.
 - c. Site marking takes into consideration laterality, surface (i.e. flexor/extensor), level (spine) or specific lesion/digit to be treated.
 - d. The mark is made using a marker that is sufficiently permanent to remain visible after skin prep and the mark is to be placed such that it is visible after the patient is prepped and draped.
 - e. The mark is made using the physician/AHP's initials.
 - i. First and last initials are used. If the first and last initials are "N.O." a third initial is used.
 - ii. The physician/AHP may choose to also draw a line at the proposed incision site.
 - f. In the event of multiple primary procedures by different physicians/AHPs, each site must be marked prior to admission to the OR/procedural area.
 - g. The site marking should be done with the patient/family awake and involved, to the extent possible.
 - h. For minimal access procedures intended to treat a lateralized internal organ, the intended side is indicated by a mark at or near the insertion site.
 - i. Marking for procedures performed at the patient's bedside will occur prior to prepping/draping or starting the procedure.
2. For spinal procedures, in addition to preoperative skin marking of the general spinal region, special intraoperative radiographic techniques may be used for marking the exact vertebral level.
3. Dental Procedures: The operative tooth name(s), number(s) and/or letter(s) are indicated on the documentation (OR schedule, H&P/plan for surgery, order for consent) and the operative tooth/teeth are marked with the physician's/AHP's initials on the dental radiographs or dental diagrams. The radiograph/diagram is posted in the procedure room prior to start of the procedure.
4. Nerve blocks: The anesthesiologist shall confirm the surgical/procedure site, through a comparison of the patient's verbal response and a review of the medical record and procedural consent form, prior to the administration of sedation and/or initiation of a nerve block. The Anesthesiologist may place a pre-surgical nerve block only after the surgical site has been marked by the physician/AHP.
5. Special Use Armband:
 - a. A special use armband is used when the surgical site is required to be marked, but cannot be marked because of one of the following situations:
 - i. The patient refuses
 - ii. The patient is a neonate
 - iii. The proposed site is technically or anatomically difficult to mark (e.g., perineum)

- iv. Movement of the patient to mark could compromise the safety of the patient or outcome of the procedure (e.g. patient with unstable spine fracture)
- b. The first and last name of the patient, a second patient identifier, and the planned procedure, including site and side, are written on the armband. In the event of laterality, the armband is applied on the side of the intended procedure.
- c. The physician/AHP must initial the armband.
- d. The armband is removed at the conclusion of the procedure or immediately prior to prepping if necessary to perform the surgical/procedural prep on the banded limb.

D. SCHEDULING:

- 1. Scheduling for the procedure must include the following information:
 - a. Patient name and second patient identifier (date of birth [DOB], medical record number [MRN], or financial identification number [FIN]). Cases cannot be scheduled unless this information is available (with the exception of an emergency, when a delay procuring information could adversely affect the patient).
 - b. Entire procedure, exact site, level, digit and side/ laterality. No abbreviations may be used.
 - c. See department specific scheduling procedures for additional scheduling requirements.

E. PRE-PROCEDURE VERIFICATION PROCESS:

- 1. Upon admission, the patient's identity is verified by the person admitting the patient. An appropriate identification band is affixed to the patient's arm (or leg). See Patient Care Services Policy Identification, Patient.
- 2. **Inpatient Unit/Floor:** Before the patient leaves the unit/floor (**inpatients**) the Registered Nurse (RN):
 - a. Reviews the medical record to verify the following items are available, accurately matched to the patient and are all in agreement for the procedure/site/side to be performed:
 - i. H&P (must be electronic or ~~printed~~**scanned to the electronic health record [EHR], and be dated** within 30 days prior to surgery/procedure)– review the plan for surgery
 - ii. Electronic H&P update completed day of surgery/procedure (**if available**)
 - iii. Orders for consent (**including verification of original order, if paper/scanned orders**)
 - iv. Consent form
 - v. Surgery/procedural schedule
 - vi. Imaging studies report (as applicable)
 - b. Completes the pre-procedure checklist (as applicable).
 - c. Ensures site marking is completed if patient is going directly to the operating room.
 - d. Any discrepancies identified during the pre-procedure verification process shall require a "hard stop" and a "huddle" to be called at the patient's bedside to resolve the discrepancy.
- 3. ~~In Pre-Op Hold/pre-procedure area the~~**The pre-operative/pre-procedural RN/HCP:**
 - a. Reviews the medical record to verify the following items are available, accurately matched to the patient and are all in agreement for the procedure/site/side to be performed:
 - i. H&P (must be electronic or ~~printed~~**scanned to the EHR, and be dated** within 30 days prior to surgery/procedure)– review the plan for surgery
 - ii. Electronic H&P update completed day of surgery/procedure
 - iii. Orders for consent (**including verification of original order, if paper/scanned orders**)
 - iv. Consent form
 - v. Surgery/procedural schedule
 - vi. Imaging report and images, as ordered

- b. Reviews the pre-procedure checklist to ensure accuracy and completeness.
 - b.i. Outpatients: The Pre-Operative/Pre-Procedural RN completes the consent form and pre-operative/pre-procedure checklist for outpatients.**
- c. Ensures site marking is completed, as applicable.
- d. Any discrepancies identified during the pre-procedure verification process, shall require a "hard stop" and a "huddle" to be called at the patient's bedside to resolve the discrepancy.
- 4. ~~Prior to transferring the patient to the operating room/procedural area the surgical/procedural RN circulator is a different nurse from the pre-operative/pre-procedure RN, the Pre-Procedure verification process shall be conducted again by the surgical/procedural RN circulator prior to transporting the patient to the OR/Procedural RN procedure room.~~
 - a.e. In IR, Cath lab CCL and the Gastroenterology procedure room (OR 12), the pre-procedure verification by the surgical/procedural RN circulator may be conducted in the procedure room before start of the procedure.
 - b.f. Reviews the medical record to verify the following items are available, accurately matched to the patient and are all in agreement for the procedure/site/side to be performed:
 - i. H&P (must be electronic or ~~printed~~ scanned to the EHR, and be dated within 30 days prior to surgery/procedure)– review the plan for surgery
 - ii. Electronic H&P update completed day of surgery/procedure
 - iii. Orders for consent (including verification of original order, if paper/scanned orders)
 - iv. Consent form
 - v. Surgery/procedural schedule
 - vi. Imaging report and images, as ordered
 - g. Reviews the pre-procedure checklist to ensure accuracy and completeness.
 - e.i. Outpatients: The pre-operative/pre-procedural RN completes the consent form and pre-operative/pre-procedure checklist for outpatients.**
 - d.h. Ensures necessary implants or special equipment are available, as applicable.
 - e.i. Ensures site marking is completed, as applicable.
 - f.j. Any discrepancies identified during the pre-procedure verification process, shall require a "hard stop" and a "huddle" to be called at the patient's bedside to resolve the discrepancy.

F. **TIME-OUT:**

- 1. The Time Out is conducted immediately before starting the procedure.
- 2. During the Time Out, all other noise and activities in the room are suspended (to the extent possible, without compromising patient safety).
- 3. Use the medical record and patient armband to verify:
 - a. Patients' identity verified using two patient identifiers per Patient Care Services: Identification of Patients Policy and comparing two sources of identification (patient's armband, if visible, and medical record). If the armband is not visible during the Time Out, one of the following alternatives must be used:
 - i. A patient identification band is placed on an exposed extremity (alterative wrist, ankle) and this band is used to confirm two patient identifiers during the Time Out.
 - ii. Two team members confirm the patient identity (two identifiers) upon arrival to the surgical/procedural area. One of the team members must remain with the patient during the entire pre-procedural phase and confirm the patient identity during the Time Out.
 - iii. Two team members confirm patient identity (two identifiers) upon arrival to the surgical/procedural area. The two patient identifiers are written on the white board in the procedure room and confirmed by the two team members. During

the final Time Out, the team confirms patient identity against the information on the white board.

- 1) This patient identification process shall be used in surgical services.
- b. Physician/AHP calls for the Time Out after the patient is prepped and draped.
- c. All personnel in the OR/procedure room **may** introduce **themselves** by name and role.
- d. The circulating RN/assistive HCP (such as Emergency Medical Technician, Respiratory Care Practitioner, Radiology Technician, Anesthesia Technician):
 - i. Uses the consent form to read the patient's name, approved second identifier, and procedure (including site and side).
 - ii. Verifies all sterility indicators were checked, as applicable.
 - iii. Reviews equipment issues or concerns.
 - iv. States the Fire Risk Assessment score.
 - v. Verifies the following precautions were taken when using alcohol-based prep solutions:
 - 1) At least 3 minutes passed for prep to dry and fumes dissipated before draping or using surgical equipment.
 - 2) Prep solution is not pooled.
 - 3) Prep solution-soaked materials are removed from the field prior to draping or using surgical equipment.
- e. The anesthesiologist (if applicable, or circulating RN if no anesthesiologist present):
 - i. States antibiotic administered, dose and time.
 - ii. Reviews any patient-specific concerns.
- f. The surgeon/procedural physician/AHP:
 - i. Verifies the site is marked (if applicable)
 - ii. Verifies essential imaging is displayed
 - iii. Reviews critical or unexpected steps in the procedure
 - iv. States anticipated operative duration
 - v. States anticipated blood loss
 - vi. Asks if all agree
- g. The scrubbed person states agreement and readiness for consented procedure.
- h. All Staff members in the OR at the time of the time out must state "I Agree" or state their concern/discrepancy.
4. Initiation of the Time Out is the responsibility of the physician/AHP performing the procedure.
5. The Time Out is conducted in a fail-safe mode:
 - a. The surgery/invasive procedure is not started until all questions are resolved.
6. The time out includes all members of the procedural team who will be participating in the procedure at its inception.
7. The Time Out is documented in the patient's electronic health record.
8. If two or more procedures are being performed on the same patient, a Time Out is performed to confirm each subsequent procedure before it is initiated.

G. RELATED DOCUMENT(S):

1. Patient Care Services: Identification of Patients Policy

H. REFERENCES:

1. JAMA Surgery (2017). Centers for disease control and prevention guideline for the prevention of surgical site infection, 2017. *JAMA Surgery*, E1-E8. doi: 10.1001/jamasurg.2017.0904
2. The Joint Commission. (2020, July). National patient safety goals effective July 2020 for the hospital program. Retrieved from <https://www.jointcommission.org/standards/national-patient-safety-goals/hospital-2020-national-patient-safety-goals/>



Tri-City Medical Center
Oceanside, California

PATIENT CARE SERVICES

ISSUE DATE: 04/03 SUBJECT: Vaccination Administration

REVISION DATE: 06/03, 09/05, 08/08, 04/11, 12/14
07/17 POLICY NUMBER: ~~IV.I.10~~

Department Approval:	04/17/10/21
Clinical Policies & Procedures Committee Approval:	05/17/11/21
Nursing Leadership Executive Council Approval:	05/17/11/21
Pharmacy and Therapeutics Approval:	05/17/02/22
Medical Executive Committee Approval:	06/17/03/22
Administration Approval:	04/22
Professional Affairs Committee Approval:	07/17 n/a
Board of Directors Approval:	07/17

A. **PURPOSE:**

1. National Childhood Vaccine Injury Act (NCVIA) [42 U.S.C. Sections 300aa-14 and 300aa-26, 42 C.F.R. Section 100.3] requires health care providers to ~~furnish~~ provide a Vaccine Information Statement (VIS) to a patient (or the patient's legal representative) before administering specific vaccines. The patient or the patient's legal representative must be given this information to keep and in appropriate cases, the written material is supplemented with visual presentations, oral explanations, or videotape
 - a. VIS are required for the following under the NCVIA
 - i. -Diphtheria, tetanus and pertussis containing vaccines (DTaP, DT, Td, and Tdap)
 - ii. *Haemophilus influenzae* type b (Hib)
 - iii. Hepatitis A
 - iv. Hepatitis B
 - v. Human Papillomavirus (HPV)
 - vi. Influenza (both Inactivated and Live, Intranasal vaccines)
 - vii. Measles-Mumps-Rubella (MMR)
 - viii. Measles-Mumps-Rubella-Varicella (MMRV)
 - ix. Meningococcal
 - x. Novel Viral Vaccines e.g., COVID - 19
 - xi. Conjugate (PCV13)
 - xii. Polio
 - xiii. Rotavirus
 - xiv. Varicella
 - b. The Centers for Disease Control and Prevention (CDC) encourages healthcare providers to provide a VISs when administering the following vaccines:
 - i. Adenoviruses
 - ii. Anthrax
 - iii. Cholera
 - iv. Japanese Encephalitis (Ixiaro)
 - v. Pneumococcal Polysaccharide
 - vi. Rabies
 - vii. Shingles
 - viii. Typhoid
 - ix. Yellow Fever

- 1.c. ~~measles, mumps, rubella, polio, diphtheria, tetanus, hepatitis B, Varicella (chickenpox), haemophilus influenzae type B (Hib), pertussis and pneumococcal conjugate vaccinations. The patient or the patient's legal representative must be given this information to keep and in appropriate cases, the written material is supplemented with visual presentations or oral explanations.~~
2. Each health care provider who administers a vaccine is required to document the following information in the patient's medical record (this includes an electronic medical record, or in a permanent log):
 - a. Administration date
 - b. Injection site
 - c. Vaccine manufacturer and lot number of the vaccine, expiration date of vaccine
 - d. Name and title of the healthcare provider administering the vaccine
 - d.e. ~~Address of the location (site) where the vaccine is administered, and title of the healthcare provider administering the vaccine~~
 - e.f. Publication date of the VIS given to the patient or legal representative and the date the VIS materials were/was given.

B. POLICY:

1. Federal and California state laws do not require special informed consent prior to vaccination.
2. Not all vaccines are covered by the National Childhood Vaccine Injury Act, but at Tri-City Healthcare District (TCHD), appropriate VIS will be given and reviewed prior to any vaccination. The most current copies of VIS are available at <http://www.cdc.gov/vaccines/> or www.immunize.org as well as on the hospital intranet on the home page under patient education.
3. If the patient has a medical record, the information is charted there. If the patient is seen and an individual chart is not constructed (i.e. flu-shot clinic) the above information is recorded in a log. Stickers or a stamp can be used to prompt the health care provider to record required information (see example below).

Vaccine	Date of Admin.	Manufacturer	Lot #	VIS Edition Date	Date VIS Given
Name/Title of Health Care Provider Administering					

4. Any adverse occurrence from administration of a vaccination must be reported. Refer to Patient Care Services: Vaccine, Reporting Adverse Events Policy and Administrative Policy: 236 Mandatory Reporting Requirements.

C. RELATED DOCUMENT(S):

1. Centers for Disease and Prevention (CDC). 2019, May 7). Document the vaccinations(s). <https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html#law> Centers for Disease and Prevention (CDC). 2019. Facts about viss. Retrieved from <https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html#law>.
- 4.2. Administrative Policy: 236 Mandatory Reporting Requirements
- 2.3. Patient Care Services: Vaccine, Reporting Adverse Events Policy

ADMINISTRATIVE POLICY-MANUAL

ISSUE DATE: 08/04

SUBJECT: Failure Mode & Effects Analysis (FMEA)

REVISION DATE: 07/06, 08/10, 10/15

POLICY NUMBER: 8610-389

Administrative Policies & Procedures Content Expert:	02/22
Administrative Policies & Procedures Committee Approval:	09/1503/22
Medical Executive Committee Approval:	n/a
Administration Approval:	04/22
Professional Affairs Committee Approval:	10/15 n/a
Board of Directors Approval:	10/15

A. PURPOSE:

1. To improve safety and reduce the risk of errors Tri-City Healthcare District (TCHD) selects one high risk process and conducts a proactive high-risk assessment.

B. POLICY:

1. TCHD utilizes the Failure Mode and Effects Analysis (FMEA) method. The Patient Safety Committee (PSC) oversees the FMEA process.
2. Processes selected for FMEA application represent a high-risk or high-vulnerability area, utilizing available information about sentinel events and other high risk and/or critical path issues known to occur in health care institutions that provide similar care and services. This selection is based on:
 - a. Identified and/or suspected areas of patient safety improvement opportunities at TCHD, based on review of information sources available within the facility.
 - b. Information published periodically by the Joint Commission that identifies the most frequently occurring types of sentinel events and patient safety risk factors.
 - c. Other recognized sources that identify high risk and high-occurring vulnerabilities, such as the National Quality Forum's Safe Practices for Better Healthcare, the Institute for Safe Medication Practices (ISMP) information, Food and Drug Administration databases and advisories.
 - d. New processes affecting patient care before they are implemented
3. At least one high-risk process is assessed every eighteen months using the FMEA methodology.
4. The ~~PSC Patient Safety Committee~~ approves the prioritization of FMEA initiation and reports to, the Quality Assurance Performance Improvement (QAPI) Committee, ~~to the Professional Affairs Committee~~ and then the Board of Directors.
5. ~~Patient Safety Committee (PSC)~~ recommends an interdisciplinary team and team leader to implement the FMEA based on the scope of the project.
 - 5.a. ~~The Risk Manager or designee in collaboration with the PSC Patient Safety Committee~~ determine the need to implement a FEMA and work with the appropriate leaders to ensure processes developed as a result of the FEMA are completed and monitored

C. REFERENCE:

1. The Comprehensive Accreditation Manual Joint Commission (202145) – Leadership Standard

**ADMINISTRATIVE POLICY
DISTRICT OPERATIONS**

ISSUE DATE: 04/93 **SUBJECT:** Hospital Records Retention

REVISION DATE(S): 06/02, 04/03, 06/06, 05/09, 08/12 **POLICY NUMBER:** 8610-237
04/15

Administrative Policies & Procedures Content Expert Department Approval: 03/1502/1807/21
Administrative Policies & Procedures Committee Approval: 03/1502/1803/22
Medical Executive Committee Approval: n/a
Administration Approval: 04/22
Professional Affairs Committee Approval: 04/15 n/a
Board of Directors Approval: 04/15

A. PURPOSE:

1. To identify a hospital records retention schedule, which meets Tri-City Healthcare District (TCHD) needs and the requirements for regulatory standards.

B. POLICY:

1. ~~Tri-City Healthcare District~~ TCHD may at its discretion, pursuant to this policy and applicable law, follow the California Hospital Association (CHA) "~~Hospital Records Guide~~" **Record and Data Retention Schedule** recommended guidelines. The guide is not designed to serve as a substitute for legal counsel. If there are differences of opinion or where law is unclear, legal counsel should be consulted.
2. Each hospital department is required to establish its own internal hospital records retention policy, which should be appended to the Department's Policy Manual.

C. REFERENCE RELATED DOCUMENT(S):

1. ~~A California Hospital Association Record Retention Schedule~~ is available in Medical Records.
2. Board Policy: #14-008 Records Retention and Destruction

D. REFERENCE(S):

- 2-1. California Hospital Association (2011). *Record and Data Retention Schedule*. Sacramento, CA: California Hospital Association.

**ADMINISTRATIVE POLICY
DISTRICT OPERATIONS**

ISSUE DATE: 02/07

SUBJECT: Space and Office Allocation

REVISION DATE: 08/09, 03/15, 01/18

POLICY NUMBER: 8610-289

Department Review:	11/17/12/21
Administrative Policies & Procedures Committee Approval:	11/17/12/21
Administration Approval:	04/22
Professional Affairs Committee Approval:	01/18 n/a
Board of Directors Approval:	01/18

A. PURPOSE:

1. Establish guidelines with regard to space allocation throughout the facility including off site locations. ~~Office of Statewide Health Planning and Development~~ **Department of Health Care Access and Information (HCAI) (OSHPD)** space shall be utilized for Patient Care revenue producing functions whenever possible.

B. POLICY:

1. All requests for space shall be initiated by submitting either a **Request for Space/Project or an Request for Space/ Renovation form sent in writing via email** to the Facilities Management Department. Director of Facilities will **present requests to the Space/Allocation planning committee for review and approval.** ~~any~~Any requests, and depending on the scope will be discuss with the C-Suite members as necessary.
2. Manager/Director levels and above should have private offices to facilitate staff confidentiality.
 - a. All other personnel requiring space shall share office space that meets Occupational Safety and Health Administration (OSHA) space guidelines.
 - b. No one shall have more than one office in any Tri-City Healthcare District (TCHD) building or buildings.
 - c. Temporary offices located in any converted patient rooms must have the ability to be reverted back to a patient room within 24 hours.
3. A request for office furniture, carpet, computers, etc. must be approved according to the Administrative Policy: 232 Signature Authority and requests sent respectively to Facilities Management, or Purchasing or Information Technologies Departments..
 - a. ~~An inventory of potentially usable office furniture will be kept by Facilities staff and should be reviewed prior to ordering any furniture.~~
 - b-a. An ergonomic review **will be completed upon request.** ~~prior to ordering office furniture is recommended.~~ **Refer to Employee Health and Wellness Services: Ergonomic Policy.**
4. Storage space shall be kept to a minimum to avoid clutter and possible fire code and/or safety violations.
 - a. Furniture or equipment that is no longer useful should be disposed of according to district guidelines per Administrative Policy: 200 Equipment Transfer, Storage, Trade-In, and Disposal and not kept in storage indefinitely. Once equipment or furniture is deemed unusable and needs to get disposed, the parent department will place the equipment or furniture in the dumpster located by the loading dock. If you need assistance, a work order needs to be submitted to the Environmental Services Department through the intranet.
5. ~~There can be no storage in the corridors.~~

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

1. Administrative Policy: 200 Equipment Transfer, Storage, Trade-In, and Disposal
2. Administrative Policy: 232 Signature Authority
- 2.3. Employee Health and Wellness Services: Ergonomic Policy**

**ADMINISTRATIVE POLICY-MANUAL
INFORMATION TECHNOLOGY**

ISSUE DATE: 06/03

SUBJECT: Fax Transmissions

REVISION DATE: 02/05; 05/12; 06/12, 02/16

POLICY NUMBER: 8610-616

Administrative Policies & Procedures Content Expert Department Approval Date(s):	10/1512/21
Administrative Policies & Procedures Committee Approval:	10/1503/22
Medical Executive Committee Approval:	n/a
Administration Approval:	04/22
Professional Affairs Committee Approval:	02/16 n/a
Board of Directors Approval:	02/16

A. PURPOSE:

1. To provide guidance to Tri-City Healthcare District (TCHD) employees who use facsimile transmission (Fax Transmission) services.

B. DEFINITIONS:

1. Fax Transmission: identifies any form of facsimile transmission currently sanctioned for use at TCHD. It encompasses faxing via manual and computer assisted methods.
2. Protected Health Information (PHI): individually identifiable health information transmitted or maintained in paper or electronic form that is created or received by TCHD AND
 - a. Relates to the past, present or future physical or mental health or condition of an individual; OR
 - b. Relates to the provision of health care to an individual; OR
 - c. Relates to the past, present or future payment, AND
 - d. Identifies the individual OR with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

C. POLICY:

1. This policy addresses Fax Transmission and informs employees of their rights and obligations.
2. Employees may use Fax Transmission to communicate with each other or with outside persons or organizations. Fax Transmissions are TCHD property, with the purpose of facilitating TCHD communications. Fax Transmissions are intended for TCHD business related purposes only. TCHD encourages the use of Fax Transmissions to improve communications and productivity. Each employee has a responsibility to maintain and enhance TCHD's public image and to use Fax Transmissions in a productive and legal manner.
3. All TCHD policies and practices apply to Fax Transmissions, including those policies regarding intellectual property protection, privacy, misuse of TCHD resources, sexual harassment or other unlawful harassment, information and data security, and confidentiality. In addition, any communication that is sent via Fax Transmission is a communication on behalf of TCHD. Therefore, any TCHD Fax Transmission must be professional and business-related.
4. To reinforce this and other confidentiality policies, each employee must sign the TCHD Confidentiality Agreement **per Administrative Policy: Confidentiality 455** annually on his/her review date.
5. When using Fax Transmissions, appropriate security measures must be strictly followed. Each employee who uses Fax Transmissions is personally accountable for any action that results in a breach of TCHD security or confidentiality.
6. The transmission of any kind of sexually explicit information on any company system is a violation of our policy on sexual harassment. In addition, sexually explicit material may not be accessed, archived, stored, distributed, edited, or recorded using our telephone resources.

7. Employees must not use Fax Transmissions knowingly to violate the laws and regulations of the United States or any other nation. Use of any company resources for illegal activity is grounds for corrective action or immediate dismissal, and we will cooperate with any legitimate law enforcement activity.
8. An employee must use a cover sheet when using Fax Transmissions, except in cases where facsimiles are transmitted automatically via a computer system. A sample cover sheet is attached to this policy.
9. Each facsimile must contain, in the cover sheet or the body of the text, the following disclaimer:
 - a. *This message and any included attachments are from the Tri-City Healthcare District and are intended only for the addressee. The information contained in this message is confidential and may constitute non-public information under international, federal, or state securities laws and is intended only for the use of the addressee. Unauthorized forwarding, printing, copying, distributing, or using such information is strictly prohibited and may be unlawful. If you are not the addressee, please promptly destroy this message and notify the sender of the delivery error by fax or phone.*
 - b. With regards to PHI:
 - i. Individually identifiable health information should be protected with reasonable administrative, technical, and physical safeguards to ensure its confidentiality, integrity, and availability and to prevent unauthorized or inappropriate access, use, or disclosure.
 - ii. Do not send PHI over FAX unless it cannot be sent over other, more secure channels. i.e. delivery by hand, secure email, etc.
 - iii. Only send the PHI actually needed: do not send extra information.
 - iv. Make sure that PHI FAXes never remain on the FAX machine after receipt, and that they are promptly delivered to intended recipient.
10. Management and Administration:
 - a. The TCHD Information Technology Department is responsible for assuring security of TCHD facsimile services.
 - b. All messages, message audit reports, and records of Fax Transmissions are official records and are the property of TCHD. TCHD reserves the right to access and disclose, at any time, all documentation of Fax Transmissions.
 - c. Employees should not assume that Fax Transmissions are private. TCHD may monitor and record Fax Transmissions.
 - d. Adherence to this Policy is neither voluntary nor optional. Violation of this policy may constitute grounds for formal counseling, up to and including termination, as described in Administrative Policy 424, section 2.3.2. If necessary, TCHD also reserves the right to advise appropriate legal officials of any illegal violations.
 - e. Each employee is expected to report unauthorized use or violation of this policy.

D. **FORMS:**

1. Fax Transmission Form - **SAMPLE**

E. **RELATED DOCUMENTS:**

1. Administrative Policy: ~~8610-424~~, Coaching and Counseling for Work Performance **424**
- 4.2. Administrative Policy: **Confidentiality 455**
- 2.3. Administrative Policy: ~~8610-522~~, Faxing Protected Health Information **522**

F. **REFERENCES:**

1. Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, HIPAA

Fax Transmittal Sheet SAMPLE



Tri-City Medical Center

DATE: _____ NUMBER OF PAGES INCLUDING THIS SHEET: _____

TO: _____ → ATTENTION: _____

FAX #: _____

THIS FAXED INFORMATION HAS BEEN DISCLOSED TO YOU FROM RECORDS WHOSE CONFIDENTIALITY IS PROTECTED BY FEDERAL LAW. FEDERAL REGULATION (42 CFR, PART 2) PROHIBITS YOU FROM MAKING ANY FURTHER DISCLOSURE OF IT WITHOUT THE SPECIFIC WRITTEN CONSENT OF THE PERSON TO WHOM IT PERTAINS, OR AS OTHERWISE PERMITTED BY SUCH REGULATIONS. A GENERAL AUTHORIZATION FOR THE RELEASE OF MEDICAL OR OTHER INFORMATION IS NOT SUFFICIENT FOR THIS PURPOSE.

Patient Name: _____ -MR#: _____

Information Sent Via Facsimile:

_____ Emergency Room Record → _____ Radiology Reports
_____ Discharge Summary → _____ Operative Reports
_____ History & Physical Report → _____ Lab/Pathology Reports
_____ Consultation Report → _____ Other (Please Specify)

COMMENTS: _____

Faxed By: _____

This facsimile transmission is intended only for the use of the individual or entity to which it is addressed and may contain information which is legally privileged. If you are not the intended recipient, you are hereby notified that any disclosure, distribution or copying of the transmitted material is strictly prohibited. If you have received this telecopy in error, please immediately notify me by telephone or arrange for return of the original transmission.

*****TRI-CITY MEDICAL CENTER FAX TRANSMITTAL SHEET*****



6700-1027

End of Sheet (Continued)



Tri-City Medical Center

**ADVANCED HEALTH CARE
FOR YOU**

**Tri-City Medical Center
4002 Vista Way, Oceanside, CA 92056
Fax Transmittal Form**

To: _____ **From:** _____
Phone: _____ **Phone:** _____
Fax: _____ **Fax:** _____
Date Sent: _____
Number of Pages (including cover): _____
SUBJECT: _____
COMMENTS: _____

☐ Urgent _____ ☐ Review _____ ☐ Please Reply _____

CONFIDENTIALITY NOTICE:

~~This message and any included attachments are from Tri-City Healthcare District and are intended only for the addressee. The information contained in this message is confidential and may constitute non-public information under international, federal, or state securities laws and is intended only for the use of the addressee. Unauthorized forwarding, printing, copying, distributing, or using such information is strictly prohibited and may be unlawful. If you are not the addressee, please promptly delete this message and notify the sender of the delivery error by e-mail. Thank you.~~

~~Revision Date: 2/16~~

**ADMINISTRATIVE POLICY MANUAL
INFORMATION TECHNOLOGY**

ISSUE DATE: 12/00

SUBJECT: Internet Access

REVISION DATE: 05/03; 02/05; 06/12, 02/16

POLICY NUMBER: 8610-603

Administrative Policies & Procedures Content Expert	Department Approval Date(s):	10/1512/21
Administrative Policies & Procedures Committee Approval:	10/1503/22	
Medical Executive Committee Approval:	n/a	
Administration Approval:	04/22	
Professional Affairs Committee Approval:	02/16	n/a
Board of Directors Approval:	02/16	

A. PURPOSE:

1. To provide Internet Services to authorized individuals (authorized Internet users) associated with Tri-City Healthcare District (TCHD), including employees, internal and external case managers, and authorized physicians, vendors and other persons engaged in legitimate business at TCHD where there's a need to access websites that can only be accessible through an authorized login. Internet Services are provided to those individuals who receive approval from a Department Director.

B. DEFINITIONS:

1. The term Internet Services identifies all Internet facilities, including browsing the World Wide Web, transferring files, Internet based discussion groups, chat services, mailing lists, electronic bulletin board systems and any online services to which TCHD subscribes.

C. POLICY:

1. This policy addresses Internet Services, informs authorized Internet users of their rights and obligations, and formally notifies authorized Internet users of usage monitoring. With advance notice, authorized Internet users will not be put in an embarrassing situation, and are notified that TCHD may:
 - a. Monitor, access, retrieve, download, copy, listen to, or delete anything stored in, created, received or sent via Internet Services, and
 - b. Limit and/or restrict any authorized user's use of Internet services, and to inspect, copy, remove or delete any unauthorized use without notice
 - c. Use any information in the system
2. Authorized Internet users may communicate with each other or with outside persons or organizations via Internet Services. Authorized Internet users should not have any expectation of personal privacy for information stored in, created, received, or sent via Internet Services.
3. TCHD Internet Services are intended for TCHD business related purposes only. TCHD encourages the use of the Internet Services to improve communications, to improve reliability of computer systems, and to improve productivity. However, Internet Services are TCHD property, with the purpose of facilitating TCHD communications. Each Authorized User of Internet Services has a responsibility to maintain and enhance TCHD's public image and to use Internet Services in a productive and legal manner.
4. All TCHD policies and practices apply to Internet Services, including those policies regarding intellectual property protection, privacy, misuse of TCHD resources, sexual harassment or other unlawful harassment, information and data security, and confidentiality. In addition, any communication that is sent over the Internet is a communication on behalf of TCHD. Therefore, any TCHD Internet communication must be professional and business-related.
5. Each Authorized Internet User must be considerate regarding the amount of time spent on the

- Internet so that others may have access to the system. Excessive and unnecessary use can affect the efficiency of the system or cause network overload. ~~Each individual granted Internet Services at TCHD is provided with a written copy of this policy.~~
- 5-6. The Authorized User of Internet Services must submit an approved System Access Request Form, with "Internet Access" checked. The System Access Request form states, "If requesting Internet Access, I have read, understand, and agree to abide by Administrative Policy 603, Internet Access."
 - 6-7. To reinforce this and other confidentiality policies, each employee must sign the TCHD Confidentiality Agreement **per Administrative Policy: Confidentiality 455** ~~annually on his/her review date.~~
 - 7-8. While use of the Internet offers significant benefits, it can also expose the TCHD computer systems to risks and compromise if appropriate security measures are not strictly followed. Each Internet User is personally accountable for any action that results in a breach of TCHD security or confidentiality.
 - 8-9. The display of any kind of sexually explicit image or document on any company system is a violation of our policy on sexual harassment. In addition, sexually explicit material may not be accessed, archived, stored, distributed, edited, printed, or recorded using our network resources.
 - 9-10. TCHD's Internet facilities and computing resources must not be used knowingly to violate the laws and regulations of the United States or any other nation. Use of any company resources for illegal activity is grounds for corrective action or immediate dismissal, and we will cooperate with any legitimate law enforcement activity.
 - 10-11. Any software or files downloaded via the Internet into TCHD's network become the property of TCHD. Any such files or software may be used only in ways that are consistent with their licenses or copyrights.
 - 11-12. No employee may use company facilities knowingly to download or distribute pirated software or data.
 - 12-13. No employee may use TCHD's Internet facilities to deliberately propagate any malwares, virus, worm, Trojan horse, back door or trap door program code.
 - 13-14. No employee may use TCHD's Internet facilities knowingly to disable, send pack storm, nuke or overload any computer system or network, or to circumvent any system intended to protect the privacy or security of another user.
 - 14-15. Each employee using the Internet facilities at TCHD shall identify himself or herself honestly, accurately and completely (including one's department where requested) when participating in chats or newsgroups, or when setting up accounts on outside computer systems. Only those employees or officials who are duly authorized to speak to the media, to analysts or in public gatherings on behalf of TCHD may speak/write in the name of TCHD to any newsgroup or chat room. Chat rooms and newsgroups are public forums where it is inappropriate to reveal confidential information, customer data, patient data, trade secrets, and any other material covered by existing TCHD policies and procedures.
 - 15-16. Computers that use internet data connectivity may compromise the security of the TCHD network. Contact Information Technology for advice on how to permit access to external sources without compromising TCHD network security. Many services can be accessed via firewall-protected Internet connections.

D. **PROCEDURE:**

- 1. The System Access Request Form is used to request Internet Access provided by the TCHD Information Technology Department. Blank forms are attached to this Policy.
- 2. Employee
 - a. A Department Director/**designee** may request Internet Access for an employee by filling out, signing and submitting a System Access Request Form (see System Access Request Form (SAR) attachment to this Policy), to the Information Technology Department. "Internet" must be checked.
 - b. An Information Technology representative will provide instructions and password information to the requestor.

- ~~e. To reinforce this and other confidentiality policies, each employee must sign the TCHD Confidentiality Agreement annually on his/her review date.~~

3. Business Partners

- a. An external case manager, authorized physician, vendor, or other person engaged in legitimate business at Tri-City Healthcare District (TCHD) who believes he/she has a legitimate need for Internet Access may obtain a System Access Request Form (see Provider/Provider's Staff attachment to this Policy). The form is to be filled out, signed by a Department Director/designee, and submitted to the Information Technology Department. "Internet" must be checked.
- b. An Information Technology representative will provide instructions and password information to the requestor.

E. **MANAGEMENT AND ADMINISTRATION:**

1. The TCHD Information Technology Department is responsible for assuring security of the TCHD network. The Information Technology Department provides all network access, and must approve all requests for Internet Services. All requests for telephone lines and Internet Service accounts must be approved by Information Technology.
2. The TCHD Information Technology Department provides software virus protection. Notify the Information Technology Department immediately if a software virus is detected.
3. If an Authorized Internet User plans to send files to an external entity via File Transfer Protocol (FTP) or other method, the Authorized Network User must assure that approved security procedures are used in transmitting the data. Any Protected Health Information (PHI) that is transferred or at rest must be encrypted. Request assistance from the TCHD Information Technology Department data to assure that data transmission is secure. No patient PHI may be transmitted outside of TCHD's Local Area Network without the coordination of the Information Technology Department.
4. Official Records
 - a. All messages, audit reports, and records of Internet Services are official records and are the property of TCHD. TCHD reserves the right to access and disclose, at any time, all documentation of Internet Services
5. Copyrighted Materials
 - a. Copyrighted materials belonging to entities other than TCHD may not be transmitted by employees via Internet Services. All employees obtaining access to other companies' or individuals' materials must respect all copyrights and may not copy, retrieve, modify, download or forward copyrighted materials, except with permission, or as a single copy to reference only.
 - b. Computer programs are copyrighted material, and may not be copied without adhering to the requirements listed on the purchased product's software licensing agreement.
6. User IDs and Passwords
 - a. User IDs and passwords help maintain individual accountability for Internet usage. The Information Technology Department will assign a single password to a person to be used for Network Services, Email, and Internet access. Any employee who obtains a password or ID must keep that password confidential. Company policy prohibits the sharing of passwords.
7. Security
 - a. The TCHD Information Technology Department will review Internet activity and analyze usage patterns, and distribute periodic reports of this data to the Organizational Compliance Committee and Department Directors to assure that TCHD's Internet resources are devoted to maintaining the highest levels of productivity. TCHD can monitor and record all Internet usage. TCHD security systems are capable of recording, for each user, each World Wide Web site visit, and TCHD reserves the right to do so at any time.
 - b. Employees should not assume that Internet Services are private, and should encrypt and/or authenticate confidential data during transmission.
 - c. TCHD has installed a variety of firewalls, proxies, and Internet address screening

programs and other security systems to assure the safety and security of the networks. Any employee who attempts to disable, defeat, or circumvent any security facility will be subject to appropriate corrective action as defined by policies.

8. **Violations**

- a. Adherence to this Policy is neither voluntary nor optional. Violation of this policy may constitute grounds for formal counseling, up to and including termination, as described in Administrative Policy 424, Coaching and Counseling for Work Performance. If necessary, TCHD also reserves the right to advise appropriate legal officials of any illegal violations.

9. **Legal Notice**

- a. California Penal Code 502 states that unauthorized use of a computer in the state of California is a felony.

10. **Notification of Improper Use**

- a. Each employee is expected to report unauthorized use or violation of this policy to Management or the Values Line.

F. **FORMS:**

1. System Access Request Form (SAR) **SAMPLE**
2. System Access Request Form (SAR) Provider/Provider's Staff **SAMPLE**

G. **RELATED DOCUMENTS:**

1. Administrative Policy ~~8610-424~~: Coaching and Counseling for Work Performance **424**
- ~~4.2.~~ **Administrative Policy: Confidentiality 455**
- ~~2.1.~~ California Penal Code 502

H. **REFERENCES:**

1. Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, HIPAA
2. California Penal Code 502

TRI-CITY HEALTHCARE DISTRICT System Access Request Form (SAR)

Select one:

<input type="checkbox"/> Employee	<input type="checkbox"/> Traveler	<input type="checkbox"/> Registry	<input type="checkbox"/> Volunteer
<input type="checkbox"/> Student	<input type="checkbox"/> Instructor	<input type="checkbox"/> Contract/Vendor	<input type="checkbox"/> Temp/Non-District Employee

Select New Account or Modify Existing Account:

<input type="checkbox"/> New Account	Start Date:	End Date (if applicable):
Requestor Name:		Email:
- OR -		
<input type="checkbox"/> Modify Existing Account	End Date (if applicable):	
Reason:	<input type="checkbox"/> Position Change	<input type="checkbox"/> Extension
<input type="checkbox"/> Transfer	<input type="checkbox"/> Return	<input type="checkbox"/> Other
Transferring From:		Last Day Working Current Position:
Requestor Name:		Email:

Account User Information: * Required Fields

*First Name:	*Middle Initial:	*Last Name:
Role/Position:	Job Code:	Job Title:
Current Employee In Same Position/Job Title:		
Cost Center:	Department Name:	
Nurse Units (required for staff assignment):		
Company/Practice/Vendor Name (if applicable):		

Access Requested for the following:

<input type="checkbox"/> Affinity (Patient Accounting) <input type="checkbox"/> Cerner <input type="checkbox"/> Email <input type="checkbox"/> Internet <input type="checkbox"/> Kronos (Manager/Supervisor) <input type="checkbox"/> Lawson (Finance/HR) <input type="checkbox"/> Other:	<input type="checkbox"/> PACs - Radiology <input type="checkbox"/> PACs - Cardiology <input type="checkbox"/> Pyxis Med Station <input type="checkbox"/> Remote Access <input type="checkbox"/> Report Writing (Power Insight) <input type="checkbox"/> RL Solutions File Management Access <input type="checkbox"/> Other:
---	---

E-Mail Distribution – please list email distribution groups to assign:

1.
2.
3.
4.
5.

TRI-CITY HEALTHCARE DISTRICT System Access Request Form (SAR)

I am aware of and agree to abide by the privacy and security policies of Tri-City Healthcare District and its affiliates as it applies to the protected health information as well as organizational information. I understand that I must only access that information which is the minimum necessary for me to carry out my duties within the organization and any other access is strictly forbidden.

- Never share my password or access information that is not required for my assigned duties.
- Always log in and off appropriately when using a workstation.
- Never access or disclose organizational or protected health information except within the scope of my position.
- Only copy information from the organizational data bases as authorized.
- Always take reasonable precautions when originating, receiving or transferring database information (virus).
- Never remove organizational or protected health information from the organization (paper or electronic) unless authorized.

I understand that violations of Tri-City Healthcare District (TCHD) privacy and security policies are grounds for disciplinary action to include, but not limited to loss of privileges, termination, or possible criminal prosecution.

Account User Signature _____ Date _____

Manager/Supervisor Approval of Request

I authorize the above named individual to have access to the information. Additionally I have reviewed with this individual organizational privacy and security policies and the consequences of failure to comply.

Signature _____ Date _____

Print Name _____

PLEASE EMAIL THE COMPLETED FORM TO: SARIT@tmc.com

Information Systems Review & Implementation of Request

Implemented by: (IT Representative) _____ Date _____

Staff Member Notified/Educated as to Log in Process/Password Selection

IT USE ONLY:

Initial User Login Name and Password _____ Entered by _____ Date _____



TRI-CITY HEALTHCARE DISTRICT

Information Technology Department System Access Request Form (SAR)

Please check one ☐ Employee ☐ Contractor ☐ Registry/Student ☐ Temp/Non-
Employee

☐ New Account☐ Modify Existing AccountRequestor
Name:

Phone:

Start
Date:☐ Affinity☐ LBI☐ Internet☐ Other: _____☐ Aionex☐ KRONOS WFAN☐ Remote Access☐ Other: _____☐ Gerner☐ Radiology Imaging
(PAC)☐ Other: _____☐ Other: _____☐ API☐ RL Solutions Mgt☐ Other: _____☐ Other: _____

Note: If mobile device email synch is required, manager approval is needed and an Exchange connection license will be charged to the departments cost center.

E-MAIL DISTRIBUTION LIST: Please type in the email distribution list as show in email address global list.

1Assistant Nurse Manager

2Administration

6Leadership Committee

RN

1Admin-Super

3Directors

8ASR Committee

Other

1ExeCouncil

4Management

9Clinical-Educators

Start Date: _____ End Date: _____

Last Name: _____ Middle Initial (Required or NA): _____

First Name: _____ Employee ID (Required for Employee): _____

Department Name: _____ Nurse Units (Required for Staff Assignment): _____

Job Title: _____ Cost Center: _____

By signing this request, I hereby agree to abide by Policy 608, Access to Restricted Electronic Information by TCHD Authorized Business Partners, and all other hospital policies, both current and future, regarding confidentiality and use of computers. If requesting Internet Access, I have read, understand, and agree to abide by Policy 603, Internet Access. If requesting Outlook or Webmail Access, I have read, understand, and agree to abide by Policy 604, Email Access. If requesting Gerner, I have read, understand, and agree to abide by Policy 602, Network Access. If requesting Remote or Portable Computing, I have read, understand, and agree to abide by Policy 623, Remote or Portable Computing. If requesting Affinity Access, I understand that Affinity passwords are issued to employees in person, and that I will obtain my password from the Information Technology Department by displaying my TCMC ID badge.

I know that any violation of these policies could lead to corrective action, dismissal or even criminal prosecution.

Signature: _____ Date: _____

REQUIRED: Name of a co-worker who performs the same job function and assigned same security requirements:

Name: _____ Role / Position (Required): _____

Department Manager (Print): _____ DATE: _____

Department Manager (Signature): _____

IT USE ONLY:

Initial User Login Name and Password: _____ Entered by: _____ Date: _____

PLEASE EMAIL THE COMPLETED FORM TO: SARIT@TCMC.com

Revision Date: 2/16



Tri-City Medical Center

ADVANCED HEALTH CARE
FOR YOU

TRI-CITY HEALTHCARE DISTRICT
Information Technology Department System Access Request Form (SAR)

Please check one:

☐

Provider

☐

Provider's Staff

☐ New Account

☐ Modify Existing Account

Staff Physician ☐ Y ☐
No

Requestor
Name:

Phone:

APPLICATIONS :

PROVIDER ONLY:

☐ Affinity (IT approval
needed)

☐ Radiology Imaging

☐ Cerner

☐ Dragon

☐ Remote Access

☐ Mailbox Account

Last Name: _____

Middle Initial (Required or NA): _____

First Name: _____

Access Start Date Requested: _____

Business Name: _____

Contact Information: _____

Job Title: _____

Dictation Code (Required for Staff Physicians): _____

eMail: _____

By signing this request, I hereby agree to abide by Policy 608, Access to Restricted Electronic information by TCHD Authorized Business Partners, and all other hospital policies, both current and future, regarding confidentiality and use of computers. If requesting Internet Access, I have read, understand, and agree to abide by Policy 603, Internet Access. If requesting Outlook or Webmail Access, I have read, understand, and agree to abide by Policy 604, Email Access. If requesting Cerner, I have read, understand, and agree to abide by Policy 602, Network Access. If requesting Remote or Portable Computing, I have read, understand, and agree to abide by Policy 623, Remote or Portable Computing. I know that any violation of these policies could lead to corrective action, dismissal or even criminal prosecution.

Print Name: _____

Date: _____

Signature: _____

For Staff Access Requests, someone in an authoritative position, must sign below:

Name: _____

Title: _____

Signature: _____

Date: _____

IT USE ONLY:

Initial User Login Name and Password _____ Entered by: _____

Date: _____

PLEASE EMAIL THE COMPLETED FORM TO: SARIT@TCMC.com or FAX to: (760)-940-4038

**ADMINISTRATIVE POLICY MANUAL
INFORMATION TECHNOLOGY**

ISSUE DATE: 12/00

SUBJECT: Network Access

REVISION DATE: 05/03; 02/05; 06/12, 02/16

POLICY NUMBER: 8610-602

Administrative Policies & Procedures Content Expert Approval:	10/15/12/21
Administrative Policies & Procedures Committee Approval:	10/15/03/22
Medical Executive Committee Approval:	n/a
Administration Approval:	04/22
Professional Affairs Committee Approval:	02/16 n/a
Board of Directors Approval:	02/16

A. PURPOSE:

1. To provide access to Tri-City Healthcare District (TCHD) Network Services for authorized individuals (authorized network users) associated with TCHD, including employees, internal and external case managers, and authorized physicians, vendors and other persons engaged in legitimate business at TCHD. Network Services are provided to those individuals who receive approval from a Department Director.

B. DEFINITIONS:

1. Network Access – identifies any form of access to network facilities at TCHD. It encompasses access to network services by TCHD employees, and to/from TCHD and external organizations or individuals.
 - a. Network access is available to those who are directly attached to the Local Area Network (LAN), who are connected to Network Services via dedicated Wide Area Network (WAN) connections, or who access the TCHD network via Remote Access facilities.

C. POLICY:

1. This policy addresses Network Access, informs authorized network users of their rights and obligations, and formally notifies Network Users of network monitoring. TCHD may:
 - a. Monitor, access, retrieve, download, copy, listen to, or delete anything stored in, created, received or sent via Network Services
 - b. Limit and/or restrict any authorized user's use of Internet services, and to inspect, copy, remove or delete any unauthorized use without notice
 - c. Use and disclose any information in the system requested by law enforcement officials
2. Authorized network users may access network resources for various functions such as file storage, file retrieval, printing, or entry to a system. Authorized network users should not have any expectation of personal privacy for information stored in, created, received, or sent via network resources.
3. All TCHD policies and practices apply to Network Services, including those policies regarding intellectual property protection, privacy, misuse of TCHD resources, sexual harassment or other unlawful harassment, information and data security, and confidentiality. Therefore, any use of TCHD Network Services must be professional and business-related.
- ~~4. Each individual granted Network Services at TCHD is provided with a written copy of this policy. The authorized user of Network Services must complete and sign the System Access Request Form.~~
- 5.4. While use of Network Services offers significant benefits, it can also expose the TCHD computer systems to risks and compromise if appropriate security measures are not strictly

followed. Each Network Services user is personally accountable for any action that results in a breach of TCHD security or confidentiality.

- 6-5. The transmission of any kind of sexually explicit information on any company system is a violation of our policy on sexual harassment. In addition, sexually explicit material may not be accessed, archived, stored, distributed, edited, or recorded using our network resources.
- 7-6. TCHD's Network Services must not be used knowingly to violate the laws and regulations of the United States or any other nation. Use of any company resources for illegal activity is grounds for corrective action or immediate dismissal, and we will cooperate with any legitimate law enforcement activity.

D. **PROCEDURE:**

- 1. The System Access Request Form is used to request access to various applications or services provided by the TCHD Information Technology Department. Blank forms are attached to this Policy.
- 2. Employee
 - a. A Department Director/**designee** may request new or revised Network Services for an employee by filling out, signing and submitting a System Access Request Form (see System Access Request Form (SAR) attachment to this Policy) to the Information Technology Department.
 - b. An Information Technology representative will provide instructions and password information to the requestor.
 - c. To reinforce this and other confidentiality policies, each employee must sign the TCHD Confidentiality Agreement **per Administrative Policy: Confidentiality 455**~~annually on his/her review date.~~
- 3. Business Partners
 - a. An external case manager, authorized physician, vendor, or other person engaged in legitimate business at Tri-City Healthcare District (TCHD) may request new or revised Network Services by obtaining a System Access Request Form (see Provider/Provider's Staff attachment to this Policy). The form is to be filled out, signed by a Department Director/**designee**, and submitted to the Information Technology Department.
 - b. An Information Technology representative will provide instructions and password information to the requestor.

E. **MANAGEMENT AND ADMINISTRATION:**

- 1. The TCHD Information Technology Department is responsible for assuring security of the TCHD network. The Information Technology Department provides all network access, and must approve all System Access Requests.
- 2. The TCHD Information Technology Department provides software virus protection. Notify the Information Technology Department immediately if a software virus is detected.
- 3. Remote control software is prohibited from being installed on any network-attached computer without the prior approval of the Information Technology Department.
- 4. Official Records
 - a. All messages, message audit reports, and records of Network Services are official records and are the property of TCHD. TCHD reserves the right to access and disclose, at any time, all documentation of Network Services.
- 5. Copyrighted Materials
 - a. Computer programs are copyrighted material, and may not be copied without adhering to the requirements listed on the purchased product's software licensing agreement.
- 6. User IDs and Passwords
 - a. User IDs and passwords help maintain individual accountability for Network Services. The Information Technology Department assigns a single password to an Authorized Network User to be used for Network Services, email, and Internet access. Any authorized network user who obtains a password or ID must keep that password confidential. TCHD policy prohibits the sharing of passwords.
 - b. Mobile communication devices such as smartphones and smart devices must be

secured with a password to protect any data that might reside on the device.

7. **Security**

- a. The TCHD Information Technology Department may review Network Services and analyze usage patterns, and distribute periodic reports of this data to the Organizational Compliance Committee and Department Directors.
- b. Authorized network users should not assume transmission of network files is private. If network files are being sent to an external entity via File Transfer Protocol (FTP) or other method, the authorized network user must assure that approved security procedures are used in transmitting the data. Request assistance from the TCHD Information Technology Department data to assure that data transmission is secure.
 - i. No patient Protected Health Information (PHI) may be transmitted outside of TCHD's Local Area Network without the coordination of the Information Technology Department.
- c. TCHD has installed network firewalls, switches, Internet address screening programs and other security systems to assure the safety and security of the networks. Any employee who attempts to disable, defeat, or circumvent any security facility will be subject to appropriate corrective action as defined by policies.

8. **Violations**

- a. Adherence to this Policy is neither voluntary nor optional. Violation of this policy may constitute grounds for formal counseling, up to and including termination, as described in Administrative Policy 424, Coaching and Counseling for Work Performance. If necessary, TCHD also reserves the right to advise appropriate legal officials of any illegal violations.

9. **Legal Notice**

- a. California Penal Code 502 states that unauthorized use of a computer in the state of California is a felony.

10. **Notification of Improper Use**

- a. Authorized Network User is expected to report unauthorized use or violation of this policy.

F. **FORMS:**

1. System Access Request Form (SAR)
2. System Access Request Form (SAR) Provider/Provider's Staff

G. **RELATED DOCUMENTS:**

1. Administrative Policy ~~8610-424~~: Coaching and Counseling for Work Performance **424**
- ~~4.2.~~ **Administrative Policy: Confidentiality 455**

H. **REFERENCES:**

1. California Penal Code 502
2. Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, HIPAA

ADMINISTRATIVE POLICY MANUAL
INFORMATION TECHNOLOGY

ISSUE DATE: 6/03

SUBJECT: Voicemail Access

REVISION DATE: 2/05; 7/12, 01/16

POLICY NUMBER: 8610-617

Administrative Policies & Procedures Content Expert	Approval Date(s):	10/15/12/21
Administrative Policies & Procedures Committee Approval:	11/15/03/22	
Medical Executive Committee Approval:	n/a	
Administration Approval:	04/22	
Professional Affairs Committee Approval:	01/16	n/a
Board of Directors Approval:	01/16	

A. PURPOSE:

1. To provide Voice Mail to authorized individuals (Authorized Voice Mail Users) associated with Tri-City Healthcare District (TCHD), including employees, external case managers, authorized physicians, vendors, and other persons engaged in legitimate business at TCHD. Voice Mail Services are provided to those individuals who receive approval from a department director. Those employees who do not currently have Voice Mail capability may request it from the Information Technology Department as described below.

B. DEFINITIONS:

1. The term Voice Mail identifies any form of voice messaging currently sanctioned for use at TCHD. It encompasses voice messaging among TCHD employees, and to/from TCHD and external organizations or individuals.

C. POLICY:

1. This policy addresses Voice Mail, and informs Authorized Voice Mail Users of their rights and obligations, and formally notifies Authorized Voice Mail Users of usage monitoring **including but not limited to:** ~~With advance notice, Authorized Voice Mail Users will not be put in an embarrassing situation, and are notified that TCHD:~~
 - a. Monitor, access, retrieve, download, copy, listen to, or delete anything stored in, created, received or sent via Voice Mail
 - b. Limit and/or restrict any authorized user's use of Voice Mail User's use of Voice Mail Services, and to inspect, copy, remove or delete any unauthorized use without notice
 - c. Use any information in the system
2. Authorized Voice Mail Users may communicate with each other or with outside persons or organizations via Voice Mail. Authorized Voice Mail Users should not have any expectation of personal privacy for information stored in, created, received, or sent via Voice Mail.
3. Voice Mail Services are TCHD property, with the purpose of facilitating TCHD communications. Voice Mail Services are intended for TCHD business related purposes only. TCHD encourages the use of Voice Mail to improve communications and productivity. Each Authorized Voice Mail User has a responsibility to maintain and enhance TCHD's public image and to use Voice Mail in a productive and legal manner.
4. Authorized Voice Mail Users may communicate with each other or with outside persons or organizations via Voice Mail. Authorized Voice Mail Users should not have any expectation of personal privacy for information stored in, created, received, or sent via Voice Mail.
5. Voice Mail Services are TCHD property, with the purpose of facilitating TCHD communications. Voice Mail Services are intended for TCHD business related purposes only. TCHD encourages the use of Voice Mail to improve communications and productivity. Each Authorized Voice Mail User has a responsibility to maintain and enhance TCHD's public image and to use Voice Mail

in a productive and legal manner.

6. All TCHD policies and practices apply to Voice Mail Services, including those policies regarding intellectual property protection, privacy, misuse of TCHD resources, sexual harassment or other unlawful harassment, information and data security, and confidentiality. In addition, any communication that is sent via Voice Mail is a communication on behalf of TCHD. Therefore, any TCHD Voice Mail communication must be professional and business-related.
7. To reinforce this and other confidentiality policies, each employee must sign the TCHD Confidentiality Agreement **per Administrative Policy: Confidentiality 455** annually on his/her review date.
8. Appropriate security measures must be strictly followed. Each Voice Mail user is personally accountable for any action that results in a breach of TCHD security or confidentiality.
9. The transmission of any kind of sexually explicit information on any company system is a violation of our policy on sexual harassment. In addition, sexually explicit material may not be accessed, archived, stored, distributed, edited or recorded using our telephone resources.
10. TCHD's Voice Mail facilities must not be used knowingly to violate the laws and regulations of the United States or any other nation. Use of any company resources for illegal activity is grounds for corrective action or immediate dismissal, and we will cooperate with any legitimate law enforcement activity. (Administrative Policy 8610-403, Harassment Policy)
11. Management And Administration
 - a. The TCHD Information Technology Department is responsible for assuring security of TCHD telephone services. The Information Technology Department provides all telephone access, and must approve all requests for Voice Mail Services.
 - b. Official Records
 - i. All messages and records of Voice Mail Services are official records and are the property of TCHD. TCHD reserves the right to access and disclose, at any time, all documentation of Voice Mail Services.
 - c. Passwords
 - i. Passwords help maintain individual accountability for Voice Mail usage. Each Authorized Voice Mail User will maintain a confidential Voice Mail password. TCHD policy prohibits the sharing of passwords.
 - d. Security
 - i. ~~Employees should not assume that Voice Mail Messages are private. The TCHD Information Technology Department may review Voice Mail activity and analyze usage patterns, and distribute periodic reports of this data to the Executive Council and Department Directors to assure that TCHD's Voice Mail resources are devoted to maintaining the highest levels of productivity.~~ TCHD can monitor and record all Voice Mail usage. TCHD security systems are capable of recording Voice Mail messages for each user, and TCHD reserves the right to do so at any time.
 - e. Violations
 - i. Adherence to this Policy is neither voluntary nor optional. Violation of this policy may constitute grounds for formal counseling, up to and including termination, as described in Administrative Policy 8610-424, Coaching and Counseling for Work Performance. If necessary, TCHD also reserves the right to advise appropriate legal officials of any illegal violations.
 - f. Notification of Improper Use
 - i. Each employee is expected to report unauthorized use or violation of this policy.

D. **REFERENCES:**

1. Administrative Policy ~~8610-403~~; Harassment Policy **403**
2. Administrative Policy ~~8610-424~~; Coaching and Counseling for Work Performance **424**
- 2-3. **Administrative Policy: Confidentiality 455**

**PROCEDURE: 12-LEAD EKG PROCEDURE**

Purpose: All EKG technicians will be knowledgeable in obtaining a 12-lead EKG, to evaluate the electrical impulses generated by the heart during the cardiac cycle to assist with diagnosis of cardiac arrhythmias, blocks, damage, infection, or enlargement.

Supportive Data: ELI 350

Equipment: 12-lead EKG Machine

A. POLICY:

1. Once ordered, an EKG will be performed. Stat EKG's will be done in 10 minutes or less. Notification of a patient's MD or RN if the following automated EKG interpretation appears :
 - a. Ventricular Tachycardia.
 - b. Ventricular Fibrillation.
 - c. Complete heart block.
 - d. Pause >3 seconds
 - e. Acute MI.
2. In the Emergency Department, the technician will personally hand the ECG preliminary tracing to the physician.
3. In the inpatient units, the technician will personally hand the ECG preliminary tracing to the patient's nurse.

B. PROCEDURE:

1. Introduce yourself and explain procedure. .
2. Identify the patient by using two (2) patient identifiers.
3. Enter patient information into cart.
 - a. Turn machine on
 - b. Work list (password EKG1), OK
 - c. Download MWL.
 - d. Query code (OK)
 - e. WiFi connection for patient list
 - f. Highlight (patient name).
 - g. Load ID
 - h. Patient Information (OK)
 - i. Run EKG for (10 seconds).
 - j. Auto (ready to print), next enter
 - k. Print (EKG)
 - l. XMT transmission status (OK)
4. Apply electrodes using correct lead placement.
 - a. V1 and V2 on either side of sternum, 4th intercostal space.
 - b. V4 at the mid clavicular line, 5th intercostal space.
 - c. V3 halfway between V2 and V4.
 - d. V5 and V6 on same level with V4 in the anterior and mid axillary lines.
 - e. LL on the left leg, RL on the right leg, LA on left arm and RA on right arm.
5. Record 12-lead EKG. Ensure a good baseline, i.e. without artifact, somatic tremor or wandering baseline and save on diskette.
 - a. Artifact: an artifact is anything on the EKG that is not caused by the currents generated during the cardiac cycle. Artifacts include interference, 60 cycle, somatic tremor and wandering baseline.
 - b. 60 cycle: caused by leakage of the electrical power.
 - i. To correct change the "short wire with the alligator clip" (the electrode lead


Cardiology Department Review	Division of Cardiology	Pharmacy & Therapeutics Committee	Medical Executive Committee	Administration	Professional Affairs Committee	Board of Directors
11/18, 10/21	12/18, 04/22	n/a	n/a	01/19, 04/22	n/a	02/19

adapter) in the lead showing the 60 cycle. Other attempts can include changing the plug, unplug the bed when able, and ensure proper electrode contact with patient. If continued issues, have machine inspected by BioMed and utilize other machine.

- c. Somatic Tremor: caused by tense muscles. Ask the patient to relax. Make sure all extremities are on the bed, hands unclenched and patient lying flat if possible.
- d. Wandering Baseline: An artifact in which all the complexes are present, but not "isoelectric" (not straight baseline).

C. CRITICAL RESULTS REPORTING:

- 1. Diagnostic procedures within the department of cardiology/catheterization lab are reviewed and evaluated by the cardiologist. Departmental staff is not responsible for interpreting or evaluating test results to determine whether a test result is critical.
- 2. STAT ECG constitutes a critical test.
- 3. The following ECG tracings, as read from the ECG report, are consider a critical result.
 - a. Ventricular Tachycardia
 - b. Ventricular Fibrillation
 - c. Complete Heart Block
 - d. Marked Sinus Bradycardia
 - e. Acute Myocardial Infarction
 - f. STEMI
 - g. Code Blue
 - h. Rapid Response
- 4. Upon verification of the above critical results, the technician must follow the 12-Lead EKG procedure, which outlines the communication procedure.

 Tri-City Medical Center	Cardiology
PROCEDURE: 24 HOUR HOLTER MONITOR SYSTEM HOOK UP AND INITIATE RECORDING	
Purpose:	Cardiovascular technologist (CVT) shall be knowledgeable in performing a hook-up for a 24-hour holter monitor study. A physician's order is required before initiation of a Holter hook-up. The CVT performs the procedure with the cardiologist interpreting the data.
Supportive Data:	Manuals (Holter)
Equipment:	Holter recorders with patient cable and accessories, Holter Analysis System

A. POLICY:


1. Used for the purpose of arrhythmia analysis.
2. Recording ECG data of patients requiring ambulatory (Holter) monitoring over a 24 hour or 48 hour period.
3. The 3 channel, 5-wire patient cable records 24 hours of data and displays channel I, II, and V. The 2-channel, 5-wire patient cable records up to 48 hours of data and displays channel 1 and channel 2.
4. Stored ECG data will be downloaded for analysis to a Holter Analysis System with a USB interface cable after the recorder has been disconnected from the patient cable. After the data is downloaded, the memory can then be cleared and the recorder is ready for use on the next patient.
5. Confirm physician's order
6. Introduce yourself and use (2) patient identifiers to verify correct patient.
7. CVT will explain the test to patient.
8. Perform "Standard Precautions" at all times.
9. Maintain patient privacy.

B. PROCEDURE:

1. Prepare the Recorder:
 - a. Connect recorder to USB interface cable on an Analysis System
 - b. Select "Enter ID" from the "Patient List" page
 - c. Select "OK" to "Set time"
 - d. Select last 7 days-Query (or use last name) from "Work List" page. (may need to hit Query a few times)
 - e. Hi-light patient
 - f. OK - puts MR # onto recorder box
 - g. Save
 - h. Remove recorder // USB cable
2. Prepare the patient and initiate the recording:
 - a. Identify the (5) electrode sites on the torso by referring to the user manual
 - b. Shave (if needed), wipe oils from the electrode sites with alcohol prep pad and lightly use sandpaper strip on electrode sites to remove any dead skin. Use sween if needed
 - c. Attach lead wires to electrodes. Select either 3 channel (24hr) or 2 channel (48hr) set of wires.
 - d. Attach the electrodes to the proper electrode sites.
 - e. Attach the patient cable to the recorder
 - f. Remove the battery door of the recorder, insert a new batteries, and close the battery door
 - g. Press the "Enter" button to move through the menu displays
 - h. Verify the current time setting, Press Enter
 - i. Verify the ID number, Press Enter
 - j. Verify the ECG signal quality, Press Enter x 3 (Check all (3) channels for good

Cardiology Department Review	Division of Cardiology	Pharmacy & Therapeutics Committee	Medical Executive Committee	Administration	Professional Affairs Committee	Board of Directors
11/18, 10/21	12/18, 04/22	n/a	n/a	01/19, 04/22	n/a	02/19

- k. QRS, minimal artifact and avoid big T waves
 - l. The time shows, Press Enter
 - m. To begin recording, press and hold the "Enter" button for a period (3) seconds. An R indicates recording mode and displays the current time
 - n. Entering optional diary events - To mark an event, press the "Enter" button.
 - o. Place tape over each electrode snap to ensure electrode attachment throughout the recording
 - p. Insert recorder into the disposable pouch and arrange the pouch on the patient's torso securely
 - q. Fill out the necessary information on the front of the diary.
 - r. Explain to the patient:
 - i. How to use the event button, if applicable. (Same "Enter" button)
 - ii. How to use the diary and to return the diary with the recorder
 - iii. Continue with normal activities, as directed by their physician
 - iv. Do not get the recording device, electrodes and wires wet.
 - v. Allow patient to dress and instruct them to return in 24 hours for removal of the device
3. Documentation:
- a. Write on the patient's facesheet the date, recording device number and the time that the recorder began recording
 - b. Place the patient folder in the locked cabinet for return follow up and analysis
 - c. The scheduler will process billing charges for the outpatient's. The CVT will process billing charges for the (rare) inpatient Holter
4. Ending a recording session:
- a. At the end of a 24 or 48 hour period, the time is cleared from the device. A reversed color to indicate the recording period has ended and that the recorder is full
 - b. Remove the battery door of the device and remove the batteries. Replace the battery door
 - c. Dispose of the battery properly
 - d. Remove the electrodes, the lead wires and the tape from the patient and retrieve the patient diary. Allow the patient to dress and inform them that the interpreted report will be sent to their referring doctor in approximately (2 - 3) working days
 - e. Remove the patient cable from the recorder
 - f. Place the recorder in the proper patient folder for system analysis
 - g. Clean the exterior surfaces of the recorder, the patient cable and the lead wires with an approved sanitary cloth

 Tri-City Medical Center	Cardiology
PROCEDURE:	24 HOUR HOLTER MONITOR SYSTEM – SCANNING ANALYSIS
Purpose:	Cardiovascular technologists (CVT) shall be knowledgeable in performing a Holter monitor scanned analysis on adults. The Cardiologist interprets the results and prepares the final report.
Supportive Data:	Manuals (Holter)
Equipment:	Holter recorders and Holter Analysis System

A. POLICY:

1. Used for the purpose of arrhythmia and pacemaker analysis.
2. Holter system is intended to automatically acquire, analyze, edit, review, report and store prerecorded ECG data of patients that have been connected to a digital This acquired cardiac data and analysis is reviewed, edited, saved and printed by the CVT.
3. The printed data is analyzed, interpreted and signed by a Cardiologist who also creates the final and signed report for the referring physician.


B. PROCEDURE:

1. Acquire a recording:
 - a. Remove batteries, if not already done.
 - b. Connect recorder to USB interface cable on a Holter Analysis System
 - c. Select an "Empty" line on list
 - d. Select "Connect To"
 - i. Shows ID, recording length, etc.
 - ii. Select "Start"
 - e. Highlight "Patients Name" from list (if name not on list, try a Query, or re-order – see notes)
 - f. Select "OK" and fill in:
 - i. Indications
 - ii. Medications
 - iii. Referring MD
 - iv. Reviewing MD
 - v. Tech
 - vi. Analyst
 - g. Select "Auto Scan", "OK"
 - h. If 48hr recording (2 channel):
 - i. After acquiring, select no to review day 2?
 - ii. The program will move to Day 1.
 - iii. Complete day 1 and mark as reviewed
 - iv. The program will ask to review day 2, reply yes
 - v. Day 1 must always be completed before day 2
2. Patient Diary Symptoms
 - a. Select "Edit", "Diary Entry List", "Enter", "OK"
3. Choose best leads for analysis (zoom to 40 seconds)
 - a. Review at least the first ten minutes of recording on all 3 leads (I, II, V)
 - b. Determine which 2 leads are the clearest and have the 2 best defined QRS complexes.
 - i. If lead II & V, then go to step 4.
 - ii. If lead I is better than either lead II or V, then go to "Patient>Rescan". Select "Autoscan" and answer yes to selecting new channel combination for analysis. Select best leads.
4. Mark Artifact (zoom out to 600 seconds)
 - a. Zoom out all the way and view all 3 leads. Page down through entire recording marking

Cardiology Department Review	Division of Cardiology	Pharmacy & Therapeutics Committee	Medical Executive Committee	Administration	Professional Affairs Committee	Board of Directors
11/18, 10/21	12/18, 04/22	n/a	n/a	01/19, 04/22	n/a	02/19

- as artifact large sections of artifact (half a line or more).
5. Review Templates (zoom to 40 seconds)
 - a. Review "Ventricular" first, then "Normal", then "Supraventricular"
 - i. WARNING! Use tab button to review at least the first dozen beats in any bin over 50 before relabeling. DO NOT relabel a bin just because how the first few beats appear.
 - b. Select "Templates & ECG". Go to "Format>Ventricular"
 - i. In ventricular templates relabel as artifact any small template bins that are not "Wide and Bizarre". Label larger bins as necessary". If shaped like normal beats, then label "Normal".
 - c. In "Normal" templates, find the first template bin that has just 1 sample. Right click and select "Label All Following as Artifact". Then go back to page 1 of "Normal" templates, highlight the whole page and label "Normal". If prompted, click "Proceed".
 - d. In "Supraventricular" first relabel any bins that do not resemble "Normal" shaped beats. SVT should be normal shape but early. Refresh screen by turning on, then off again the split screen. Then go back to page 1, highlight the whole page and label "Normal". If prompted, click "Proceed".
6. Review "Auto Strips" (zoom to 40 seconds)
 - a. Turn on split screen and select "Profile & ECG".
 - b. Move along the Summary row and confirm "Auto Strips".
 - i. Min HR, Max HR, Supra +3 if any, Vent +3 if any, Pause (Max R-R). If samples are incorrect, mark as artifact then hit the backspace button. Add page strips if needed.
 - c. Edit>Strip List>click on "Add Auto Strips"
 - i. Click on "Time" column and delete duplicates except if HR or long RR strips. Click "OK".
7. Review other events
 - a. Profile & ECG
 - b. Move along Summary Row adding samples of diary events. Supraventricular & Ventricular (from TOTAL columns), AFIB and pauses as necessary. Add a few samples of each and Page Strips if there are a high number of samples.
 - c. Edit>Strip List. Click on TIME column and delete duplicates, except if HR or long RR strips.
 - i. Click on DURATION column, then "OK"
8. Report Preview
 - a. View>Report Preview
 - i. Page down through report and verify for accuracy and completeness.
 - b. Report Options>
 - i. Select best lead, Select 24 hours, OK , Print (prints full disclosure)
 - ii. Choose cardio printer when available or back room ECG printer.
 - c. View>Report Preview
 - i. Select "Load Defaults">OK
 - 1) This resets full disclosure and prevents sending it to Cerner – the file is too big!)
 - d. Close> tab to close report (not red X)
 - i. Patient>Open Patient>Select YES to "send to Dicom?"
 - 1) This sends a report to Cerner, but not full disclosure.
9. Clear recorder
 - a. Patient List>"Erase">OK (erases data and resets time)
 - i. If this is not completed, it will clear itself when initiated for next hookup, but if not initiated with next hook up, then recorder will not record)
10. Note Do not use red X box in upper right corner to close windows
11. Complete charges in Cerner
 - a. Go to CARDIOVASCULAR tab using "completed" filter

- b. Click on patients name
 - c. At bottom of screen
 - i. Right click on 1st line> OK
 - ii. Right click on 2nd line>select reviewing physicians name>OK
 - d. Can do preview to confirm strips are in patients chart.
12. Place the printed full disclosure, final report summary and patients demographic paperwork in a folder and place in the reviewing Cardiologists in-box for final report processing.

 Tri-City Medical Center	Cardiology
PROCEDURE:	ECHOCARDIOGRAM - CONTRAST BUBBLE STUDY (AGITATED SALINE CONTRAST INJECTION)
Purpose:	Cardiovascular Technologist (CVT) shall be knowledgeable in performing an Agitated Saline Contrast (ASCI) Exam. The CVT acquires the images and an MD or RN performs the contrast injection. A contrast bubble study is used to identify shunt abnormalities, especially in the setting of a CVA or TIA.
Supportive Data:	ASE 2013 "Detection of Right-to-Left Atrial Communication Using Agitated Saline Contrast Imaging"
Equipment:	Cardiac ultrasound machine, (2) 10 ml syringes (leur lock tip); (1) three-way stopcock; (2) Vial Access Cannulas; (1) Extension Set (short tubing); (3-4) 30 ml Bacteriostatic 0.9% Sodium Chloride vials, for injection; alcohol swabs

A. POLICY:

1. Confirm physician's order.
2. Use two (2) patient identifiers to verify correct patient.
3. CVT will explain the test to patient.
4. Perform "Standard Precautions" at all times.
5. Maintain patient privacy.

B. PROCEDURE:

1. Preparation:
 - a. Perform color flow imaging (CFI). Need to see flow clearly passing directly across the atrial septum. ASCI may not be needed if clear CFI demonstrates an intraatrial communication.
 - b. The MD/RN will verify an IV is patent, preferably in the antecubital vein. If using another IV site, the site must have an 18 gauge or larger cannula and must be able to accommodate a 10ml rapid bolus. If the IV is not patent or is not adequate for this procedure, restart an appropriate IV.
 - c. Attach the three-way stopcock to the IV hub.
2. Performing the Procedure:
 - a. Connect patient to ECG on the echocardiography machine.
 - b. The CVT will obtain the optimal 2D echocardiographic view (4CH most common and occasionally PSAX or SUBC), optimize settings and patient position.
 - c. MD or RN will attach the three way stopcock to the nearest port to the IV site.
 - d. MD or RN will attach one (1) leur lock syringe to the stopcock port. MD or RN will draw 8.5 mL 0.9% sodium chloride and add 1.5 mL of air. Shuttle 8.5ml sodium chloride between the two syringes rapidly three or more times to agitate.
 - e. On the CVT cue, the MD/RN will turn the stopcock and inject the entire contents of the syringe rapidly
 - f. As soon as the MD/RN begins pushing the contrast, acquire 8-12 sec digital loops.
 - g. If competitive flow from IVC causing loss of contrast along the RA side of atrial septum, then perform manual compression of the liver to suppress IVC flow. (Need to differentiate IVC flow from negative contrast flow from an ASD.)
 - h. Obtain images with normal respiration and with provocative maneuvers (PM).
 - i. Use PM to increase the RA pressure above the LA pressure.
 - i. Use Valsalva, sniff or cough.
 - ii. Should see complete opacification of RA and leftward bowing of the atrial septum to the LA.
 - iii. Repeat if not successful.

Cardiology Department Review	Division of Cardiology	Pharmacy & Therapeutics Committee	Medical Executive Committee	Administration	Professional Affairs Committee	Board of Directors
11/18, 10/21	12/18, 04/22	n/a	n/a	01/19, 04/22	n/a	02/19

- j. Minimum of 4- 5 injections if negative study.
- 3. Positive Study
 - a. Any number of bubbles seen in LA or LV within 5 seconds of initial entrance of contrast into RA.
- 4. Negative Study
 - a. 4-5 injections, full opacification of RA and evidence of bowing into the LA and no left heart contrast seen within 5 beats after successful PM or at rest
- 5. Indeterminate Study
 - a. Non successful in full opacification of RA along atrial septum and/or could not demonstrate bowing into the LA and no left heart contrast seen within 5 beats.
 - b. Image quality suboptimal.
- 6. The CVT will view the images and determine diagnostic value.
- 7. Transfer the exam images to CPACS workstation. Complete the CVT preliminary worksheet and place folder in cardiologist box.
- 8. Record the exam information on the CVT log.
- 9. CVT will process the appropriate billing charges for inpatients through Cerner. Scheduler will process charges for outpatients.

**PROCEDURE: TRANSESOPHAGEAL ECHOCARDIOGRAM (TEE)**

Purpose: Cardiovascular technologists (CVT) shall be knowledgeable in performing a Transesophageal Echocardiogram (TEE) study. A physician's order is required and a Cardiologist must be consulted by the ordering physician before initiation of a TEE procedure. The Cardiologist, assisted by an echo technician and registered nurse (RN), performs the procedure.

Equipment: Transesophageal Echocardiography Probe, Cardiac ultrasound machine, sterile gel packets, disposable bite block, lidocaine spray, crash cart

A. POLICY

1. Pre-procedure orders and sedation documentation must be completed by the Cardiologist.
2. Consent - RN will obtain patient's signed consent for inpatients. The Cardiologist will explain the procedure to the patient at time of consultation. Any applicable contra-indications will be decided by the Cardiologist.
3. Use two (2) patient identifiers to verify correct patient. Sonographer will explain his/her role to patient.
4. Perform Standard Protocol at all times.
5. Registered nurse will initiate the "Time Out" Procedure.

B. PROCEDURE:

1. Catherization Lab or Portable TEE:
 - a. Equipment:
 - i. TEE probe, individual sterile gel packets, gloves, bite-block, towel/pillow case, lidocaine spray, and copy of views. If a bubble study is anticipated, have the bubble study injection kit available.
 - b. To Perform the Study:
 - i. Connect the probe to the port. Select the proper study type on the ultrasound machine.
 - ii. If portable, ensure equipment needed is available: i.e.; oxygen, suction, cardiac monitor for heart rate and rhythm and necessary sedation medications.
 - iii. Assist physician in handling the probe for insertion.
 - iv. Acquire, magnify and alter views in accordance with physician's directions.
 - v. If bubble study injection is necessary the attending nurse will administer upon the Cardiologist instructions and according to procedure.
 - vi. Assist in withdrawal of the probe with gloved hands, towel and pillowcase.
2. Operating Suite TEE:
 - a. Disinfect the surface of the machine with appropriate disinfectant.
 - b. Tech needed in OR:
 - i. Prepare ultrasound machine with patient's information and proper study type.
 - ii. Dress in appropriate OR attire, including mask, hat, shoe covers and gloves.
 - iii. Tech is to coordinate with charge or lead person to ensure sterility is maintained in department
 - iv. Acquire, magnify and alter views in accordance with physician direction. Use color flow and Pulse Wave Doppler when appropriate.
 - c. Intraoperative TEE
 - i. Usually probe placement occurs by Anesthesia.
 - ii. In case of a certified cardiac Anesthesiologist, billing and reading of the Intraoperative TEE becomes the Anesthesiologist responsibility.

Cardiology Department Review	Division of Cardiology	Pharmacy & Therapeutics Committee	Medical Executive Committee	Administration	Professional Affairs Committee	Board of Directors
11/18, 10/21	12/18, 04/22	n/a	n/a	01/19, 04/22	n/a	02/19

- iii. In all other cases, Cardiologist will complete diagnostic TEE read and bill 93314 with 26 modifier.
- iv. At end of procedure disconnect probe, take machine back to echo lab and disinfect.
- v. Cleaning the Probe: SPD to clean and disinfect the probe.
- vi. Transfer exam to CPACS digital workstation.

C. **BILLING AND REPORT PROCESSING:**

- 1. Catheterization Lab or Portable exams - Echo tech will process the billing charges. Place demographic sheet in Cardiologist's in-box for report processing, if needed.
 - a. Batch Bill:
 - i. Cardiology Services
 - 1) Transesophageal Echo
 - a) TEE
 - i) TEE=93312
 - b) Echo color flow (C/F)
 - i) Echo C/F 93325 (add on to 93312)
 - ii) ECHO, Pulsed Wave Doppler=93320 (add on to 93312)
 - c) Physician Component=modifier-26

**MEDICAL STAFF
CONTINUING MEDICAL EDUCATION (CME)**

ISSUE DATE: 03/06

SUBJECT: Cultural and Linguistic
Proficiency and Implicit Bias

REVISION DATE(S): 05/08, 08/12, 09/14, 08/18, 03/20,
08/21

POLICY NUMBER: 8710-601

Medical Staff Department Approval:	40/2010/21
Continuing Medical Education Committee Approval:	40/2401/21
Pharmacy & Therapeutics Committee Approval:	n/aN/A
Medical Executive Committee Approval:	02/2003/22
Administration Approval:	08/2404/22
Professional Affairs Committee:	n/a
Board of Directors Approval:	08/21

A. PURPOSE:

1. The California legislature intended Assembly Bill (AB) 1195 and AB 241 to “encourage physicians and surgeons to meet the cultural and linguistic concerns” of California diverse patient populations. Planners, faculty and speakers are central to adhering to state law as noted in Business and Professions (B&P) Code 2190.2, which codifies the aforementioned legislation. B&P Code 2190.1 defines CLC and IB and these definitions were further refined by the CMA CME team under the guidance of an Advisory Committee composed of physicians and health equity experts. The CLC and IB definitions reiterate how patient’s social determinants of health impact their access to care. Presenting the CLC and IB definitions reminds planners, faculty and speakers to consider legislative intent when planning, developing, executing and evaluating CME activities To ensure subjects of cultural and linguistic competency in the practice of medicine are included in Continuing Medical Education (CME) activities in accordance with California Bill AB 1195. The IMQ/CMA policy applies to non-exempt CME activities and addresses the essential elements for compliance with Assembly Bill 1195, and was updated by the Boards of CMA and IMQ in July and August 2013.

B. DEFINITIONS:

1. **Cultural Competency and Linguistic Competency (CLC):** The ability and readiness of health care providers and organizations to humbly and respectfully demonstrate, effectively communicate, and tailor delivery of care to patients with diverse values, beliefs, identities and behaviors, in order to meet social, cultural and linguistic needs as they relate to patient health~~A set of integrated attitudes, knowledge, and skills that enables a health care professional, or organization to care effectively for patients from diverse cultures, groups, and communities.~~
Linguistic Competency: ~~The ability of a physician and surgeon to provide patients who do not speak English, or who have limited ability to speak English, with direct communication in the patient’s primary language.~~
2. **Implicit Bias (IB):** The attitudes, stereotypes and feelings, either positive or negative that affect our understanding, actions and decisions without conscious knowledge or control. Implicit bias is a universal phenomenon. When negative, implicit bias offer contributes to unequal treatment and disparities in diagnosis, treatment decisions, levels of care and health care outcomes people base on race, ethnicity, gender

- identity, sexual orientation, age, disability and other characteristics.
3. **Diversity:** Having many different forms, types or ideas; showing variety. Demographic diversity can mean a group composed of people of different genders, races/ethnicities, cultures, religions, physical abilities, sexual orientations or preferences, ages, etc.

C. **POLICY:**

1. **Identification of CLC Disparity:** The goal of this standard is for medical education to address how IB affects-perceptions and treatment decisions, which lead to disparities in health outcomes. Unintended biases in decision-making may contribute to health care disparities by shaping behavior and producing differences in medical treatment along lines of race, ethnicity, gender identity, sexual orientation, age, socioeconomic status or other characteristics. ~~Planners are responsible for proactively identifying one (or more) CLC disparities when planning an educational activity with clinical content. The CLC disparity must be relevant to the identified gaps or learning needs of the target audience or our patient population.~~
2. **Faculty Tri-City Staff** is not responsible for identifying CLC disparities it is the **responsibility of the speaker and/or planners.**
3. The planner will document on the planning form if there is no clinical care component, or no CLC disparity identified.
4. **Objectives:** Tri-City Medical Center shall include cultural and linguistic objectives in CME activities that address cultural beliefs, which may include cause, severity, treatment, and acceptability of the patient's own illness, as well as, language barrier implications, and the need for providing appropriate interpreters and appropriately interpreted material. Objectives shall include at least one, or a combination of, the following:
 - a. Application of linguistic skills to communicate effectively with the target population.
 - b. Utilization of cultural information to establish therapeutic relationships.
 - c. Elicitation and incorporation of pertinent cultural data in diagnosis and treatment.
 - d. Understanding and application of cultural and ethnic data to the process of clinical care.
5. **Cultural Diversity Form:** Each CME speaker shall complete and sign a *Cultural Diversity* form which informs the speaker of the requirement that cultural and linguistic information/resources are required for each CME activity with clinical content. **See attached**
6. Cultural references shall be made available to attendees at CME activities.

D. **FORM(S):**

1. **CLC & IB Standards Planning Worksheet**~~Cultural Diversity Form~~ – Sample.

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

1. Tri-City Medical Center “A Guideline for General Cultural Awareness” – Sample.

F. **REFERENCE(S):**

1. ~~Institute for Medical Quality (IMQ)/California Medical Association (CMA) 2014 CME Accreditation Criteria and Policies for Continuing Medical Education (CME) *with annual report glossary.~~
- 2.1. **Links to AB1195 and AB241**
https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=200520060AB1195

Cultural Diversity Form - Sample



Tri-City Medical Center CULTURAL DIVERSITY FORM

Date: _____

Topic: _____

Speaker: _____

The California legislature passed AB 1195, which states that as of July 1, 2006 Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component.

DEFINITIONS: Cultural competency means a set of integrated attitudes, knowledge, and skills that enables a health care professional or organization to care effectively for patients from diverse cultures, groups, and communities. Linguistic competency means the ability of a physician and surgeon to provide patients who do not speak English with the limited ability to speak English, direct communication in the patient's primary language.

We believe there is relevant cultural diversity information relating to one or more of the following: age, gender, race, socio-economic status, sexual orientation, religion, language, ethnicity, etcetera that impacts the care of patients. If you are required to include it in your presentation. If no relevant cultural diversity information is identified, this should be documented.

Therefore, the following objectives should be added to the activity publicity to potential attendees and also to the attendee evaluation form:

Discuss the impact of culturally relevant diversities (gender, age, race, religion, ethnicity, language, sexual orientation, socio-economics, etc.) that relate to demographics, diagnosis, and treatment.

I have read this form and will comply with AB 1195 as outlined above.

Signature: _____

Date: _____



CULTURAL AND LINGUISTIC COMPETENCY (CLC) and IMPLICIT BIAS (IB) Standards

Planning Worksheet

This worksheet is designed to assist continuing medical education (CMED) planners in ensuring a given CME activity follow the cultural and linguistic competency (CLC) and implicit bias (IB) standards required by law and developed by the California Medical Association (CMA)

Name of CME Activity: _____

Date of CME Activity: _____

Select the statement which is most applicable:

☐ This activity will contain curriculum that includes the understanding of CLC and IB

☐ This activity will not contain curriculum that includes the understanding of CLC and IB. I certify that the topic of this activity is research focused and/or does not contain a direct patient care component.

Standard 1: Website the text of (or direct links to) AB1195 and AB241 were posted to the provider's organization website.

☐ Yes

☐ NO

☐ It was not feasible to include this information on the website. Information was provided using an alternative method.

Please specify:

Standard 2: Definition All individuals in control of content were provided with the definition of CLC and IB¹

☐ Yes

☐ No

Standard 3: Resources All individuals in control of content were directed to or provided with CCLC and IB educational resourced.

☐ Yes

☐ No

Please specify:

¹ As defined by CMA at cma-docs.org/CME-standards

Standards 4 and 5: Patient Populations and Disparities

What are the commonalities of your organization's patient population?

What CLC factors were communicated to planners, faculty and speakers relevant to this population?

What are some disparities that may influence the health outcomes of these patients if not properly mitigated?

**Standard 6: Diversity Individuals in control of content represent a diverse²
Perspective on the proposed topic.**

☐ Yes

☐ No

Comments:

² The following definition has been adapted from the National Institute of Health-Diversity: Having many different forms, types or ideas; showing variety. Demographic diversity can mean a group comprised of people of different genders, races/ethnicities, cultures, religions, physical abilities, sexual orientations or preferences, ages, etc.

Standard 7: Incorporated what are some of the CLC and IB educational resources included, referenced or introduced during this activity?

PHARMACY

ISSUE DATE: NEW

SUBJECT: Peri-operative Antimicrobials
Prophylaxis

REVISION DATE(S):

Pharmacy Department Approval:	11/20
Infection Control Committee	11/20
Pharmacy & Therapeutics Committee Approval:	01/21
Operating Room Committee Approval:	02/22
Medical Executive Committee Approval:	03/22
Administration Approval:	04/22
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	

A. POLICY:

1. To provide a guideline for the safe and effective utilization of **peri-operative** antimicrobials for surgical site infection ~~prophylaxis~~**prevention**
2. Appropriate use of antimicrobial prophylaxis prevents post-operative infections at the site of surgery, post-operative morbidity and mortality due to infectious complications, reduces the duration and cost of the patient's health care needs, and minimizes the adverse consequences for the microbial flora of the patient or institution

B. PROCEDURE:

1. Pre-operative dose timing
 - a. Patients receiving therapeutic antimicrobials for a remote infection before surgery should also be given antimicrobial prophylaxis before surgery
 - i. If the agents used therapeutically are appropriate for surgical prophylaxis, administering an extra dose within 60 minutes before surgical incision is sufficient. Otherwise, the antimicrobial prophylaxis recommended for the planned procedure should be used (See **Surgical Peri-operative Antimicrobial Prophylaxis Recommendations** ~~Table 1~~ for recommendations)
 - b. The optimal time for administration of preoperative doses is within 60 minutes before surgical incision
 - c. Fluoroquinolones and vancomycin require administration over 1-2 hours; therefore, administration of these agents should begin within 120 minutes before surgical incision
 - d. Antimicrobial administration needs to be timed such that the bactericidal concentration of the agent is established in the serum and tissues when the incision is made. For the prevention of surgical site infections, it is important to infuse most, if not ALL of the drug before ~~cutting incision is made~~
 - e. See **Surgical Peri-operative Antimicrobial Prophylaxis-Re-dosing Intervals and Infusion Times Recommendations** ~~Table 2~~ for timing recommendations
2. Antimicrobial selection and dosing
 - a. The agent chosen should have activity against the most common surgical-site pathogens
 - b. Recommendations for the selection of prophylactic antimicrobials for various surgical procedures are provided in **Surgical Peri-operative Antimicrobial Prophylaxis Recommendations** ~~Table 1~~

- c. Alternative antimicrobial combinations aside from those recommended in **Surgical Peri-operative Antimicrobial Prophylaxis-Recommendations** Table 1 may be warranted if prior culture results determine patient is colonized at the surgical site or currently infected with a pathogen not commonly covered by the recommended antimicrobial
3. Antimicrobial re-dosing intervals
 - a. Intra-operative re-dosing is needed to ensure adequate serum and tissue concentrations of the antimicrobial if the duration of the procedure exceeds two half-lives of the drug or there is excessive blood loss during the procedure (>1,500 mL blood loss)
 - b. Re-dosing interval should be measured from the time of administration of the pre-operative dose, not from the beginning of the procedure
 - c. Re-dosing may not be warranted in patients in whom the half-life of the antimicrobial agent is prolonged (e.g., patients with renal insufficiency or renal failure)
4. **Peri-operative Antimicrobial Prophylaxis-duration**
 - a. Evidence supports that post-operative antimicrobial administration is not necessary for most procedures and guidelines recommend that in clean and clean-contaminated procedures, administration of additional prophylactic antimicrobial agents is not necessary after surgical incision is closed, even in the presence of a drain
 - b. If post-operative antimicrobials are ordered, the duration of antimicrobial prophylaxis should be less than 24 hours for most procedures
 - i. A duration of up to 48 hours for cardiothoracic prophylaxis has been an accepted practice, but ~~will-with~~ little evidence supporting the practice
 - ii. There ~~are-is~~ no data to support the continuation of antimicrobial prophylaxis until all indwelling drains and intravascular catheters are removed **and has the potential to lead to antimicrobial resistance or *Clostridioides difficile* infection.**

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

1. ~~Surgical Peri-operative-Antimicrobial Prophylaxis-Recommendations~~
2. ~~Surgical Peri-operative -Antimicrobial Prophylaxis-Re-dosing Intervals and Infusion Times Recommendations~~

D. **REFERENCE(S):**

1. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: <http://www.micromedexsolutions.com>.
2. Bratzler DW, Dellinger EP, Olsen KM, et al; American Society of Health-System Pharmacists; Infectious Disease Society of America; Surgical Infection Society; Society for Healthcare Epidemiology of America. Clinical practice guidelines for antimicrobial prophylaxis in surgery. Am J Health Syst Pharm. 2013 Feb 1;70(3):195-283.
3. Berrios-Torres SI, Umscheld CA, Bratzler DW et al. Centers for disease control and prevention guidelines for the prevention of surgical site infection. JAMA Surgery. 2017 Aug 1; 152(8):784-791



Tri-City Medical Center
Oceanside, California

Peri-operative Antimicrobial Recommendations

Type of Procedure		Pre-op	Alternative in β -lactam allergy
Cardiac			
Coronary artery bypass, cardiac device insertion procedure (e.g. pacemaker implantation), ventricular assist devices		Cefazolin 2 g (3 g in pts weighing >120 kg) or cefuroxime 1.5 g	Clindamycin 900 mg or vancomycin 15 mg/kg
General surgery			
Open biliary procedure		Cefazolin 2 g (3 g in pts weighing >120 kg), cefoxitin 2 g, cefotetan 2 g, ceftriaxone 2 g, or ampicillin-sulbactam 3 g	Metronidazole 500 mg + aminoglycoside ¹ or fluoroquinolone ² Clindamycin 900 mg or vancomycin 15 mg/kg + aminoglycoside ¹ or aztreonam 2 g or fluoroquinolone ²
Laparoscopic biliary procedure	Elective, low risk	None	None
	Elective, high risk	Cefazolin 2 g (3 g in pts weighing >120 kg), cefoxitin 2 g, cefotetan 2 g, ceftriaxone 2 g, or ampicillin-sulbactam 3 g	Clindamycin 900 mg or vancomycin 15 mg/kg + aminoglycoside ¹ or aztreonam 2 g or fluoroquinolone ² Metronidazole 500 mg + aminoglycoside ¹ or fluoroquinolone ²
Appendectomy for uncomplicated appendicitis		Cefoxitin 2 g, cefotetan 2 g, or cefazolin 2 g, (3 g in pts weighing >120 kg) + metronidazole 500 mg	Clindamycin 900 mg + aminoglycoside ¹ or aztreonam 2 g or fluoroquinolone ² Metronidazole 500 mg + aminoglycoside ¹ or fluoroquinolone ²
Small intestine	Non obstructive	Cefazolin 2 g (3 g in pts weighing >120 kg)	Clindamycin 900 mg + aminoglycoside ¹ or aztreonam 2 g or fluoroquinolone ²
	Obstructed	Cefazolin 2 g (3 g in pts weighing >120 kg) + metronidazole 500 mg, cefoxitin 2 g, cefotetan 2 g	Metronidazole 500 mg + aminoglycoside ¹ or fluoroquinolone ²
Hernia repair (hernioplasty and herniorrhaphy)		Cefazolin 2 g (3 g in pts weighing >120 kg)	Clindamycin 900 mg or vancomycin 15 mg/kg
Colorectal		Cefazolin 2 g (3 g in pts weighing >120 kg) + metronidazole 500 mg, cefoxitin 2 g, cefotetan 2 g, ampicillin-sulbactam 3 g, ceftriaxone 2 g + metronidazole 500 mg, or ertapenem 1 g	Clindamycin 900 mg + aminoglycoside ¹ or aztreonam 2 g or fluoroquinolone ² Metronidazole 500 mg + aminoglycoside ¹ or fluoroquinolone ²

Peri-operative Antimicrobial Recommendations

Type of Procedure	Pre-op	Alternative in β -lactam allergy
Neurosurgery		
Elective craniotomy and cerebrospinal fluid-shunting procedure	Cefazolin 2 g (3 g in pts weighing >120 kg)	Clindamycin 900 mg or vancomycin 15 mg/kg
Implantation of intrathecal pumps	Cefazolin 2 g (3 g in pts weighing >120 kg)	Clindamycin 900 mg or vancomycin 15 mg/kg
Orthopedic		
Clean operations of hand, knee, or foot (not involving foreign material)	None	N/A
Spinal procedures with and without instrumentation	Cefazolin 2 g (3 g in pts weighing >120 kg)	Clindamycin 900 mg or vancomycin 15 mg/kg
Hip fracture repair	Cefazolin 2 g (3 g in pts weighing >120 kg)	Clindamycin 900 mg or vancomycin 15 mg/kg
Implantation of internal fixation devices	Cefazolin 2 g (3 g in pts weighing >120 kg)	Clindamycin 900 mg or vancomycin 15 mg/kg
Total joint replacement	Cefazolin 2 g (3 g in pts weighing >120 kg)	Clindamycin 900 mg or vancomycin 15 mg/kg
Urology		
Lower tract instrumentation with risk factors for infection (includes transrectal prostate biopsy)	Fluoroquinolone ² , trimethoprim-sulfamethoxazole ³ , or cefazolin 2 g (3 g in pts weighing >120 kg)	Aminoglycoside ¹ \pm clindamycin 900 mg
Clean without entry into urinary tract	Cefazolin 2 g (3 g in pts weighing >120 kg)	Clindamycin 900 mg or vancomycin 15 mg/kg
Clean with entry into urinary tract	Cefazolin 2 g (3 g in pts weighing >120 kg)	Fluoroquinolone ² or aminoglycoside ¹ \pm clindamycin 900 mg
Involving Implanted prosthesis	Cefazolin 2 g (3 g in pts weighing >120 kg) \pm aminoglycoside ¹ , or cefazolin \pm aztreonam 2 g, or ampicillin-sulbactam 3 g	Clindamycin 900 mg \pm aminoglycoside ¹ or aztreonam 2 g, vancomycin 15 mg/kg \pm aminoglycoside ¹ or aztreonam 2 g
Clean-contaminated	Cefoxitin 2 g or cefazolin 2 g (3 g in pts weighing >120 kg) + metronidazole 500 mg	Fluoroquinolone ² or aminoglycoside ¹ + metronidazole 500 mg or clindamycin 900 mg
Vascular		
Vascular procedures	Cefazolin 2 g (3 g in pts weighing >120 kg)	Clindamycin 900 mg or vancomycin 15 mg/kg
1. Aminoglycoside dose: gentamicin 5mg/kg based on dosing weight; use adjusted body weight if obese (>20% ideal body weight) 2. Fluoroquinolone dose: levofloxacin 500mg or ciprofloxacin 400mg 3. Trimethoprim-sulfamethoxazole dose: 160mg of trimethoprim component		

Surgical Peri-Operative Antimicrobial Prophylaxis Re-dosing Intervals and Infusion Times Recommendations

Antimicrobial	Half-life in Adults with Normal Renal Function, hr	Recommended Re-dosing Interval (From Initiation of Pre-operative Dose) Intra-operative Re-dosing Interval	Infuse over time	Time of INITIATION prior to cut for adequate levels	Delayed Procedure Re-Dosing Interval
Ampicillin-sulbactam	0.8-1.3	2 hrs	30 min Min: 15 min 30 min	Optimal: 30 min Min: 15 min 30 min	1-2 hrs: 1.5g >2 hrs: 3g
Ampicillin	1-1.9	2 hrs	30 min Min: 15 min 30 min	Optimal: 30 min Min: 15 min 30 min	1-2 hrs: 1g >2 hrs: 2g
Aztreonam	1.3-2.4	4 hrs	30 min Min: 5 min 30 min	Optimal: 30 min Min: 10 min 30 min	1-2 hrs: 1g >2 hrs: 2g
Cefazolin	1.2-2.2	4 hrs	30 min Min: 5 min 30 min	Optimal: 30 min Min: 10 min 30 min	1-2 hrs: 1g >2 hrs: 2g
Cefuroxime	1-2	4 hrs	30 min Min: 5 min 30 min	Optimal: 30 min Min: 10 min 30 min	1-2 hrs: 750mg >2 hrs: 1g
Cefotaxime	0.9-1.7	3 hrs	30 min Min: 5 min 30 min	Optimal: 30 min Min: 15 min 30 min	1-2 hrs: 1g >2 hrs: 2g
Cefoxitin	0.7-1.1	2 hrs	30 min Min: 5 min 30 min	Optimal: 30 min Min: 15 min 30 min	1-2 hrs: 1g >2 hrs: 2g
Cefotetan	2.8-4.6	6 hrs	30 min Min: 5 min 30 min	Optimal: 30 min Min: 15 min 30 min	1-2 hrs: 1g >2 hrs: 2g
Ceftriaxone	5.4-10.9	NA	30 min 30 min	Optimal: 30 min Min: 15 min 30 min	1-2 hrs: 1g >2 hrs: 2g
Ciprofloxacin	3-7	NA	60 min 60 min	Optimal: 60 min Min: 30 min 60 min	2-6 hrs: 200mg >6 hrs: 400mg
Clindamycin	2-4	6 hrs	30 min 30 min	Optimal: 30	1-3 hrs:

Surgical Peri-Operative Antimicrobial Prophylaxis Re-dosing Intervals and Infusion Times Recommendations

Antimicrobial	Half-life in Adults with Normal Renal Function, hr	Recommended Re-dosing Interval (From Initiation of Pre-operative Dose) Intra-operative Re-dosing Interval	Infuse over time	Time of INITIATION prior to cut for adequate levels	Delayed Procedure Re-Dosing Interval
				min Min: 15 min 30 min	300mg >3 hrs: 600mg
Ertapenem	3-5	NA	30 min 30 min	Optimal: 30 min Min: 15 min 30 min	1-2 hrs: 500mg >2 hrs: 1g
Fluconazole	30	NA	400mg = 120 min 400mg = 120 min	Optimal: 60 min Min: 30 min 60 min	2-6 hrs: 200mg >6 hrs: 400mg
Gentamicin	2-3	NA	30 min Min: 15 min 30 min	Optimal: 30 min Min: 15 min 30 min	1-3 hrs: 2.5mg/kg >3 hrs: 5mg/kg
Levofloxacin	6-8	NA	60 min 60 min	Optimal: 60 min Min: 30 min 60 min	2-6 hrs: 250mg >6 hrs: 500g
Metronidazole	6-8	NA	60 min Min: 30 min 60 min	Optimal: 30 min Min: 15 min 30 min	2-6 hrs: 250mg >6 hrs: 500mg
Moxifloxacin	8-15	NA	60 min 60 min	Optimal: 60 min Min: 30 min 60 min	2-6 hrs: 200mg >6 hrs: 400mg
Piperacillin-tazobactam	0.7-1.2	2 hrs	30 min 30 min	Optimal: 30 min Min: 15 min 30 min	>2 hrs: 3.375g
Vancomycin	4-8	NA	1g = 60 min 1.5 g = 120 min 1.5 g = 120 min	Optimal: 90 min Min: 60 min 90 min	2-6 hrs: 500mg >6 hrs: 1g

**SECURITY
SECURITY EQUIPMENT**

ISSUE DATE: 11/93 **SUBJECT:** Authorized Security Department
Uniforms and Safety Equipment

REVIEW DATE: 12/95, 10/97, 06/00, 02/01, 05/03, 06/09, 06/11 **POLICY NUMBER:** 401

REVISION DATE: 02/01, 07/03, 06/09, 09/15, 11/20

Department Approval: 05/2003/22
Environmental Health and Safety Committee Approval: 08/2003/22
Administration Approval: 10/2004/22
Professional Affairs Committee Approval: n/a
Board of Directors Approval: 11/20

A. PURPOSE:

1. To establish guidelines for the wearing and issuing of approved Security Department attire, uniforms and safety equipment by all security personnel.

B. POLICY:

1. All on duty ~~medical center~~ Security Department personnel will wear only approved **professional attire**, uniforms and safety equipment items while acting in the capacity of security officer. In addition, ~~all~~ uniform items are to be issued in accordance with this policy.

C. APPROVED UNIFORM APPAREL:

1. Required Uniform Items (Department Issue)
 - a. Uniforms will be clean and pressed with visible vertical creases on the pant legs and on shirt sleeves.
 - b. Boots will be clean and polished ~~and all equipment will be maintained.~~
 - c. A supervisor ~~or designee~~ will routinely check uniforms and equipment to verify compliance.
 - i. ~~Trousers~~
 - ii. ~~Shirt~~
 - 1) ~~Long sleeve shirts are to be worn with a solid Blue Break away tie and plain silver tie bar.~~
 - iii. ~~Jacket~~
 - d. Department patches are to be worn on both sleeves of any approved shirt, sweater, and jacket and in the center of ~~management~~ approved ball cap.
 - e. Department issued security badge will be displayed in plain sight in an appropriate manner.
 - f. Medical Center photographic identification badge will be worn in plain sight with the photograph showing.
 - g. **Duty Belt will be made of nylon with plastic buckle and black in color.**
 - f.h. **Four Belt keepers matching duty belt.**
2. ~~Required~~ Additional Uniform Items (~~Officer's~~ expense).
 - a. ~~Duty Belt will be made of nylon with plastic buckle and black in color.~~
 - b. ~~Four Belt keepers matching duty belt.~~
 - e.a. One Key Ring matching duty belt.

- d.b. Footwear will consist of any of the following and will be maintained in a clean and neat condition.
 - i. Military style boots **or shoes**, with plain toe, ~~and full leather upper~~, black in color, and having plain type sole.
 - ii. High Tech brand (or equivalent) style uniform boot **or shoe**, black in color with standard sole.
 - 1) All low cut style footwear will be worn with plain black or dark blue colored socks. High top boots may be worn with white, black, or blue socks (sock color will not be visible while wearing boots).
 - 2) Prior approval from the Security Supervisor must be obtained for the wearing of any other style of footwear.
- 3. Optional Uniform Items (~~O~~fficers expense)
 - a. Approved plain navy blue or black ball cap style security hat with approved security patch centered on the front.
 - b. Crew style tee shirt. Color will be Black, White, or Blue only.
 - c. The wearing of appropriate insignias. Insignias must be approved by the Security Supervisor prior to being worn and can only be worn in a manner displaying proper respect and protocol.
- 4. Safety Equipment (~~Department~~Hospital Issue)
 - a. ~~One nylon pouch to carry personal protective equipment.~~
 - i. ~~Nylon pouch to carry the following items.~~
 - 1)a. Non-latex medical exam gloves (or equivalent)
 - 2)b. Safety glasses
 - 3)c. Spit sock.
 - b.d. Department furnished Two-Way Motorola radio.
 - i. Officer will be issued ~~his~~their own personal radio for use while on duty. The Officer will be solely responsible for maintaining ~~his~~their issued radio and keeping it in good operating condition. Any damage to the Officer's radio must be immediately reported to his supervisor. Damage due to neglect will be the responsibility of the assigned Officer.
- 5. Optional Safety Equipment (Officer expense)
 - a. Mini style flashlight with case matching duty belt.
 - b. Plain black colored gloves. Gloves will only be worn with uniform during night shifts or inclement weather.
- 6. While on duty, security officers will only wear the appropriate uniform items as described.
- 7. While on duty, Security Department personnel will only be allowed to wear the following personal affects: appropriate wristwatch. ring(s) to be limited to wedding band or one ring per hand and not bulky or excessive or would not allow the officer to perform their physical-contact duties safely. The wearing of any necklaces will be done in such a manner to be kept from plain sight. Earrings to be limited to stud type and one per ear (~~Females only~~).
- 7-8. **Light-Duty security officers are not authorized to be in Security Dept. uniforms and must wear black or dark-blue professional business attire such as shoes or boots, pants and collared shirt.**

D. ISSUANCE OF UNIFORMS:

- 1. Full Time New-Hire
 - a. Number of issued uniforms to be received by full time new-hire Security Department ~~O~~fficers will be determined by the Security ~~Manager~~Department Leadership (lead officer, supervisor, manager or director) based on Department needs.

E. REPLACEMENT OF DAMAGED UNIFORMS:

- 1. Any replacement of required Security Department uniform items that have sustained work-related damage will be subject to approval and will be replaced in accordance with the uniform

procedure to be determined by the Security ManagerDepartment Leadership (lead officer, supervisor, manager or director).

F. NON-COMPLIANCE:

1. Non-Compliance with any portion of this policy may result in disciplinary action leading to, and or including termination.



Tri-City Medical Center
Oceanside, California

**SURGICAL SERVICES
SURGERY**

ISSUE DATE:	04/94	SUBJECT:	Scheduling Surgical Procedures
REVISION DATE(S): 09/99, 04/01, 01/02, 06/03, 02/05, 02/08, 06/09, 11/10, 10/12, 12/12, 01/13, 03/14, 02/17, 08/19, 05/20			
Surgical Services Department Approval:		02/2002/22	
Department of Anesthesiology Approval:		n/a	
Operating Room Committee Approval:		03/2002/22	
Pharmacy & Therapeutics Committee Approval:		n/a	
Medical Executive Committee Approval:		04/2003/22	
Administration Approval:		05/2004/22	
Professional Affairs Committee Approval:		n/a	
Board of Directors Approval:		05/20	

A. PURPOSE:

1. To provide scheduling guidelines for surgery, endoscopy, elective cesarean sections (in OB-OR) and procedures requiring an anesthesia provider.

B. DEFINITIONS:

1. Add-On Cases: Additions to the surgery schedule after the "final schedule" has been published. The "final schedule" is published by 4:00pm for the next day.
2. Elective Case: Surgery can be scheduled at the time best suited for the surgeon and the patient.
3. Urgent Case: Surgical intervention is needed within 4-6 hours of presentation. Urgent procedures are placed in an available time on the OR schedule.
4. Emergent Case: Surgical intervention is needed within one hour of presentation and may require that another scheduled or add-on case is bumped.
5. Emergency: Surgical intervention is needed immediately upon presentation to preserve life or limb. Emergency procedures are performed in the first available operating room and may require that another scheduled or add-on case is bumped.

C. SCHEDULING ELECTIVE CASES:

1. All elective surgical and endoscopic procedures ~~and elective cesarean sections in OB-OR~~ will be scheduled through the Surgery scheduling office.
2. There are 12 rooms in the Tri-City Medical Center (TCMC) OR suite which are utilized as follows:
 - a. Ten (10) operating rooms (OR 1-10) can accommodate any type of case.
 - b. OR 6 is reserved for cardiac cases.
 - c. OR 11 is the Cystoscopy Room and is considered a wound class II room. Only certain procedures may be performed in this room due to the open drain:
 - i. Circumcision
 - ii. Endourology procedures
 - iii. Percutaneous Suprapubic Cystotomy
 - iv. Vasectomy
 - v. Orchiectomy
 - d. OR 12 is the GI Endoscopy Room

3. Expected available surgery rooms Monday-Thursday (may fluctuate based on staffing, surgical volume and surgical acuity):
 - a. 0715-1700 hours: 8 rooms
 - b. 1700-1900 hours: 4 rooms
 - c. 1900-2100 hours: 3 rooms
 - d. 2100-2300 hours: 2 rooms
4. Expected available surgery rooms on Friday (may fluctuate based on staffing, surgical volume and surgical acuity):
 - a. 0715-1700 hours: 7 rooms
 - b. 1700-1900 hours: 4 rooms
 - c. 1900-2100 hours: 3 rooms
 - d. 2100-2300 hours: 2 rooms
5. Elective cases shall be scheduled by the surgery scheduling office between the hours of 0800 and 1630, Monday through Friday, at 760-940-7382. After 1430, cases scheduled for the following day are scheduled by staff at the Surgery desk (760-940-5400).
 - a. Elective cases are performed Monday through Friday from 0715 (0815 on Thursday) to 2300 hours. Elective cases should not extend beyond 2300.
6. Start Times:
 - a. The Start time of a procedure (time on the OR schedule) is the time the patient is expected to be in the OR. Start time of first cases are tracked and report to the OR committee monthly.
 - b. The start time of elective or add-on case requested for 1600 or later cannot be guaranteed. In those instances, the surgeon's preferred start time will be noted, and the surgeon will be given one hour's notice of expected start time. If the surgeon cannot start at the expected time, the next surgeon to start will be offered the time.
7. Delays:
 - a. Surgeons who notify the OR they will be late for their scheduled start time must provide an expected time of arrival. Delays of more than 30 minutes, or delays that will impact another surgeon's schedule will cause the first surgeon to be bumped back to the next available start time.
 - b. Surgeons who are not in the hospital 30 minutes past the scheduled time of surgery and are unable to be contacted will be bumped back to the next available start time once they either arrive at the hospital or contact the OR.
8. Cases are scheduled on a consecutive, first-come first-served basis, or in a surgeon's block time.
9. Procedures may be scheduled by the surgeon or the surgeon's office staff only.
10. The process for scheduling an elective case is as follows:
 - a. The surgeon's office calls the TCMC Surgery Scheduling department to reserve a case time.
 - i. ~~The surgeon's office completes a written "TCMC Surgery Scheduling Patient Information" booking form and faxes to the TCMC Surgery department fax server (Fax # 760-940-7138) within 48 hours of the telephone reservation.~~
 - ii.i. ~~Upon receiving the written booking form, the TCMC Surgery Scheduler will schedule the case, obtain a financial account number (FIN#) and book a Pre-Operative Education appointment.~~
 - iii.ii. ~~The TCMC Surgery Scheduler will write provide the FIN# and the date and time of the Pre-Operative Education appointment to the surgeon's office scheduler on the "TCMC Surgery Scheduling Patient Information" booking form, and will fax the form back to the surgeon's office as confirmation.~~
 - b. ~~The surgeon's office enters~~ **must enter** ~~electronic orders or faxes written orders to the TCMC Surgery Scheduling department fax server at least one week prior to surgery date. Electronic orders will also be accepted.~~ **Faxed or paper orders will not be accepted.**

- i. If the case is scheduled less than one week prior to the date of surgery, ~~written or~~ electronic orders are required by the next business day.
11. Patient Requirements:
 - a. Surgery patients must be at least 18 years of age at the time of surgery, except in the case of emergency.
 - i. **Patients 14-17 years of age presenting with surgical emergency are to be surgically treated at TCMC. Patients shall be transferred to Rady Children's Hospital if they require post-operative hospital admission.**
 - ii. Any requested patient who is under 18 years of age must be reviewed/approved prior to scheduling by the Chief of Anesthesia or designee.
12. The surgeon must have the appropriate privileges granted to be allowed to schedule a procedure.
 - a. Current privilege lists are maintained through the E-PRIV system, accessible through TCMC Intranet.
 - b. If the physician's privilege status is still not clear, the Medical Staff Office is contacted for clarification. The Administrative Supervisor may be contacted for assistance outside of Medical Staff Office hours.
 - c. It is the responsibility of the surgeon to acquire an assistant or proctor as necessary for designated procedures.

D. **PRE-OPERATIVE EDUCATION APPOINTMENT SCHEDULING GUIDELINES:**

1. Patients may be scheduled for a telephone ~~vs. in-person~~ Pre-Operative Education appointment.
2. ~~Those patients who qualify for a telephone Pre-Operative Education appointment include:~~
 - a. ~~Debilitated patients~~
 - b. ~~Nursing home patients~~
 - c. ~~Requests from physician's office if HMO is doing blood work and the patient has a transportation problem~~
 - d. ~~Patients who are rescheduled for surgery and have already attended a Pre-Operative Education appointment~~

E. **SCHEDULING ADD-ON URGENT, EMERGENT, OR EMERGENCY PROCEDURES:**

1. Urgent, Emergent, and Emergency cases may be performed at any time.
2. Urgent, Emergent, and Emergency cases shall be scheduled through the Main OR desk in person or via telephone (760-940-5400).
3. Required information when scheduling an add-on case includes:
 - a. Patient name, date of birth, age, and medical record number
 - b. Patient phone number, Social Security number, and insurance information (excludes in-house patients)
 - c. Patient current location in the hospital
 - d. NPO status
 - e. Pre-Op diagnosis and Procedure to be performed
 - f. Physical needs/mobility limitations
 - g. Surgeon and assistant (if applicable)
 - h. Instrumentation/Equipment/X-ray needed
 - i. Relevant cardiac/medical history
 - j. Time of surgeon availability

F. **WEEKEND/HOLIDAY CASES:**

1. For Saturday and Sunday 0730-1500, 2 rooms are available for Add-on cases and 1 room is available for emergency cases or a heart. For 1500-0730, 1 room is available for Add-on cases and 1 room is available for emergency cases or a heart.
2. Memorial Day, Labor Day, July 4th, Thanksgiving, Christmas, and New Year's Day have one urgent and one emergent room only. No elective surgeries are scheduled on these holidays.
3. President's Day will be treated like a regular weekend day.

4. Weekend and holiday cases are not to be scheduled more than 24 hours prior to the day of surgery.
5. Add-on cases are started in order of scheduling, providing the surgeon is available and the patient is ready for surgery.
6. If the first scheduled add-on case cannot be performed in the first available time, the next case's surgeon will be contacted and offered to start at the available time. Upon availability of the next time to start an add-on case, the surgeon for the first case will again be contact and offered the time.
 - a. The first available time is 0730. If a physician requests a specific time, e.g., 0900 to start a case, then another physician is available to start at 0730, the physician requesting the 0900 start time will be contacted to move up to 0730, or will start after the preceding case is finished.
7. For 0730 cases, the patient must be ready for transfer to the Operating Room by 0645, otherwise, the next scheduled case may replace the delayed case.
8. When the first Saturday/Sunday room is booked for three hours or more, the second room is opened. The surgeon following the 0730 slot in the first room will be offered the 0730 slot in the newly available room.
9. Robotic cases are not to be scheduled on holidays. However, robotic cases may be scheduled on weekends. ~~if the appropriately trained staff members are scheduled and the necessary vendor representatives are available.~~
10. Requests may be approved on an individual basis by **a member of the Surgery Nursing leadership team**~~the OR Nursing Director/Assistant Director~~ and Operating Room Medical Director.

G. **ENDOSCOPY:**

1. Endoscopy services are available 24/7.
2. Endoscopy procedures are scheduled in the same manner as surgical procedures.
3. Endoscopy procedures requiring an anesthesia provider are scheduled in **the appropriate block time or in an open time** on the OR schedule.

WOMEN AND NEWBORN SERVICES

ISSUE DATE: 06/03

SUBJECT: Surrogacy

REVISION DATE(S): 02/22

Women and Newborn Services Department Approval: 03/2242/18

Department of OB/GYN Approval: n/a

Department of Pediatric Approval: n/a

Pharmacy and Therapeutics Approval: n/a

Medical Executive Committee Approval: n/a

Administration Approval: 04/1904/22

Professional Affairs Committee Approval: n/a

Board of Directors Approval: 01/19

A. DEFINITION(S):

1. **Surrogate:** a woman who bears and carries a child for another through medically assisted reproduction and pursuant to a written agreement. Within the definition of surrogate are two different and distinct types:
 - a. **Traditional surrogate:** a woman who agrees to gestate an embryo, in which the woman is the gamete donor and the embryo was created using the sperm of the intended father or a donor arranged by the intended parent or parents.
 - b. **Gestational carrier:** a woman who is not an intended parent and who agrees to gestate an embryo that is genetically unrelated to her pursuant to an assisted reproduction agreement.
2. **Intended Parent:** an individual, married or unmarried, who manifests the intent to be legally bound as the parent of a child/children resulting from assisted reproduction.
3. **Judgement relating to parentage:** a court issued document that establishes a parent-child relationship between the child/children and the intended parent(s) identified in the surrogacy agreement and further establishing that the surrogate, her spouse, or partner is not a parent of, and has no parental rights or duties with respect to, the child/children.

B. POLICY:

1. In all cases, the judgement shall be used as a guide to determine who has legal authority for the child/children.
 - a. In the absence of a judgement the surrogate will maintain full custodial and legal rights of the child/children.
2. The Women and Newborn Services (WNS) Social Services shall act as the primary contact and referral coordinator for the surrogate and associated parties.

C. PROCEDURE:

1. **Pre-registration of surrogate and child/children**
 - a. The Social Worker will request a copy of the judgement, which will be placed in the Perinatal Watch List Binder on Labor and Delivery.
 - i. Inform the surrogate to bring in the original certified copy of the judgement at the time of admission.
 - b. The Access Management Representative will
 - i. Obtain and verify the following information from the surrogate:
 - 1) Pre-registration form

- 2) Insurance information of responsible financial party (including a photocopy)
 - a) Verify the insurance provided is an active account and ensure surrogacy is a covered benefit.
 - 3) TCMC financial agreement for surrogacy
 - a) If additional financial arrangements are needed, the admission department shall process them accordingly.
 - 4) Request a copy of the judgement, if not already received.
 - ii. Create a pre-admit account for the surrogate and child/children.
 - iii. Follow up with the surrogate and intended parent(s) to discuss contractual obligations for financial responsibilities.
2. Admission of surrogate for delivery:
 - a. The WNS Unit Secretary will do the following:
 - i. Notify Admitting of the surrogate admission for labor
 - 1) Admitting will activate the account and inform the WNS unit secretary when completed.
 - ii. Print a patient ID band and verify patient information is correct and place on her wrist.
 - iii. Assemble the surrogate chart to include, at minimum, the following:
 - 1) A copy of the judgement from the Perinatal Watch List Binder
 - a) If the original certified copy of the judgement is available the WNS unit secretary will also place it with the newborn paperwork in the surrogate chart.
 - 2) Facesheets and labels
 - 3) Prenatal records and lab results
 - a) Electronic records for surrogate chart and a paper copy for the child's/children's chart.
 - 4) Signed electronic Conditions of Admission (COA) for the surrogate only
 - b. The admitting RN will:
 - i. Complete a full admission of the surrogate
 - ii. Enter a Social Work referral in Cerner
 - iii. Have the intended parent(s) sign the COA for the child/children
3. Admission of child/children in the presence of the original certified copy of the judgement:
 - a. The delivery RN will:
 - i. Notify the WNS Unit Secretary and of the date, time, sex and pediatrician of the child/children
 - b. The WNS Unit Secretary will notify Admitting of the child's/children's birth data
 - i. Admitting will then activate the pre-admit account for the child/children with the reported birth data.
 - 1) When activation of the account is completed, Admitting will notify the WNS Unit Secretary.
 - c. The WNS Secretary will then print the child/children ID bands, facesheets and labels and give them to the RN caring for the child/children.
 - d. The WNS Secretary will assemble the child's/children's charts, which will include the original certified judgement.
 - e. The RN caring for the child/children will then apply the bands per the PCS Procedure: Newborn Identification Banding and Electronic Alarm Device.
 - i. The adult/ "parent" bands will go to the intended parent(s)
4. Admission of child/children in the absence of the original certified copy of the judgement:
 - a. If there is no judgement present, the child/children will be admitted under the surrogate name and all bands will be made in that name.

- i. One of the intended parents may be banded with 1 of the adult/" parent" bands containing the surrogate name.
 - b. When the intended parent(s) arrive with the original certified copy of the judgement:
 - i. The WNS Social Worker will verify the judgement
 - ii. The unit secretary will send a communication notice to admitting for the child's/children's name to be changed and EHR to be unlinked.
 - 1) The name change will be corrected in the EHR and the hard chart documents.
 - 2) The admissions office will update insurance and emergency contact information as needed.
 - 3) Newborn identification bands will be made to reflect the name change.
 - 4) The Newborn Metabolic Screening form will be updated to reflect the name change utilizing the comment box.
 - iii. The intended parent(s) and child/children will be re-banded with new identification bands with the intended parent(s) information.

D. RELEASE OF INFORMATION/CONSENT:

- 1. Administrative Compliance Policy: Disclosure of Protected Health Information (PHI) 8610-513
- 2. Original Certified Judgement present
 - a. Release of information regarding the child/children will be provided by the hospital staff in person or via telephone to the intended parent(s).
 - i. All consents for care/procedures will be signed by the intended parent(s).
- 3. Absence of Original Certified Judgement
 - a. Release of information regarding the child/children will be provided in person or via telephone to the surrogate whose ID bands match those of the child/children until the original certified judgement is present or written permission granted by the surrogate is present in the child/children chart.
 - i. The surrogate will sign all consents for care/procedures.

E. VISITATION:

- 1. Refer to WNS Policy: Visitation in NICU, PCS Policy: Visiting Guidelines, WNS Policy: Partners in Care for Women and Newborn Services

F. BIRTH CERTIFICATE:

- 1. The birth certificate(s) is filled out by the intended parent(s) in the presence of the original certified judgement.
- 2. The medical information in the birth certificate pertaining to the pregnancy and labor and delivery shall pertain to the surrogate.
 - a. For other surrogacy details regarding the birth certificate, refer to the San Diego County Vital Records and Statistics manual or call the vital records department.
- 3. An original certified copy of the judgement will be given to the birth clerk to attach to the birth certificate
 - a. For multi-fetal pregnancies, an original certified copy of the judgment must be attached to each child's birth certificate for submission to the county.

G. DISCHARGE:

- 1. Original certified copy of the judgement present:
 - a. Discharge must be cleared by admissions/financial counselor before the child/children are released from the hospital with the intended parent(s).
 - b. The discharge process for the unit will be followed
- 2. Absence of original certified copy of the judgement:

- a. The child/children will be discharged to the surrogate.
- b. Discharge must be cleared by admissions/financial counselor before the surrogate and the child/children may be released from the hospital.

H. FETAL/NEONATAL DEMISE:

1. Original certified copy of the judgement present:
 - a. The intended parent(s) will make any decisions needed and sign all paperwork.
2. Absence of original certified copy of the judgement:
 - a. The surrogate will make any decisions needed and sign all paperwork.

I. RELATED DOCUMENTS:

1. Administrative Compliance Policy: Disclosure of Protected Health Information (PHI) 8610-513
2. WNS NICU Policy: Visitation in the NICU
3. PCS Policy: Visiting Guidelines
4. WNS Policy: Partners in Care for Women and Newborn Services
5. PCS Procedure: Newborn Identification Banding and Electronic Alarm Device

J. REFERENCES:

1. California Consent Manual 2018

A. DEFINITIONS:

1. ~~Surrogate: A pregnant woman who has agreed to carry baby(ies) for another person(s).~~
2. ~~Intended/Legal Parent(s): Person(s) identified in a Judgment of maternity and paternity as the Intended/Legal Parent(s) with all parental rights.~~
3. ~~Judgment of Maternity and Paternity (herein after Judgment): A court order signed by a superior court judge with an official court seal that specifies the Intended/Legal Parent(s) of the baby(ies) born or to be born via a Surrogate and states that the Surrogate is not the Intended/Legal Parent(s). This document indicates the names that must be used on the birth certificate(s).~~
- a. ~~Note: If there is not a Judgment, the Surrogate will be given full custodial and legal rights and the baby(ies) (s) will be kept under the Surrogate's last name. The Surrogate will also sign all consents for herself and the baby(ies) if the Judgment has not been received by the hospital.~~

B. POLICY:

1. ~~Tri-City Medical Center (TCMC) Women and Newborn Services (WNS) including Neonatal Intensive Care Unit (NICU) provides comprehensive, quality, family-centered care within an interdisciplinary framework. Situations regarding the appropriate discharge of minors (e.g., newborns) may arise at any time.~~
2. ~~WNS personnel discharging baby(ies) within the context of a Surrogate and the Intended /Legal Parents parent(s) shall adhere to the following (including but not limited to):~~
 - a. ~~Tri-City Medical Center policies and procedures~~
 - b. ~~Governmental regulations and laws~~
 - c. ~~Court orders~~
3. ~~In all cases, the Judgment shall be used as a guide to determine who has legal authority for the newborn baby(ies).~~
4. ~~TCMC Social Services shall act as the primary contact and referral coordinator for the Surrogate and associated parties.~~
5. ~~Prior to admission when a Surrogate is identified she shall be referred to the hospital perinatal Social Worker(SW).~~

C. PROCEDURE:

1. ~~The SW shall:~~
 - a. ~~Request a copy of Judgment (faxed or mailed to the hospital) and instruct patient to bring original certified copy of Judgment to hospital upon admission for delivery or prior to discharge.~~

- b. ~~Notify Obstetrical (OB) Pre-admitting clerk of the surrogacy and provide any paperwork or information collected, including copy of the Judgment, when available.~~
 - c. ~~When available, place copy of Judgment in the Perinatal Watch List Book and in designated folder in SW office.~~
 - d. ~~Upon admission provide original certified copy of Judgment to Birth Clerk (when received).~~
 - e. ~~Ensure that copy of Judgment is on baby's(ies') chart(s).~~
 - 2. ~~The OB admission clerk shall:~~
 - a. ~~Provide the Surrogate with the surrogacy packet, this packet may include but is not limited to:~~
 - i. ~~Pre-registration form~~
 - ii. ~~Insurance information request (requiring photocopy of responsible party's insurance card(s))~~
 - iii. ~~The TCMC financial agreement for surrogate, Intended/Legal Parent(s) and Surrogacy Agency or Private Attorney (Refer to Financial Responsibility Agreement for Hospital Care Provided to Baby(ies) Born of Surrogacy Agreement and to a Surrogate Mother)~~
 - iv. ~~Request for copy of Judgment (all pages, may be faxed or sent as a photo copy), with instructions to bring the certified legal Judgment(s) to the hospital upon admission for delivery~~
 - b. ~~Provide copies of received completed, or required documents to the admitting clerk for creating the pre-admission record~~
 - c. ~~Provide identifying information, (i.e., Judgment) regarding the pregnancy and surrogacy arrangements to:~~
 - i. ~~The birth clerk~~
 - ii. ~~The OB admitting clerk~~
 - iii. ~~Labor and Delivery shall receive a copy of the Judgment to keep on a file in the Perinatal Watch List Binder~~
 - iv. ~~Social Worker (SW)~~
 - v. ~~Copies shall also be attached to the Surrogate and baby(ies) charts when admitted and newborn delivered~~
 - d. ~~Enter the pre-registration information into the system and shall scan all documents, including a copy of the received Judgment into the computer system during normal business hours. During other business hours the regular admissions office or during non-business hours the Emergency Department Clerk will be able to assist and act as the OB admitting clerk.~~
 - e. ~~Pre-verify all provided insurance information to ensure that it is an active account to ensure surrogacy is a covered benefit. Should additional financial arrangements be needed, admissions shall process them accordingly.~~
3. ~~The Patient Financial Information:~~
 - a. ~~The TCMC financial agreement for Surrogate, Intended/Legal Parent(s) and Surrogacy Agency or Private Attorney will be given to the Patient Financial Services by the person that pre-admits or admits the patient~~
 - b. ~~This information shall be forwarded to Patient Financial Services (PFS)/hospital financial counselor to ensure that the Intended/Legal Parent(s) have also signed the Conditions of Admission (COA)~~
 - c. ~~Insurance information for agreements that require the Surrogate couple to assume financial responsibility of hospital stay for mother (if applicable) and baby(ies), including NICU costs if applicable. In all cases, the Judgment shall be used as a guide to determine who has legal authority for the baby(ies).~~
 - d. ~~The hospital financial counselor(s) shall be alerted about the planned surrogacy and will contact the identified agency or private attorney and the Intended/Legal Parent(s) to discuss contractual obligations including base costs for all care for the Surrogate (if~~

- applicable) and the baby(ies) in the NICU if required. They will also be advised that the physician charges are not included in the hospital charges.
- e. ~~Admissions will pre-verify all insurance coverage to ensure surrogacy is a covered benefit. Should additional financial arrangements be needed, admissions will process them accordingly. They will forward this information to the hospital financial counselor (to ensure that the Intended/Legal parent(s) have also signed the COA).~~
 - f. ~~Upon delivery, the original certified copy of the Judgment will be given to the birth clerk for processing of the birth certificate. Copies shall also be attached to the Surrogate and the baby(ies) charts and the Perinatal Social Worker notified.~~
4. ~~The admitting Labor and Delivery RN/or Unit Secretary upon the Surrogate's admission for delivery shall:~~
- a. ~~Obtain the legal Judgment on file for the Surrogate and Intended/Legal Parent(s) in the Perinatal Watch List book, and place copies of the documents on the Surrogate and the baby(ies) charts~~
 - b. ~~Notify the OB admission clerk/or designee upon the arrival of the Surrogate for admission to labor and delivery, and then upon birth of baby(ies) for admission into the system~~
 - i. ~~The OB admission clerk/or designee shall contact Patient Financial Services (PFS) (extension 3160), who shall contact the insurance company of the Surrogate's admission and obtain authorization for hospital care for the Surrogate and the newborn baby(ies).~~
 - c. ~~Enter a Social Work referral in Cerner:~~
 - i. ~~This will initiate the process for a Social Worker evaluation for all parties involved in the Surrogate pregnancy after admission of surrogate~~
5. ~~Admitting/ID Banding: (Patient Care Services (PCS) Procedure: Identification of Newborns)~~
- a. ~~Signed or certified Judgment present:~~
 - i. ~~If there is a Judgment present at the time of birth, the baby(ies) shall be admitted by an admissions staff member under the Intended/Legal Parent's(s') last name. All of the four plastic bands will be printed per PCS Procedure: Identification of Newborns. This information shall include:~~
 - 1) ~~The last name, and first name of the legal parent identified on the legal Judgment as the legal mother~~
 - 2) ~~At the time of birth, include the sex of the newborn, date of birth and time of birth (24-hour clock) on all of the four bands~~
 - ii. ~~Separate and attach the set of four completed bands as follows: (Refer to PCS Procedure: Identification of Newborns). The two smaller bands will be applied to the newborn.~~
 - 1) ~~One large band will be placed on the Intended/Legal Mother's wrist or the Intended/Legal father's wrist if there is no legal mother.~~
 - 2) ~~The fourth (large) band labeled as above, will be placed on the other Intended/Legal Parent's(s') wrist (if applicable) or can be placed on the identified significant other's wrist per the discretion of the legal parent.~~
 - b. ~~Absence of signed or certified Judgment:~~
 - i. ~~If there is no Judgment present, the baby(ies) will be admitted under the Surrogate name and all bands will be made in that name. (Refer to PCS Procedure: Identification of Newborns)~~
 - 1) ~~The Intended/Legal Parent(s) will be banded with 1 of the adult baby(ies) bands containing the surrogate name.~~
 - ii. ~~When the Intended/Legal Parent(s) arrive with the signed Judgment papers:~~
 - 1) ~~Social Worker will verify the Judgment.~~
 - 2) ~~Unit Secretary will have baby(ies) name changed by main admission office utilizing a communication notice.~~

- a) ~~The name change will be corrected on the Medical Record hard chart documents~~
- b) ~~The name change will be reflected in the Electronic Health Record (EHR).~~
- c) ~~The main admissions office will update insurance and emergency contact information as needed.~~
- d) ~~Newborn identification bands will be made to reflect the name change. Refer to PCS Procedure: Identification of Newborns.~~
- e) ~~The Newborn Metabolic Screening form will be updated to reflect the name change utilizing the comment box.~~
- 3) ~~The Intended/Legal Parent(s) and baby(ies) will be banded with one ID band containing the surrogate name and the following information:~~
- 4) ~~Unit Secretary will have baby(ies) name changed utilizing the main admission office by utilizing a communication notice.~~
 - a) ~~The name change will be corrected on the Medical Record hard chart documents~~
 - b) ~~The name change will be reflected in the Electronic Health Record (EHR).~~
 - c) ~~The main admissions office will update insurance, patient data and emergency contact information as needed.~~
 - d) ~~Newborn identification bands will be made to reflect the name change. Refer to PCS Procedure: Identification of Newborns.~~
 - e) ~~The Newborn Metabolic Screening form will be updated to reflect the name change.~~

~~D. RELEASE OF INFORMATION/CONSENT: (Administrative Compliance Policy: Disclosure of Protected Health Information (PHI) 8610-513)~~

- 1. ~~Signed or certified Judgment present:~~
 - a. ~~Release of information regarding the baby(ies) will be provided by the hospital staff in person or via telephone to the Intended/Legal Parent(s). (All consents for care/procedures will be signed by the Intended/Legal Parent(s).)~~
- 2. ~~Absence of signed or Certified Judgment:~~
 - a. ~~Release of information regarding the baby(ies) will be provided in person or via telephone to the Surrogate whose ID bands match those of the baby(ies) only. The Intended/Legal Parent(s) will not receive any information regarding the baby(ies) until a Judgment is present or written permission granted by the Surrogate is present in the baby(ies) chart(s). The Surrogate will sign all consents for care/procedures.~~

~~F. VISITATION: (Reference WNS Policy: Visitation in NICU, PCS Policy: Visiting Guidelines, WNS Policy: Partners in Care for Women and Newborn Services)~~

~~G. BIRTH CERTIFICATE:~~

- 1. ~~If there is a Judgment present, the names of the Intended/Legal Parent(s) will be listed on the original birth certificate.~~
 - a. ~~A certified copy of the Judgment must be given to the birth clerk to attach to the birth statistics. For the multi-fetal pregnancy, an original certified copy of the Judgment must be attached to each baby's(ies') birth certificate for submission to the county.~~
 - b. ~~The birth certificate is filled out by the Intended/Legal Parent(s) according to the Judgment, although medical information in the birth certificate pertaining to the pregnancy and labor and delivery shall pertain to the Surrogate.~~
 - c. ~~For other surrogacy details regarding the birth certificate, refer to the San Diego County Vital Records and Statistics manual or call the vital records department.~~

H. ~~DISCHARGE:~~

1. ~~"Original Certified copy" Judgment present at TCMG~~
 - a. ~~Discharge must be cleared by admissions/PFS financial counselor (ext.3160) before the baby(ies) is released from the hospital with the Intended/Legal Parent(s).~~
 - b. ~~Discharge process for the unit will be followed.~~
2. ~~Absence of "Original Certified copy" Judgment~~
 - a. ~~Surrogate assumes care of infant when cleared for discharge.~~
 - b. ~~Surrogate must follow standard discharge procedures including discharge teaching.~~
 - c. ~~Discharge must be cleared by admissions/PFS financial counselor (ext.3160) before the Surrogate and the infant(s) can be released from the hospital.~~

I. ~~FETAL DEATH/DEMISE:~~

1. ~~Judgment present~~
 - a. ~~Intended/Legal Parent(s) will follow standard procedures for release of remains.~~
2. ~~Absence of Judgment~~
 - a. ~~Surrogate will follow standard procedures for release of remains.~~

J. ~~RELATED DOCUMENT(S):~~

1. ~~Administrative Compliance Policy: Disclosure of Protected Health Information (PHI) 8610-513~~
2. ~~WNS NICU Policy: Visitation in the NICU~~
3. ~~WNS Policy: Infant Feedings~~
4. ~~Patient Care Services Policy: Visiting Guidelines~~
5. ~~WNS Policy: Partners in Care for Women and Newborn Services~~
6. ~~PGS Procedure: Identification of Newborns~~

K. ~~REFERENCE(S):~~

1. ~~California Consent Manual 2018~~

WOMEN AND NEWBORN SERVICES POLICY MANUAL

ISSUE DATE: 10/94

SUBJECT: WNS Admission Registration
Policy

REVISION DATE: 1/00, 6/03, 6/06, 06/13, 09/16

Department Approval:	01/22
Department of OB/GYN Approval:	n/a
Department of Pediatrics Approval:	n/a
Pharmacy & Therapeutics Committee Approval:	n/a
Medical Executive Committee Approval:	n/a
Administration Approval:	04/22
Professional Affairs Committee Approval:	09/16 n/a
Board of Directors Approval:	09/16

A. PURPOSE: To provide guidelines for the WNS staff, ensuring a consistent process for the registration and admission of patients to WNS.

A.

B. POLICY:

1. ~~Preadmission:~~ Any obstetrical (OB) patient who has sent pre-admission forms to Tri-City Medical Center (TCMC) will have a pre-admission number issued by the admitting/registration department for anticipated vaginal birth.
 - a. The pre-admission number will be used when the patient arrives to the Labor and Delivery (L&D) unit for evaluation or direct admission.
 - b. The pre-admission number will not be used for outpatient antepartum testing such as scheduled non-stress test or preop education visits.
2. Patients scheduled for a cesarean section (C-Section) will have a pre-admission number assigned to them by the L&D Unit Secretary or person scheduling the case.
 - a. The pre-admission number will be used when the patient comes in for her pre-operative teaching and laboratory work visit.
 - b. The pre-admission number will be activated when the patient arrives on her scheduled surgery date.
3. Patients who have not pre-registered for delivery at TCMC: the unit secretary will use the OB Quick Registration option in Cerner to search for her in the electronic health system.
 - a. If she has been a patient at TCMC then a new account number (FIN) will be assigned for that visit.
 - b. If she has never been a patient at TCMC then a medical record number (MRN) and FIN will be assigned.
4. At the time of patient check-in, the unit secretary will print a patient face sheet and verify the patient demographics.
 - a. Patients who have never been a patient at TCMC before or need to have information updated will complete a registration form.
 - i. The unit secretary will fax the registration form, a copy of the patient's insurance and identification cards (if available) to the registration department.
5. The unit secretary will have the patient sign the conditions of admission (COA) form electronically and place a patient identification bracelet on the patient's wrist.
6. When the patient is discharged without being admitted the paper work associated to the visit should be returned to the unit secretary for disassembly and the unit secretary will discharge the visit in the electronic health system.

7. When the patient is admitted the unit secretary will send a communication notice, in the electronic health system, to registration with the admission information.
 - a. The secretary will then prepare the patient chart for admission
8. Newborns will be issued an MRN and FIN after delivery, through the mother's record, which will connect the records.
 - a. The unit secretary will verify the name of pediatrician, gender and time of birth with the primary registered nurse (RN) reporting the information.
 - b. The unit secretary will send a communication notice, in the electronic system to registration with the admission information on all newborns delivered at TCMC.
 - c. See Assignment of Medical Record Numbers and Standard Naming Guidelines policy for naming of newborns.
 - d. The unit secretary will then print the infant identification bands, adult bands, face sheet, and patient labels.
 - i. Newborn identification bands will be verified per the Newborn Identification Banding and Electronic Alarm Device policy.
 - e. For newborns delivered by a surrogate see the Surrogacy policy for registration information,
 - f. See the Adoption policy for registration of newborns being adopted.

C. RELATED DOCUMENTS:

1. Admissions Criteria Policy
2. Adoption Policy
3. Assignment of Medical Record Numbers and Standard Naming Guidelines Policy
4. Cerner Downtime Policy
5. Newborn Identification Banding and Electronic Alarm Device
6. Surrogacy Policy

1. _____

C. ADMISSION TO LABOR AND DELIVERY:

1. ~~All patients who have sent pre-admission forms to Tri-City Medical Center will have a pre-admit number issued by the admitting/registration department for anticipated vaginal birth.~~
 - a. ~~Unit secretaries will use the pre-admit number when the patient comes to the L&D unit to be evaluated regardless of the reason for the visit.~~
2. ~~Patient's scheduled for Cesarean Section will have a pre-admission number assigned to them by the surgery scheduling center.~~
 - a. ~~Do not use this account until the patient comes in for pre-operative laboratory work.~~

D. ADMISSION TO A (LABOR-DELIVERY-RECOVERY LDR) ROOM:

1. ~~The patient will be given an account number for this visit and if a medical record number is needed because the patient has not been pre-admitted, the unit secretary will use the OB quick registration option in Cerner.~~
2. ~~Patients who do not have updated information in the computer will be asked to complete a registration form and provide the unit secretary her insurance and identification card, if available.~~
 - a. ~~Copies of registration information and the cards shall be made and faxed to the appropriate department depending on these days and times:~~
 - i. ~~Registration notices are sent to the main hospital registration/ admitting department Monday – Friday from 0500-1800 and Saturday from 0730-1600.~~
 - ii. ~~Registration notices are sent to the Emergency Department (ED) Monday – Thursday 1800-0500, Friday 1800-0730 and Saturday – Monday from 1600-0500.~~
 - iii. ~~The main hospital registration is closed on Sundays.~~
3. ~~The unit secretary will have the patient sign, date and time the conditions of admission (COA):~~
 - a. ~~For herself and her infant(s).~~
 - i. ~~In the event of anticipated multiple deliveries, (e.g. twins), the mother is required to sign a COA for each infant.~~
4. ~~Obstetrical outpatient visits/ evaluation~~

- a. ~~The patient is assigned an account number by the unit secretary for each visit and if the patient is admitted this will continue to be her account number.~~
 - b. ~~When the patient is discharged the paperwork should be returned to the unit secretary for coding and disassembly. Paperwork should include:~~
 - i. ~~Her signed conditions of admission~~
 - ii. ~~Her face sheet~~
 - iii. ~~Completed charge slip and visit classification~~
 - iv. ~~Prenatal record, if obtained, can be refiled for next visit~~
 - c. ~~If the patient returns for evaluation at another time, a new account number for the most current visit will need to be issued.~~
5. ~~Obstetrical Admissions:~~
- a. ~~Send the completed registration notice to the appropriate department~~
 - b. ~~Unit secretary will ready the patient's chart for admission and include applicable consents as indicated, prenatal record, signed, dated, and timed COAs.~~
 - i. ~~Update the chart with allergies and any other pertinent information.~~
6. ~~Newborn Admission:~~
- a. ~~When the infant is born, the infant will be issued a medical record number and account number through the mom's record, which can connect the records.~~
 - b. ~~The Unit Secretary will verify that the name of the pediatrician/neonatologist assigned to the family, gender of the baby and birth time.~~
 - i. ~~For multiples, the use of Baby A, B or C should be used to register each baby separately.~~
 - c. ~~The unit secretary shall print up the infant identification bands, face sheet, patient labels and give them to the primary nurse for review and verification.~~
 - d. ~~The notice of admission/registration will be sent to appropriate department.~~

WOMEN AND NEWBORN SERVICES (WNS)

ISSUE DATE: NEW-05/15

SUBJECT: Women and Newborn Services
(WNS) Disaster Response Plan

REVISION DATE(S):

Women and Newborn Services Department Approval-Date(s): 11/2102/15
Department of OB/GYN Approval-Date(s): n/a
Department of Pediatrics Approval-Date(s): n/a
Pharmacy and Therapeutics Approval-Date(s): n/a
Medical Executive Committee Approval-Date(s): n/a
Administration Approval: 04/22
Professional Affairs Committee Approval-Date(s): 05/15 n/a
Board of Directors Approval-Date(s): 05/15

A. DEFINITION:

- ~~1. HICS Hospital Emergency Incident Command System Contains standard operating procedures that direct the hospital's response to various disaster events.~~

A. POLICY:

- Refer to Disaster Plan Activation Hospital Wide Policy (#4071) and Emergency Operations Procedure Manual for additional information.
- The Obstetrical (OB) Operating Rooms (OR) and Post-Anesthesia Care Unit (PACU) may be utilized by the main operating room personnel and other surgical specialties during the disaster event.
- The incident commander will issue the order for evacuation, if necessary.
- If an area of WNS is in immediate danger the WNS Leadership Team or designee may initiate and direct evacuation in coordination with the OB providers on call.

B.5. Patients will be triaged for evacuation utilizing the "Obstetric Triage by Resource Allocation for Inpatient" (OB TRAIN) Model.

- ~~1. Due to the varying types and magnitudes of emergency events, Tri-City Medical Center (TCMC) has adopted the HICS system to help direct and manage disaster response. Depending on the extent of the event, Women's and Newborn's Services (WNS) will continue to provide care to those patients already admitted and would be expected to continue to evaluate obstetrical patients with clinical needs during the disaster.~~
- ~~2. All scheduled procedures to include surgeries, inductions and/or outpatient testing will be evaluated based on medical need and canceled, as appropriate.~~
- ~~3. The operating rooms and recovery area in the WNS may be utilized by the main operating room personnel and other surgical specialties during the disaster event, if a surge in surgical services is anticipated.~~
- ~~4. In order to anticipate patient surges and/or staffing requirements house wide, the WNS leadership team in collaboration with the Chairman of the Obstetrics Department and the Chairman of the Pediatrics Departments may need to review patients eligible for early discharge, as directed by the HICS Command Center~~

- ~~5. All visitors should be asked to leave, if possible.~~

B. PROCEDURE:

- The WNS Leadership Team (or designee) shall:
 - Send a representative to the incident command center.
 - Initiate the disaster call list.

- c. **Review Mothers and Newborns with the OB provider and Pediatrician (on shift) to determine if any patients can be discharged home.**
 - i. **Any unstable newborns will be transferred to the Neonatal Intensive Care Unit (NICU).**
 - ii. **Stable newborns, if approved, will be discharged home with the mother or a designated support person with enough supplies for 24 hours.**
- d. **Determine evacuation order in conjunction with the OB provider on shift per OB TRAIN model and evacuate to designated area.**
 - i. **Evacuation Order:**
 - 1) **Blue Bands- evacuate and discharge home as appropriate. Stable newborns may be transported in mothers' arms.**
 - 2) **Green Bands- evacuate and transport to another facility via ambulance (BLS).**
 - 3) **Yellow Bands- evacuate and transport to another facility via ambulance (ALS).**
 - 4) **Red Bands- evacuate and transport to another facility via ambulance (ALS).**
 - a) **Must be accompanied by an OB Physician or LD Registered Nurse (RN).**
 - 5) **Yellow and Red Bands should be evacuated last but transferred to another facility first when possible.**
 - 6) **Injured staff is to be evacuated with the first evacuated patient.**
 - 7) **All patients with an epidural who are being evacuated/transferred will have the catheter capped off.**
 - ii. **Utilize the evacuation routes designated in the hospital disaster plan to evacuate.**
 - 1) **Mothers that are not able to ambulate will be evacuated via stair chair.**
 - 2) **Newborns that are not in the mothers' arms may be placed in the apron for transport.**
- G.e. **Designate Roles:**
- 1. **NOTIFICATION:**
 - a. ~~The Department will be notified of the disaster plan activation from the Private Branch Exchange (PBX) operator, who will announce "CODE ORANGE" using the overhead paging system.~~
 - b. ~~The Director of WNS (or designee) shall report to the HICS Command Center located in French Room number 1, to receive information about the disaster and directions from the Incident Commander.~~
 - i. **RESPONSIBILITIES: Manager/Charge Nurse/Designee:**
 - 1) **Remain on the unit to manage the current patient census, staffing needs, plan for possible patient influx and/or patient evacuation.**
 - 2) **Count and submit an accurate unit census and immediate bed availability to the Incident Command Center**
 - 3) **Utilize the OB-TRAIN model to prioritize transport based on acuity of care, if indicated.**
 - 4) **Collaborate with the OB provider on call and Pediatrician on call to determine the order of evacuation based on patient acuity status.**
 - 5) **Determine what procedures need to be canceled or redirected to another department or facility per OB provider on call guidance**
 - 6) **Assign duties to unit staff as necessary**
 - ii. **Primary Nurse:**
 - 1) **Remain on the unit to manage patient care and other duties assigned to them by the Manager/Charge Nurse/Designee.**
 - 2) **Report status/acuity of patient assignment using the OB-TRAIN model to the Manager/Charge Nurse/Designee.**

- 3) Prepare patient for possible discharge home, transfer to another department, or evacuation to a different facility
 - a) Print Medical Record, including prenatal record and lab results
 - b) Collect enough supplies for 24 hours, if the patient is being discharged home
 - c) Emergency medications or supplies, for transfer or evacuation
 - 4) Phone triage of OB patients
 - 5) Assist with triage/admission/delivery of OB patients as they arrive to the unit
 - iii. OB Surgical Technician:
 - 1) Remain on unit to assist with care coordination, supply acquisition and patient transport.
 - 2) Assist the Primary Nurse with preparation for discharge, transfer or evacuation of patients
 - 3) Assist the Primary Nurse with admissions and preparation for delivery
 - 4) Provide surgical support to the Main Operating Room
 - iv. Acute Care Technician:
 - 1) Remain on the unit to assist the Primary Nurse with patient care, transfers, discharges, and evacuation
 - 2) Supply acquisition for patients as directed by the Primary Nurse
 - 3) Assist with answering phone calls
 - 4) Act as a runner for communication updates, supplies, etc.
 - 5) Provide patient care support to other departments in the hospital if necessary
 - v. Unit Secretary:
 - 1) Remain on the unit and begin "Call Back" process as directed by the WNS Leadership Team/designee.
 - 2) Keep track of patient flow: admissions to the unit, transfers, transports, and discharges
 - 3) Answer phone calls and provide information as directed from the Manager/Charge RN/Designee
 - f. Do not use elevators for evacuation unless authorized by on-the-scene Fire Department personnel.
 - g. Remain at designated evacuation site and do not return to the evacuated area unless ordered to do so by the incident commander.
 - h. Assess and stabilize mothers and newborns as soon as they reach the evacuation site.
 - i. Arrange transportation to other hospitals if needed.
 - j. Reassure all patients and visitors that the emergency plan is in operation and not to be alarmed.
 2. In the event of a power failure or medical gas failure:
 - a. Notify Bio Engineering, Respiratory Care Department, and the OB provider on call at the first indication of problems.
 - b. Use flashlights located in the Emergency Box for a power failure.
 - c. Make sure all necessary equipment is plugged into a red outlet.
 - d. Obtain Vital Signs manually if needed.
 - e. Obtain Fetal Heart Tones via the hand held doppler or fetoscope using intermittent fetal monitoring, if unable to use electronic fetal monitoring.

C. DOCUMENTATION:

1. Patient documentation per downtime protocol.

D. RELATED DOCUMENTS:

- 2-1. The "Obstetric Triage by Resource Allocation for Inpatient" Model

- a. ~~WNS Director/designee~~ Depending on the type of disaster anticipated, the ~~director/designee~~ may be:
 - i. ~~Given an assignment as a HICS Leadership role~~
 - ii. ~~Asked to implement the department staffing "Call Back" process to determine available staffing resources~~
 - iii. ~~Asked to notify the Chairman of the Obstetrics (OB) Department and the Chariman of the Pediatrics Departments to discuss discharge coordination of eligible patients, potential staffing challenges, clinical challenges, and evacuation possibilities.~~
 - iv. ~~Required to communicate updates to their departments~~
 - b. ~~Assistant Nurse Managers (ANM) / Charge Nurses~~ shall remain on the units to manage the current patient census, staffing needs, plan for possible patient influx and/or patient evacuation requirements. Additional duties can include:
 - i. ~~Assigning a staff member to report to the Incident Command Center to obtain information about what is expected.~~
 - ii. ~~Counting and submitting accurate unit census and immediate bed availability to the Incident Command Center as requested.~~
 - iii. ~~Starting to evaluate patients who may be eligible for early discharge and discussing options with the Department Chairmaen, as indicated~~
 - iv. ~~Canceling all scheduled procedures and outpatient testing if medically possible.~~
 - v. ~~Determining staffing requirements and reassigning personnel to the labor pool, as appropriate.~~
 - vi. ~~Collaborating with the OB Department Chairman and Pediatric Department Chairmen to determine the order of evacuation based on patient acuity status.~~
 - 1) ~~Usually the most stable patients (able to ambulate), are moved first, followed by those needing a little bit of assistance and the final group is the most critical, requiring high assistance.~~
 - vii. ~~Assigning the Obstetrical Surgical Technicians, and/or Acute Care Technicians, and/or Peri-operative Aides to gather required supplies for evacuation, as indicted.~~
 - viii. ~~Obtaining disaster supply containers for evacuation possibility.~~
 - c. ~~Primary Nurses~~ shall remain on the unit to manage patient assignments and, care coordination, and assist the ~~Manager/ANM/Charge nurse/delegee~~ to determine which patients may be eligible for discharge. Additional duties can include:
 - i. ~~Assisting with routine patient assessments, monitoring, admissions and discharges teaching needs.~~
 - ii. ~~Helping to ready patients for evacuation, as indicated.~~
 - iii. ~~Collaborating with ANM/ Manager/Charge Nurse/delegee about equipment and medication needs for patients being evacuated~~
 - iv. ~~Reporting to the labor pool for reassignment of duties, as directed~~
 - d. ~~OB Surgical Technicians~~ shall remain on the unit to assist with care coordination, supply acquisition and patient transport, if evacuated. Other duties ~~may~~ can include:
 - i. ~~Providing surgical support to the Main Operating Room, if requested~~
 - ii. ~~Gathering supplies and disaster management supply containerstub if evacuation is suspected.~~
 - iii. ~~Helping to evacuate patients to an identified location, as directed~~
 - iv. ~~Acting as a runner for communication updates, supplies, etc...~~
 - v. ~~Assisting the nurses, as directed.~~
 - e. ~~Unit Secretaries~~ shall begin "Call Back" process if directed, and these other duties:
 - i. ~~Keeping track of patient flow: admissions to the unit, transfers, transports and discharges.~~
 - ii. ~~ACTs as a runner for communication if needed.~~
 - f. ~~Other Staff~~ shall assume duties as assigned by the ~~Manager/ANM/ Charge nurse/delegee.~~
3. **EVACUATION CONSIDERATIONS:**
- a. Patient evacuations shall be determined by the Incident Command Center.

- Ideally, the most stable patients (ambulatory) should be considered first. The WNS evacuation procedure would follow the Disaster Manual recommendations.
- **Stable patients may include, but are not limited to:**
 - ~~Postpartum patients and their newborns (Infants may be transported in their mothers' arms while being moved to the evacuation area or if being discharged home). All the items in the infant crib and maternal belongings needed for 24 hours will be sent with her.~~
 - ~~Mothers that are not ambulatory will be evacuated via wheel chair/stair chair to their car with family/significant other~~
 - ~~Baby will evacuate with the mother if stable.~~
 - **Low Risk labor patients without regional anesthesia.**
 - ~~All patients in a regular contraction pattern will remain in the hospital and later evacuated once she is stable for discharge (with the infant in her arms if stable).~~
 - ~~A patient being induced or augmented with an Oxytocin drip will have the drip discontinued. If not having regular contractions or not dilated 4-6 centimeters she may be sent home if possible.~~
- **Unstable patients may include**
 - ~~Any unstable infants will be transferred to NICU to follow their evacuation plan.~~
 - ~~A mother on Magnesium Sulfate that is unstable for evacuation will remain in the hospital with staff until they are stable for evacuation.~~
 - ~~If needed, the command center would direct where the patient needs to be transported to via ambulance or critical care transport. The stable infant will stay with the mother if possible, but could be sent home with other family/significant other(s).~~
- ~~All patients for a planned Cesarean section (C/S) or induction would be cancelled.~~
 - ~~If delivery is medically necessary, the command center will dictate where the patient should go~~
- ~~All fresh C/S patients that are in the Operating Room or Recovery Room will remain in the hospital until they have become stabilized and ambulatory. The baby will stay with the mother if stable and then discharged in her arms.~~
- ~~A patient that has an epidural will remain in the hospital for delivery until stabilized for discharge with the infant in her arms, unless it is deemed that a transport to another facility is needed. In that case the Labor and Delivery RN would remain with the patient in route for labor support and delivery if it occurs.~~
 - ~~If transport is needed, the epidural will be capped off and her IV saline locked. She will be moved via gurney or bed to ambulance or critical care transport~~
- b. —— **Stable patients may include, but are not limited to:**
 - ~~Postpartum patients and their newborns (Infants may be transported in their mothers' arms while being moved to the evacuation area or if being discharged home). All the items in the infant crib and maternal belongings needed for 24 hours will be sent with her.~~
 - ~~Mothers that are not ambulatory will be evacuated via a wheel chair and the stair chair via the stairs to their car location with family/significant other and the baby will evacuate with the mother if stable.~~
 - ~~Any unstable infants will be transferred to NICU to follow their evacuation plan.~~
 - ~~A mother on Magnesium Sulfate that is unstable for evacuation will remain in the hospital with staff until they are stable for evacuation.~~
 - ~~If needed the command center would direct where the patient would need to be transported to via ambulance or critical care transport (possibly with RN if needed).~~

- i. ~~The stable infant will stay with the mother if possible, but could be sent home with other family/significant other(s).~~
- ~~Low Risk labor patients without regional anesthesia.~~
 - ~~All patients in a regular contraction pattern will remain in the hospital with the RN for delivery and later evacuated once she is stable for discharge (with the infant in her arms if stable).~~
- ~~A patient being induced or augmented with an Oxytocin drip will have the drip discontinued. If not having regular contractions, not dilated 4-6 centimeters she may be sent home if possible.~~
 - ~~All patients in a regular contraction pattern will remain in the hospital with the RN for delivery and later evacuated once she is stable for discharge (with the infant in her arms if stable).~~
- ~~All patients for a planned Cesarean section or induction would be cancelled.~~
 - ~~If medical necessity for delivery is indicated, the command center will direct staff where the patient should go for delivery.~~
- ~~All fresh Cesarean Section patients that are in the Operating Room or Recovery Room will remain in the hospital until they have become stabilized and ambulatory. The baby will stay with the mother if stable and then discharged in her arms.~~
 - ~~If needed the command center will direct where the patient needs to be transported via ambulance or critical care transport (with an RN if needed),~~
- ~~A patient that does have an epidural will also need to remain in the hospital for delivery until stabilized for discharge with the infant in her arms, unless it is deemed that a transport to another facility is needed. In that case the Labor and Delivery RN would remain with the patient in route for labor support and delivery if it occurs.~~
- ii. ~~If the transport is needed, the epidural will be capped off and her IV saline locked. If non-ambulatory she will be moved via gurney or bed for ambulance or critical care transport (with an RN if needed).~~
- iii. ~~High Risk patients/higher acuity status may require more equipment, supplies, and personnel to assist with evacuation and would be moved last.~~
- iv. ~~Permanent transport to a higher level of care via ambulance coordination would need to be arranged per Patient Care Services policies and/or the Incident Command Center.~~

D. RELATED DOCUMENT(S):

- 1. ~~Hospital Emergency Preparedness Management, Emergency Operations Plan Policy # 4001, Safety Policies and Procedures~~
- 2. ~~Evacuation Plan, Policy #7010-4004 Emergency Management Manual~~

E. REFERENCES:

- 1. Hospital disaster preparedness for obstetricians and facilities providing maternity care. Committee Opinion No. 726. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017; 130:291-7.
- 4.2. Hospital Incident Command System (HICS), San Mateo County Health Services Agency, Emergency Medical Services
- 3. Simpson, K.R.K. R, and Creehan, P.A. (2020/44), Perinatal Nursing (45th-Ed.). Philadelphia). Philadelphia, Lippincott Williams and Wilkins

Table 1. The “Obstetric Triage by Resource Allocation for Inpatient”^{*} Model ↵

Transport	Car (Discharge), Blue	Basic Life Support (Ambulance), Green	Advanced Life Support (Ambulance), Yellow	Specialized, [†] Red
Labor status	None	Early	Active	At risk for en route delivery
Mobility	Ambulatory [‡]	Ambulatory or nonambulatory	Nonambulatory	Nonambulatory
Epidural status	None	Placement greater than 1 h [§]	Placement less than 1 h [§]	Not applicable
Maternal or fetal risk	Low	Low or moderate	Moderate or high	High

^{*}OB TRAIN, Obstetric Triage by Resource Allocation for Inpatient

[†]Must be accompanied by physician or transport registered nurse

[‡]Modified Bromage scale 6=patient is able to perform a partial knee bend from standing

[§]Epidural catheter capped off

Reprinted from Daniels K, Oakeson AM, Hilton G. Steps toward a national disaster plan for obstetrics. *Obstet Gynecol* 2014;124:154–8.

2. _____

3. _____ ~~The Joint Commission (2014). 2015 Hospital Accreditation Standards. Washington, D.C, The Joint Commission~~

~~ADD UPDATED REFERENCES from Article list~~

**TRI-CITY HEALTHCARE DISTRICT
MINUTES FOR A REGULAR MEETING
OF THE BOARD OF DIRECTORS
March 31, 2022 – 3:30 o'clock p.m.
Meeting Held via Teleconference**

A Regular Meeting of the Board of Directors of Tri-City Healthcare District was held via teleconference at 3:30 p.m. on March 31, 2022.

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

Director Rocky J. Chavez
Director Nina Chaya, M.D.
Director George W. Coulter
Director Gigi Gleason
Director Marvin Mizell
Director Adela Sanchez
Director Tracy M. Younger

Also present were:

Steven Dietlin, Chief Executive Officer
Candice Parras, Chief, Patient Care Services
Ray Rivas, Chief Financial Officer
Aaron Byzak, Chief External Affairs Officer
Dr. Gene Ma, Chief Medical Officer
Jennifer Paroly, Foundation President
Anna Aguilar, Vice President, Human Resources
Jeremy Raimo, SVP, Business Development
Susan Bond, General Counsel
Dr. Jamie Johnson, Chief of Staff
Jeffrey Scott, Board Counsel
Teri Donnellan, Executive Assistant

1. The Board Chairperson, Rocky J. Chavez, called the meeting to order at 3:30 p.m. with attendance as listed above.

2. Approval of Agenda

**It was moved by Director Gleason to approve the agenda as presented.
Director Younger seconded the motion. The motion passed unanimously (7-0).**

3. Pledge of Allegiance

Director Chavez led the Pledge of Allegiance.

4. Public Comments – Announcement

Chairperson Chavez read the Public Comments section listed on the March 31, 2022 Regular Board of Directors Meeting Agenda.

5. February, 2022 Financial Statements – Ray Rivas, Chief Financial Officer

Mr. Rivas, Chief Financial Officer reported on the fiscal year to date financials as follows (Dollars in Thousands):

- Net Operating Revenue – \$228,706
- Operating Expense - \$241,602
- EBITDA - \$2,398
- EROE (\$6,207)

Mr. Rivas reported on the fiscal year to date Key Indicators as follows:

- Average Daily Census – 161
- Adjusted Patient Days – 74,852
- Surgery Cases – 4,36
- ED Visits – 33,041

Mr. Rivas also reported on the current month financials as follows (Dollars in Thousands):

- Net Operating Revenue – \$29,031
- Operating Expense - \$29,510
- EBITDA – \$1,343
- EROE – \$275

Mr. Rivas reported on the current month Key Indicators as follows:

- Average Daily Census – 191
- Adjusted Patient Days – 9,552
- Surgery Cases – 510
- ED Visits – 3,664

6. New Business – None

7. Old Business

- (a) Presentation by National Demographics Corporation on the Redistricting process and minimal change map and Zone Boundaries.

Ms. Kay Vinson, Consultant for National Demographics Corporation presented the second presentation related to the Redistricting Process which included information from her initial presentation that explained why Redistricting is Necessary, the Role of the Board during the Redistricting Process, the Goals and Objectives, as well as the Demographics Summary for the existing zones and the proposed zones, the Current Zone Map and Minimal Change Map. She explained the ideal zone size must contain approximately 57,596 people. The minimal change map reflects a 6.89 deviation solely within Zones 6 and 7.

- (b) Public Hearing to receive input from the public on the proposed minimum change map and Zone Boundaries

At the conclusion of Ms. Vinson's presentation Chairperson Chavez opened the public hearing to receive input related to the proposed minimal change map and zone boundaries.

Director Sanchez relayed a question from a constituent who questioned why the District is not divided by specific cities (Vista, Oceanside and Carlsbad) rather than zones within the cities. Chairperson Chavez explained our District comprises the three cities of Vista, Oceanside and Carlsbad, however we need to use criteria from the federal government and the State of California wherein each zone must contain approximately 57,596 people and in 2018 the District was mandated to divide the cities into zones to accommodate the population criteria.

- (c) Board discussion on the proposed minimal change map and Zone Boundaries and Consideration of Resolution No. 811 in compliance with the Decennial Redistricting Requirements

Hearing no further comments or questions, Board Chairperson Chavez called for the motion to approve Resolution No. 811 in compliance with the Decennial Redistricting Requirements.

It was moved by Director Gleason that the Tri-City Healthcare District Board of Directors approve Resolution No. 811, a Resolution of the Tri-City Healthcare District Complying with the Decennial Redistricting Requirement. Director Sanchez seconded the motion.

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

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

8. Chief of Staff

- a) Consideration of the March 2022 Credentialing Actions Involving the Medical Staff and as recommended by the Medical Executive Committee on March 28, 2022.

Dr. Johnson presented the Medical Staff Credentials which included nine Initial Appointments, three of which are ICU physicians; 11 Reappointments, 12 Resignations and one Reinstatement.

It was moved by Director Gleason to approve the March 2022 Credentialing Actions Involving the Medical Staff as recommended by the Medical Executive Committee on March 28, 2022. Director Younger seconded the motion.

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

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

9. Consideration of Consent Calendar

Chairperson Chavez called attention to the initiatives on the Consent Calendar that strategically align with Tri-City's mission.

It was moved by Director Mizell to approve the Consent Calendar as presented. Director Sanchez seconded the motion.

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

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

10. Discussion of items pulled from Consent Calendar

There were no items pulled from the Consent Calendar.

11. Comments by Members of the Public

There were no comments by members of the public.

12. Comments by Chief Executive Officer

Mr. Steve Dietlin, CEO reported Tri-City currently has 8 COVID positive inpatients, the lowest number yet during this surge compared to 75 at its height. The county is currently reporting 133 COVID positives compared to 1,400 at its height. Mr. Dietlin stated Tri-City has treated almost 1,500 COVID positive inpatients since the pandemic began. He does not anticipate our COVID positive number going down to zero in quite some time as there is a new variant that is increasing in the waste water. He also noted acuity remains high.

Mr. Dietlin reported we are moving forward with the county on the 16- bed standalone inpatient psych facility pending a date from the Oceanside Planning Commission. A ground breaking is anticipated in the coming months. Mr. Dietlin stated the new psych facility will change the model for Behavioral Health in the community along with the Crisis Stabilization centers.

Mr. Dietlin reported CDPH has given Tri-City the "green light" to move forward with the ED remodel project which is largely funded by the Foundation and Foundation partners.

Mr. Dietlin reported the Board approved a four-year successor sustainable contract with the California Nurse's Association (CNA) and he is pleased to have the Board's support.

Mr. Dietlin reported last week the Board approved the formation of a 1206(b) clinic for OB/GYN which will enhance our services and commitment to that service line.

Mr. Dietlin reported this week is National Physician's week. The Tri-City Medical Staff is over 500 members strong and have been here for over 60 years and providing great care. Mr. Dietlin recognized the physicians for their exemplary service and unwavering commitment, particularly throughout the pandemic. He also recognized our physicians, Dr. Nina Chaya, Dr. Jamie Johnson and Dr. Gene Ma who are all valued physicians in our community.

13. Board Communications

Director Chaya thanked Mr. Dietlin for his kind words. She stated she wanted to honor our Medical Staff as they are a driving force that bring our patients here and the cutting-edge procedures performed here are a testament of the skill of our physicians. Director Chaya stated the physicians greatly appreciated being recognized.

Director Mizell commented on how much he appreciates all that the physicians and nurses do at Tri-City Medical Center, especially during this pandemic.

Director Sanchez expressed her appreciation to all the physicians but particularly those who she has had the privilege of working with and the care they have provided to both her and her family, personally.

Director Sanchez thanked Mr. Dietlin for the great update and keeping the Board informed of the status of the projects moving forward as well as our achievements. She stated it is a privilege to serve on the Board during this time.

Director Gleason expressed her gratitude to Dr. Chaya, Dr. Johnson and Dr. Ma as well as all physicians at Tri-City Medical for their dedication.

Director Gleason stated she is looking forward to breaking ground on the 16-bed psych facility as well as the Emergency Department remodel. Both projects will be great for our community.

Director Coulter extended his deepest appreciation to all of our fine physicians.

Director Younger expressed how ecstatic she is that administration was able to avoid a strike and negotiate a four-year sustainable agreement with CNA.

Director Younger also extended her best wishes to all the physicians in celebration of Physician's Week.

14. Report from Chairperson

Chairperson Chavez echoed comments from fellow Board members.

Chairperson Chavez highlighted a couple of upcoming events: 1) the Carlsbad Village Street Fair on May 1st; and 2) the Foundation Golf Event on June 13th. Chairperson Chavez requested that the Foundation send information to Board members regarding the Golf event and he encouraged Board members to reach out to any business entities within their zones who may be interested in a sponsorship at the golf event.

15. Move to adjourn

It was moved by Director Mizell and seconded by Director Coulter to adjourn the meeting. The motion passed unanimously (7-0).

16. There being no further business Chairperson Chavez adjourned the meeting at 4:10 p.m.

Rocky J. Chavez, Chairperson

ATTEST:

Gigi Gleason, Secretary



Financial Information

TCMC Days in Accounts Receivable (A/R)

	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	C/M YTD Avg	Goal Range
FY22	63.3	63.8	64.7	68.2	65.6	67.0	73.8	73.6	71.7				68.0	48-52
FY21	51.1	50.9	52.7	50.7	50.9	50.7	55.4	54.6	50.9	53.0	62.4	60.9	52.0	

TCMC Days in Accounts Payable (A/P)

	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	C/M YTD Avg	Goal Range
FY22	102.6	96.5	99.7	93.7	95.8	94.8	92.0	92.3	90.2				95.3	75-100
FY21	107.1	103.1	101.1	99.6	99.6	92.7	93.9	94.6	94.0	100.5	103.5	98.1	98.4	

TCHD EROE \$ in Thousands (Excess Revenue over Expenses)

	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	C/M YTD	C/M YTD Budget
FY22	(\$900)	(\$1,011)	(\$733)	\$132	(\$1,441)	(\$1,358)	(\$1,172)	\$275	(\$2,318)				(\$8,525)	(\$2,956)
FY21	(\$1,489)	(\$923)	(\$930)	\$508	(\$175)	(\$881)	\$1,109	(\$245)	\$210	(\$554)	\$4,682	\$4,774	(\$2,817)	

TCHD EROE % of Total Operating Revenue

	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	C/M YTD	C/M YTD Budget
FY22	-3.24%	-3.67%	-2.55%	0.43%	-5.23%	-4.87%	-3.99%	0.95%	-7.66%				-3.29%	-1.18%
FY21	-6.12%	-3.74%	-3.60%	1.78%	-0.64%	-3.12%	4.13%	-0.92%	0.73%	-1.89%	14.69%	15.52%	-1.17%	



Financial Information

TCHD EBITDA \$ in Thousands (Earnings before Interest, Taxes, Depreciation and Amortization)

	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	C/M YTD	C/M YTD Budget
FY22	\$190	\$76	\$340	\$1,190	(\$359)	(\$277)	(\$105)	\$1,343	(\$1,264)				\$1,134	\$7,642
FY21	(\$191)	\$291	\$302	\$1,738	\$879	\$332	\$2,344	\$935	\$1,383	\$422	\$5,782	\$5,855	\$8,014	

TCHD EBITDA % of Total Operating Revenue

	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	C/M YTD	C/M YTD Budget
FY22	0.69%	0.28%	1.19%	3.85%	-1.30%	-1.00%	-0.36%	4.63%	-4.18%				0.44%	3.05%
FY21	-0.78%	1.18%	1.17%	6.09%	3.22%	1.18%	8.73%	3.50%	4.79%	1.44%	18.14%	19.03%	3.32%	

TCMC Paid FTE (Full-Time Equivalent) per Adjusted Occupied Bed

	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	C/M YTD	C/M YTD Budget
FY22	5.73	5.35	4.97	5.28	5.09	5.60	4.78	4.54	4.72				5.10	6.32
FY21	5.38	5.66	5.40	5.87	5.25	5.75	5.10	5.61	6.18	6.33	5.64	5.83	5.56	

TCHD Liquidity \$ in Millions (Cash + Available Revolving Line of Credit)

	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun		
FY22	\$81.4	\$76.9	\$71.5	\$57.3	\$52.4	\$54.6	\$51.2	\$58.6	\$49.2					
FY21	\$59.5	\$57.4	\$83.5	\$76.9	\$71.3	\$68.5	\$71.4	\$75.4	\$83.2	\$67.3	\$59.6	\$86.8		



Building Operating Leases
Month Ending March 31, 2022

Lessor	Sq. Ft.	Base Rate per Sq. Ft.		Total Rent per current month	LeaseTerm		Services & Location	Cost Center
					Beginning	Ending		
6121 Paseo Del Norte, LLC 6128 Paseo Del Norte, Suite 180 Carlsbad, CA 92011 V#83024	Approx 9,552	\$3.59	(a)	48,472.27	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)	32,820.75	07/01/17	06/30/22	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)	20,197.50	07/01/20	06/30/25	PCP Clinic Vista 1926 Via Centre Drive, Ste A Vista, CA 92081	7090
CreekView Orthopaedic Bldg, LLC 1958 Via Centre Drive Vista, Ca 92081 V#83025	Approx 4,995	\$2.50	(a)	20,304.29	07/01/17	06/30/22	OSNC - Vista 1958 Via Centre Drive Vista, Ca 92081	7095
JDS FINCO LLC 499 N EL Camino Real Encinitas, CA 92024 V#83694	Approx 2,460	\$2.15	(a)	7,169.67	04/01/20	03/31/22	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	Approx 4,508	\$1.75	(a)	15,031.39	09/01/21	08/31/31	Seaside Medical Group 115 N EL Camino Real, Suit A Oceanside, CA 92058	7094
500 W Vista Way, LLC & HFT Melrose P O Box 2522 La Jolla, CA 92038 V#81028	Approx 7,374	\$1.67	(a)	12,516.94	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)	39,237.00	10/01/12	10/01/22	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)	14,026.32	06/01/21	05/31/26	OSNC Encinitas Medical Center 351 Santa Fe Drive, Suite 351 Encinitas, CA 92023	7095
TCMC, A Joint Venture 3231 Waring Court, Suit D Oceanside, CA 92056 V#83685	Approx 1,444	\$2.59	(a)	3,754.00	02/01/20	03/31/22	Pulmonary Specialists of NC 3231 Waring Court Suit D Oceanside, CA 92056	7088
Total				213,530.13				

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



Education & Travel Expense
Month Ending March 2022

Cost Centers	Description	Invoice #	Amount	Vendor #	Attendees
8740 ONS		32922EDU	103.00	82013	KIM, INJA
8740 ONS ONC		32422EDU	200.00	83582	ESSMAN SARAH
8740 FETAL MONITORING		30322EDU	200.00	83827	KARLY KUHN
8610 THORACIC SUMMIT		32722EDU	356.07	78648	MA GENE
8740 DEGREE IN NURSING		32422EDU	1,255.00	78644	OZBUN, CINDI
8740 RN TO BSN PROGRAM		31722EDU	2,500.00	83669	MIRJANA POPOVIC

**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.