PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Members

- John Friel (Chair)
- Dr. Katherine (Katie) Gabriel-Cox
- Dr. Joe Gallagher
- Jose A. (Tony) Nuñez
- Marcus Pimentel

Regular Meeting Agenda

Wednesday, August 30, 2023-5:00 pm

Zoom: https://zoom.us/j/93443061917

Phone: +1 669 900 9128 WEBINAR ID: 934 4306 1917

Kathleen King Community Room - 85 Nielson Street, Watsonville

Agenda documents are available for review in person at Watsonville Community Hospital, 75 Nielson Street, Hospital Main Lobby-Visitors Desk; and electronically on the Pajaro Valley Healthcare District's website, at: PVHCDHC.ORG. To view online, visit the Board's website at: PVHCDHC.ORG and select the meeting date to view the agenda and supporting documents. Written comments on agenda items may also be submitted to the Board by email or US Mail. Comments received after 4 p.m. on the day of the meeting and before the end of the meeting will be included with the minutes record.

Email: info@pvhcd.org
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- Please include the agenda item number

U.S. Mail:
PVHCD Board of Directors
75 Nielson Street
Watsonville, CA 95076

For additional information, call 831.763.6040 or email info@pvhcd.org

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Spanish language translation is available on an as needed basis. Please make advance arrangements at least three business days before the meeting at by calling at (831) 763.6040 or by emailing at info@pvhcd.org

Las sesiones de la Mesa Directiva pueden ser traducidas del inglés al español y del español al inglés. Por favor llame por lo menos tres días hábiles antes de la junta al (831) 763.6040 o envíe un correo electrónico a info@pvhcd.orgpara solicitar interpretación.

ACCOMMODATIONS FOR PERSONS WITH DISABILITIES

The Pajaro Valley Health Care District Hospital Corporation does not discriminate on the basis of disability, and no person shall, by reason of a disability, be denied the benefits of its services, programs, or activities. If you are a person with a disability and wish to participate in the meeting and require special assistance in order to participate, please call (831)763-6040 or email info@pvhcd.org at least three business days in advance of the meeting to make arrangements. Persons with disabilities may request a copy of the agenda in an alternative format.

Pajaro Valley Health Care District Hospital Corporation
Regular Meeting Agenda- Wednesday, August 30, 2023

Call to Order

Roll Call

Closed Session Report

Agenda Modification Consideration

Public Comment on Matters Not on the Agenda

Time is set aside for members of the public to address the Board on any item not on the Board Agenda (not to exceed two minutes), which is within the subject matter jurisdiction of the Board.

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Comments from Board Members

Consent

All items listed under the Consent Calendar are considered and acted upon by one Motion. Members of the public must request that a Board Member pull an item from the Consent Agenda for discussion prior to the start of the meeting.

1. **Minute Approval: June 28, 2023, July 25, 2023, July 26, 2023, July 27, 2023, July 28, 2023, August 2, 2023, August 10, 2023, and August 17, 2023**
   Recommendation: Pass a **Motion** approving the minutes for June 28, 2023, July 25, 2023, July 26, 2023, July 27, 2023, July 28, 2023, August 2, 2023, August 10, 2023 and August 17, 2023.
   Contact: Dawn Bullwinkel, Consultant Clerk of the Board

2. **Policies/Policy Summary Approval: August 2023**
   Recommendation: Pass a **Motion** approving the Policies/Policy Summary.
   Contact: Sherri Torres, Chief Nursing Officer

3. **Finance Committee Member Appointments**
Recommendation: Pass a **Motion** approving 1) Matko Vranjes, CEO (Senior Executive); 2) Julie Peterson, CFO (Senior Executive); and Jessica Dixon, Controller (Director/Manager) to serve on the Finance Committee.
Contact: Julie Peterson, Chief Financial Officer

Discussion

4. **Pajaro Valley Health Care District Update**
Recommendation: Receive and file information from Isom Advisors on survey/voter opinion polls which included: 1) preparing a voter survey to assist District to assess the feasibility of a voter approved funding measure in the District; 2) testing voter attitudes, specific project support, tax tolerances, and overall support for local district funding measure; 3) conducting telephone surveys with a not to exceed amount of 400 voters that match demographics of those voting on proposed election dates; 4) producing a written report of findings with complete cross tabulations and 5) providing survey results presentation to District to summarize results of voter survey at the October 25, 2023 Meeting.
Contact: Matko Vranjes, Chief Executive Officer

5. **Medical Executive Committees Report August 2023**
Recommendation: Pass a **Motion** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of August 2023; 2) OPPE template for Pediatric Physicians; 3) Reappointment Application Attestation Questions; and 4) 2023 Surgical Quality Review Indicators.
Contact: Executive Sponsor-Dr. Angel, Chief of Staff, Medical Executive Committee

6. **Chief Executive Officer Matko Vranjes Oral Report on Operational Hospital Activities**
Recommendation: Receive and file.
Contact: Matko Vranjes, Chief Executive Officer

7. **Chief Financial Officer Monthly Financial Performance & Budget Update**
Recommendation: Receive and file.
Contact: Julie Peterson, Chief Financial Officer

8. **Watsonville Community Hospital (WCH) Strategic Plan Approval**
Recommendation: 1) Review the Strategic Plan with edits from July 26, 2023 Pajaro Valley Health Care District Hospital Corporation meeting and 2) Pass a Motion approving the mission, vision and values statements and Strategic Plan.
Contact: Matko Vranjes, Interim Chief Executive Officer (CEO)

Adjourn

This agenda was posted in accordance with the California Brown Act. Any materials related to an item on this Agenda submitted to the Board after distribution of the agenda packet will be made available to the public in accordance with Government Section 54957.5.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Members

- John Friel (Chair)
- Dr. Katherine (Katie) Gabriel-Cox
- Dr. Joe Gallagher
- Jose A. (Tony) Nuñez
- Marcus Pimentel

Closed Meeting Agenda

Wednesday, August 30, 2023-6:00 pm

Kathleen King Community Room - 85 Nielson Street, Watsonville

https://zoom.us/j/93443061917

Phone: +1 669 900 9128 WEBINAR ID: 934 4306 1917

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Pajaro Valley Health Care District Hospital Corporation
Closed Meeting Agenda- Wednesday, August 30, 2023

Call to Order

Roll Call

Public Comment on Matters Not on the Agenda

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Public Comment on Matters on the Agenda

Adjourn to Closed Session

1. **Conference with Labor Negotiators** (Government Code 54957.6)
   Agency Negotiator: Allyson Hauck; California Nurses Association (CNA)
   Contact: Allyson Hauck, Chief Human Resources Officer

2. **Public Employment** (Government Code 54957(b)(1))
   Title-Chief Executive Officer
   Contact: Allyson Hauck, Chief Human Resources Officer

Adjournment

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PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: August 30, 2023
Report Type: Consent

Title: Minute Approval: June 28, 2023, July 25, 2023, July 26, 2023, July 27, 2023, July 28, 2023, August 2, 2023, August 10, 2023, and August 17, 2023

Recommendation: Pass a **Motion** approving the minutes for June 28, 2023, July 25, 2023, July 26, 2023, July 27, 2023, July 28, 2023, August 2, 2023, August 10, 2023 and August 17, 2023.

Contact: Dawn Bullwinkel, Consultant Board Clerk

Analysis

After each Board meeting, the Board Clerk composes the DRAFT minutes noting the action taken by the board. Those DRAFT minutes are presented to the Board Members for their approval as a permanent record of the meeting actions.

Financial Impact: None

Attachments:

A: June 28, 2023
B: July 25, 2023
C: July 26, 2023
D: July 27, 2023
E: July 28, 2023
F: August 2, 2023
G: August 10, 2023
H: August 17, 2023

Pajaro Valley Health Care District Hospital Corporation
Closed Meeting Minutes- Wednesday, June 28, 2023

Called to Order at 5:01pm.

Roll Call
Present: Directors Cox, Gallagher, Nunez and Chair Friel
Absent: Director Pimentel

Public Comment on Matters on the Agenda

a. Roy Valdez regarding Matko Vranjes as Chief Executive Officer

Adjourned to Closed Session at 5:07 pm.

1. **Conference with Labor Negotiators** (Government Code 54957.6)
   Agency Negotiator: Allyson Hauck; California Nurses Association (CNA)
   Contact: Allyson Hauck, Chief Human Resources Officer

2. **Public Employee Recruitment Update** (Government Code 54957(b)(1))
   Conference with Labor Negotiators (Gov't Code 54957.6)
   Title-Chief Executive Officer
   Contact: Allyson Hauck, Chief Human Resources Officer

3. **Hearings/Reports** (Health and Safety Code HSC § 1461 and 32155)
   Reports of Patient Safety and Quality Committee, Medical Staff Credentials Committee, Medical Staff Interdisciplinary Practice Committee and Quality Dashboard.
   Contact: Executive Sponsor-Dr. Angel, Chief of Staff

Pajaro Valley Health Care District Hospital Corporation
Regular Meeting Minutes- Wednesday, June 28, 2023

Called to Order at 6:00 pm.

Roll Call
Present: Directors Cox, Gallagher, Nunez and Chair Friel
Absent: Director Pimentel

Closed Session Report by Chair Friel on Chief Executive Officer (CEO) Recruitment

a. CEO Recruitment Progressing
b. 40 candidates submitted
c. 8 candidates met criteria
d. 4 candidates had zoom interviews
e. 3-5 candidates' additional interviews in June and July
f. Goal to make selection in August

Agenda Modification Consideration-None.

Public Comment on Matters Not on the Agenda

a. Fred Castillo-Website response, part-time to full time workforce and meeting transparency
b. Don Whiteside-CEO recruitment compliment

Comments from Board Members-

a. Director Nunez thanks to Watsonville Hospital staff for son's care; disappointed in language used by Watsonville council referencing homelessness and desires the hospital to establish a policy to use language such as "people who are experiencing homelessness".

Consent
All items listed under the Consent Calendar are considered and acted upon by one Motion.

Motion/Second: Nunez/Gallager
Yes: Directors Cox, Gallagher, Nunez, and Chair Friel
Absent: Director Pimentel

1. **Minute Approval: May 31, 2023**
   Action: Passed **Motion No. 032-2023** approving the minutes of the May 31, 2023.
   Contact: Dawn Bullwinkel, Consultant Clerk of the Board, dbullwinkel@watsonvillehospital.com

2. **Policies/Policy Summary Approval: June 2023**
   Action: Passed **Motion No. 033-2023** approving the Policies/Policy Summary.
   Contact: Sherri Torres, Chief Nursing Officer, Sherri_StoutTorres@Watsonvillehospital.com

3. **Employee Engagement (EE) Committee Member Appointments**
Action: Passed **Motion No. 034-2023** approving:1) Senior Executive, Allyson Hauck, Chief Human Resources Officer; 2) Senior Executive, June Ponce, Foundation Executive Director 3) Hospital Director/Manager – Anna Anton, Director of Acute Care;
4) Hospital Director/Manager – Yvonne Combs, Director of Rehab Services; 5) Staff – Elizabeth Smolanovich, Staff Nurse II Telemetry; 6) Staff – Carole Kulik, Nursing Supervisor; 7) Staff/Other – Leticia Suarez, Central Scheduler; 8) Staff/Other –Kelly Strickling, Lead Lab Technician 9) Provider – TBD; and 10) Provider – TBD to serve on the EE Committee.
Contact: Allyson Hauck, Chief Human Resources Officer

4. **Quality and Patient Safety (QPS) Committee Member Appointments**
Action: Passed **Motion No. 035-2023** approving Hospital Director/Manager, Tracy Trail-Mahan-Quality and Risk; 2) Hospital Director/Manager, Jennifer Gavin-Director of Pharmacy; 3) Hospital Director/Manager, Sherri Stout-Torre-Chief Nursing Officer; 4) Matko Vranjes-Interim CEO; 5) Provider, Dr. Clay Angel-Chief of Staff and 6) Provider, Dr. Janelle Rasi-Vice Chief of Staff to serve on the QPS Committee.
Contact: Sherri Stout-Torre-Chief Nursing Officer

5. **Medical Executive Committees Report June 2023**
Action: Passed **Motion No. 036-2023** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of June 2023 and 2) OPPE templates for Anesthesia Physicians, Pathology Physicians, Emergency Medicine Physicians, Emergency Medicine AHP.
Contact: Executive Sponsor-Dr. Angel, Chief of Staff, Medical Executive Committee

Discussion

6. **Chief Executive Officer Matko Vranjes Oral Report on Operational Hospital Activities**
Action: Received and filed.
Contact: Matko Vranjes, Chief Executive Officer

7. **Chief Financial Officer Monthly Financial Performance**
Action: Received and filed.
Contact: Julie Peterson, Chief Financial Officer

8. **Nurse Staffing Levels Update**
Action: Received and filed.
Contact: Allyson Hauck, Chief Human Resources Officer

9. **Pipeline Rx Agreement Amendment**
Motion/Second: Gallagher/Nunez

Yes: Directors Cox, Gallagher, Nunez, and Chair Friel
Absent: Director Pimentel

Action: Pass a **Motion 037-2023** approving the First Amendment to the Master License and Service Agreement with Pipeline Health Holdings LLC (“Pipeline Rx”).
Contact: Matko Vranjes, Interim Chief Executive Officer

10. Philips Picture Archival and Communications System (PACS) Service Agreement for Medical Imaging Technology

Motion/Second: Cox/Nunez
Yes: Directors Cox, Gallagher, Nunez, and Chair Friel
Absent: Director Pimentel

Action: Passed **Motion No. 038-2023** approving the renewal of the PACS service agreement with Philips Healthcare for medical imaging technology with the inclusion of the standard agreement termination language.
Contact: Sergio Nell-IT Director

Adjourned at 7:20 pm.

Pajaro Valley Health Care District Hospital Corporation
Special Closed Meeting Minutes- Tuesday, July 25, 2023

Called to Order at 2:14 pm.

Roll Call
Present: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Public Comment on Matters on the Agenda Only

1. **Public Employment** (Government Code 54957(b)(1))
   Title-Chief Executive Officer Candidate Interviews
   Contact: Allyson Hauck, Chief Human Resources Officer

Adjourned to Closed Session at 2:16 pm.

Pajaro Valley Health Care District Hospital Corporation
Closed Meeting Minutes- Wednesday, July 26, 2023

Called to Order at 5:03 pm.

Roll Call
Present: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Public Comment on Matters on the Agenda-None

1. **Conference with Labor Negotiators** (Government Code 54957.6)
   Agency Negotiator: Allyson Hauck; California Nurses Association (CNA)
   Contact: Allyson Hauck, Chief Human Resources Officer

2. **Hearings/Reports** (Health and Safety Code HSC § 1461 and 32155)
   Reports of Patient Safety and Quality Committee, Medical Staff Credentials Committee, Medical Staff Interdisciplinary Practice Committee and Quality Dashboard.
   Contact: Executive Sponsor-Dr. Angel, Chief of Staff

Adjourned to Closed Session at 5:08 pm.

Pajaro Valley Health Care District Hospital Corporation
Regular Meeting Minutes Wednesday, July 26, 2023

Called to Order at 5:59 pm.

Roll Call
Present: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Closed Session Report: None

Agenda Modification Consideration:

a. Move item #7 to the first item after the Consent Calendar.

Public Comment on Matters Not on the Agenda:
a. Ms. Shields-spokesperson CNA bargaining unit regarding labor negotiations
b. Ryan-regarding labor negotiations and safe hospital environment for patients and staff

Comments from Board Members
a. Director Nunez: Thank you to Matko Vranjes, Nancy Gere and team for their work on the Community Event held on July 20, 2023.
b. Director Pimentel: Consider clarification of branding for the District, Hospital Corporation and Project (Foundation) hospital related boards.

Consent

All items listed under the Consent Calendar are considered and acted upon by one Motion.

Moved/Seconded: Nunez/Cox
Yes: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

1. **Policies/Policy Summary Approval: July 2023**
   Action: Passed **Motion No. 039-2023** approving the Policies/Policy Summary.
   Contact: Sherri Torres, Chief Nursing Officer, Sherri_StoutTorres@Watsonvillehospital.com

2. **Medical Executive Committees Report June 2023**
   Action: Passed **Motion No. 040-2023** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of July 2023; 2) OPPE template for Pediatric Physicians; 3) Reappointment Application Attestation Questions; and 4) 2023 Surgical Quality Review Indicators.
   Contact: Executive Sponsor-Dr. Angel, Chief of Staff, Medical Executive Committee

Discussion

3. **Chief Executive Officer Matko Vranjes Oral Report on Operational Hospital Activities**
   Action: Received and filed.
   Contact: Matko Vranjes, Chief Executive Officer

4. **Chief Financial Officer Monthly Financial Performance and 2024 Budget Calendar**
   Moved/Seconded: Pimentel/Nunez
   Yes: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel
   Action: Received and filed monthly financial performance reports and passed a **Motion 041-2023** accepting the 2024 Budget Calendar.
   Contact: Julie Peterson, Chief Financial Officer

5. **California Department of Health Care Access and Information (HCAI) Hospital Distressed Loan Program**
   Moved/Seconded: Gallagher/Nunez
   Yes: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel
   Action: Passed **Resolution No. 005-2023** authorizing the execution and delivery of a promissory note, Loan and Security Agreement, and certain actions in connection therewith for a loan in an aggregate amount not to exceed $8,500,000 from the California Health Facilities Financing Authority under the Distressed Hospital Loan Program.
   Contact: Julie Peterson, Chief Financial Officer

6. **Line of Credit-Santa Cruz County Bank**
   Moved/Seconded: Nunez/Gallagher
   Yes: Directors Gallagher, Nunez and Chair Friel
   Recused: Directors Cox and Pimentel
   Action: Passed **Motion No. 042-2023** 1) authorizing staff to negotiate a $5.0 million Line of Credit agreement between the Pajaro Valley Health Care District Hospital Corporation (PVHCDHC) (the "Hospital") and Santa Cruz County Bank and 2) directing staff to place a Resolution approving the final agreement on a future PVHCDHC agenda.
   Contact: Julie Peterson, Chief Financial Officer

7. **Watsonville Community Hospital Strategic Plan Approval**
   Moved/Seconded: Pimentel/Nunez
   Yes: Directors Cox, Nunez, Pimentel and Chair Friel
   No: Director Gallagher
   Action: 1) Provide Chartis with input on: a) mission, vision, and values statements, and b) strategic priorities and tactics, and c) strategic plan roadmap and accountable leaders and 2) Passed **Motion No. 043-2023** approving the mission, vision and values statements and Strategic Plan as amended and directing staff to bring back for final approval on August 30, 2023.
   Contact: Matko Vranjes, Interim Chief Executive Officer

Adjourned at 8:00 pm.

Pajaro Valley Health Care District Hospital Corporation
Special Closed Meeting Minutes- Wednesday, July 26, 2023

Called to Order at 2:07 pm.

Roll Call
Present: Directors Cox, Gallagher, Nunez, Pimentel, and Chair Friel

Public Comment on Matters on the Agenda Only-None

1. **Public Employment** (Government Code 54957(b)(1))
   Title-Chief Executive Officer Candidate Interviews
   Contact: Allyson Hauck, Chief Human Resources Officer

Adjourned to Closed Session at 2:09 pm.

Pajaro Valley Health Care District Hospital Corporation
Special Closed Meeting Minutes- Thursday, July 27, 2023

Called to Order at 2:10 pm.

Roll Call
Present: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Public Comment on Matters on the Agenda Only-None

1. **Public Employment** (Government Code 54957(b)(1))
   Title-Chief Executive Officer Candidate Interviews
   Contact: Allyson Hauck, Chief Human Resources Officer

Adjourned to Closed Session at 2:12 pm.

Pajaro Valley Health Care District Hospital Corporation
Special Closed Meeting Minutes- Friday, July 28, 2023

Called to Order-2:02 pm

Roll Call
Present: Directors Cox, Gallaher, Nunez, Pimentel and Chair Friel

Public Comment on Matters on the Agenda Only-None

1. **Public Employment** (Government Code 54957(b)(1))
   Title-Chief Executive Officer Candidate Interviews
   Contact: Allyson Hauck, Chief Human Resources Officer

Adjourned to Closed Session-2:04 pm.

Pajaro Valley Health Care District Hospital Corporation
Special Closed Meeting Minutes-Wednesday, August 2, 2023

Called to Order at 5:03 pm.

Roll Call
Present: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Public Comment on Matters on the Agenda Only-None

1. **Public Employment** (Government Code 54957(b)(1))
   Title-Chief Executive Officer
   Contact: Allyson Hauck, Chief Human Resources Officer

Adjourned to Closed Session-5:05 pm.

Pajaro Valley Health Care District Hospital Corporation
Special Meeting Minutes-Wednesday, August 2, 2023

Called to Order at 4:47 pm.

Roll Call
Present: Directors Gallagher, Nunez (4:53 pm), Pimentel, Chair Friel
Absent (Recused): Director Cox

Public Comment on Matters on Agenda Only per California Government Code 54956(a)

Discussion

1. **Authorization for Cash Advances**
   Moved/Seconded: Pimentel/Gallagher
   Yes: Directors Gallagher, Nunez, Pimental and Chair Friel
   Recused: Director Cox

   Action: Passed a **Motion No. 044-2023** authorizing Julie Peterson, CFO and Matko Vranjes, Interim CEO to negotiate and secure cash advances against future claim payments, Quality Assurance Directed Payments or Fee for Service Payments in an amount up to $5.0 million.

   Contact: Julie Peterson, Chief Financial Officer

2. **Authorization for Short Term Loans**
   Moved/Seconded: Pimentel/Gallagher
   Yes: Directors Gallagher, Nunez, Pimental and Chair Friel
   Recused: Director Cox

   Action: Passed a **Motion No. 045-2023** 1) authorizing Julie Peterson, CFO and Matko Vranjes, Interim CEO to negotiate and secure short term loan arrangements from external partners, including potentially Salud Para La Gente, not to exceed $1.5 million dollars with a maximum 8% rate cap and 2) directing staff to bring final contract back to the board on the consent calendar for ratification.

   Contact: Julie Peterson, Chief Financial Officer

Adjourned at 5:03 pm.

Pajaro Valley Health Care District Hospital Corporation
Special Closed Meeting Minutes- Thursday, August 10, 2023

Call to Order

Roll Call

Public Comment on Matters on the Agenda Only

1. **Public Employment** (Government Code 54957(b)(1))
   Title-Chief Executive Officer
   Contact: Allyson Hauck, Chief Human Resources Officer

Adjourn to Closed Session

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Pajaro Valley Health Care District Hospital Corporation
Special Closed Meeting Agenda- Thursday, August 17, 2023

Called to Order at 4:00 pm.

Roll Call
Present: Directors Cox (4:16 pm), Gallaher, Nunez (4:03 pm), Pimentel and Chair Friel

Public Comment on Matters on the Agenda Only-None

1. **Public Employment** (Government Code 54957(b)(1))
   Title-Chief Executive Officer
   Contact: Allyson Hauck, Chief Human Resources Officer

Adjourned to Closed Session at 6:45 pm.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: August 30, 2023
Report Type: Consent

Title: Policy/Summaries August 2023

Recommendation: Pass a **Motion** approving the Policies and Summary Report of August 2023.

Contact: Sherri Torres, Chief Nursing Officer, Sherri_StoutTorres@Watsonvillehospital.com

Analysis

As required under Title, 22, CMS and The Joint Commission (TJC), a list of regulatory required policies with a summary of changes are provided for your approval.

Financial Impact: None.

Attachment A:
Reports

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee:BOD

Reporting Period: August 30, 2023

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

Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
PHARMACY				
Hand Hygiene and Garbing for Sterile Compounding in a Segregated Compounding Area	PHARMXXXX	New Policy		Author: Pharmacy Director: 07/2023 CNO/VP/Sr. Leader/CEO:07/2023 PTIC: 07/2023 MEC: 08/15/2023 BOD:
Responsibilities of Sterile Compounding Personnel	PHARMXXXX	New Policy		Author Pharmacy Director: 07/2023 CNO/Vp Sr. Leader/CEO: 07/2023 PTIC: 07/2023 MEC: 08/15/2023 BOD:
Sterile Compounding Program Overview	PHARMXXXX	New Policy		Author: Pharmacy Director: 07/2023 CNO/VP/Sr. Leader/CEO:07/2023 PTIC: 07/2023 MEC: 08/15/2023 BOD:
NURSING				
Sepsis Alert for Adults	NUR4024	Sepsis Alert policy rewritten, Tittle changed from Sepsis Alert to Sepsis Alert for Adutls	Updated to match current practices including encouraged use of sepsis checklist and order sets. Specifies who responds to sepsis alert and when to call an RRT vs Sepsis Alert	Author: ED Director QPSC: 05/2023 CNO/VP Sr Leader/CEO: 06/2023, 08/2023 ED Committee: 08/09/2023 MEC: 08/15/2023 BOD:

Watsonville Community Hospital	**Hand Hygiene and Garbing for Sterile Compounding in a Segregated Compounding Area**
Policy Number/ Version:	797-2022 Version
Policy Start Date:	Initial policy version/implementation

HOW TO USE THIS DOCUMENT

- [USP 797] Language directly from the USP.
- [BEST PRACTICE] Best practice considerations
- [CONDITIONAL: If pharmacy personnel are…] Policy language that is depending the specific conditions of your organization.
- Details to be filled in by the Pharmacy are highlighted in {{brackets}}.
- Template tips are in *italics*, e.g., suggested language to include or additional clarifying information.

1. Overview and Scope

1.1. This policy describes the requirements and procedures for hand hygiene and garbing where Compounded Sterile Preparations (CSP) are prepared within a Segregated Compounding Area (SCA) within Watsonville Community Hospital

1.2. Personal hygiene and proper garbing are essential to minimizing microbial control of the sterile compounding environment. The human body sheds squamous cells at a rate of 10^6 or more per hour and these skin particles are covered in microorganisms. Touch contamination is the leading cause of CSP contamination. To minimize the risk of contamination into the sterile compounding environment, all persons who enter the sterile compounding environment must be properly garbed per this policy.

1.3. This policy applies to the compounding of Category 1 CSPs only.

1.4. This policy applies to compounding of only non-hazardous CSPs. Refer to USP <800> for additional Personal Protective Equipment (PPE) that may be required when compounding hazardous drugs.

2. Policy

2.1. [USP 797] It is the policy that all persons who enter the SCA of Watsonville Community Hospital comply with all aspects of this Hand Hygiene and Garbing policy to maintain microbial control of the sterile compounding environment.

2.2. [USP 797] Individuals entering the SCA are properly garbed and maintain proper personal hygiene and hand hygiene to minimize the risk of contamination to the environment and/or CSPs.

2.3. [USP 797] Gloves worn in the SCA are always sterile.

2.4. [USP 797] Garb is replaced immediately if it becomes soiled or if the integrity is compromised.

2.5. [USP 797] All garb is stored away from the sink to avoid splashing onto clean garb and is stored in a way that minimizes contamination.

2.6. [USP 797] All personnel responsible for sterile compounding are trained in hand hygiene and garbing and have their competency evaluated. Competency in hand hygiene and garbing is assessed by the DP or an Assigned Trainer (AT) and by passing a gloved fingertip test.

2.7. [USP 797] All personnel who ~~restock or~~ clean the SCA (excluding the PEC) are trained in hand hygiene and garbing and have their competency evaluated. Competency in hand hygiene and garbing is assessed by the DP or AT ~~and by passing a gloved fingertip test~~.

2.8. [USP 797] Replace all garb that has become visibly soiled (e.g., becomes moist or wet due to splashing of cleaning agents and/or perspiration) after cleaning and prior to resuming compounding duties; at a minimum, repeat hand hygiene and replace sterile gloves before returning to compounding.

3. Roles & Responsibilities

3.1. [USP 797] The Designated Person(s) (DP):

- Oversees the personnel who enter the SCA and ensures they comply with all procedures in the Hand Hygiene and Garbing policy.
- Evaluates if compounding personnel need to be excluded from sterile compounding based on individual special conditions. Special conditions include but are not limited to: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections
- Ensures that any non-compounding staff or visitors who enter the SCA comply with all procedures in the Hand Hygiene and Garbing policy. These include but are not limited to: engineering, environmental services, stocking personnel, inspectors, or students.

3.2. [USP 797] Compounding personnel:

- Maintain the sterile environment by performing hand hygiene and garbing procedures.
- Inform the Designated Person (DP) if they have any conditions that could contaminate the sterile compounding environment. Examples of these conditions include but are not limited to: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.

3.3. [USP 797] Non-compounding staff and visitors:

- Maintain the sterile environment by performing hand hygiene procedures.
- Don appropriate garb according to facility SOP.

4. Procedures

4.1. [USP 797] All personnel entering the SCA take appropriate steps to minimize microbial contamination of the environment and of the CSPs, including hand hygiene, garbing, and consideration of needed materials to be brought into the compounding area.

4.2. [USP 797] All individuals entering the SCA remove all items that are not easily cleanable or are not necessary for compounding. The DP may permit accommodations to the below list as long as the quality of the CSP and compounding area will not be affected, and accommodations are documented. At a minimum, individuals must:

- Remove personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests)
- Remove all cosmetics
- Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing. Cover any jewelry that cannot be removed.
- Remove earbuds and headphones

- Individuals will not bring in electronic devices that are not necessary for compounding or other required tasks into the compounding area
- Nails are clean and neatly trimmed. No nail products may be worn (all nail polish, artificial nails and extenders are not allowed)
- If eyeglasses are worn, they are cleaned with an eyeglass wipe on the lenses and with a disinfectant wipe on the frames
- ~~**[Best Practice/Conditional]** Employees will change into hospital laundered lint free scrubs prior to entering the compounding area~~
- [Best Practice] Employees entering the sterile compounding area ensure exposed skin on legs are covered (e.g., will wear socks or shoe cover "booties" long enough to cover exposed skin on legs~~) that may be present when the employee is sitting.~~
- [Best Practice/Conditional] If street clothes are worn into the compounding area, or non-pharmacy employees need to enter the sterile compounding environment, individuals will don a full non-shedding suit over street clothes prior to performing hand hygiene and garbing steps.

4.3. [USP 797] Required garb for sterile compounding Category 1 CSPs include:
- Low-lint gown with sleeves that fit snugly around the wrist and have an enclosed neck
  - [Best practice] Gowns with a thumb loop ~~are~~ may be used, if available
- Low-lint shoe covers
- Low-lint face mask
- Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair
- Sterile powder-free gloves
- [Conditional if using RABS] Disposable gloves are worn inside the gloves attached to the RABS sleeves. Sterile gloves are worn over the gloves attached to the RABS sleeve.

4.4. [USP 797] Any person entering the SCA must wash hands and forearms up to the elbows with soap and water before initiating compounding activities.
- Steps for hand hygiene:
  - Remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner
  - Wash hands and forearms up to the elbows with soap and water for at least 30 seconds
  - Dry hands and forearms up to the elbows completely with low-lint disposable towels or wipers
- Brushes and hand dryers are not used
- A non-refillable soap dispenser is located next to the sink

4.5. [USP 797] All garb for sterile compounding is stored outside the perimeter line of the SCA.

4.6. [USP 797] Order of hand hygiene and garbing is:

[CONDITIONAL: If sink is located inside the room the SCA is located]:
- Outside of the SCA:
  - Tie long hair back
  - Clean eyeglasses
- Enter SCA:
  - Don mask, head, and facial hair covers outside the perimeter line
  - ~~**Perform hand hygiene**~~
  - ~~Don gown~~
- Inside the perimeter line of the SCA:
  - Don shoe covers one foot at a time while stepping over the perimeter line

- Perform hand hygiene (sink inside perimeter line)
- Don gown
- Sanitize hands/wrists with alcohol-based hand sanitizer:
  - Apply alcohol-based hand sanitizer to dry skin on one hand (volume determined by manufacturer)
  - Rub hands together, covering all surfaces of fingers, hands, and wrists until hands are dry
- Don sterile gloves

~~**[CONDITIONAL: If sink is located outside the room the SCA is located]:**~~

- ~~Outside of the SCA:~~
  - ~~Tie long hair back~~
  - ~~Clean eyeglasses~~
  - ~~**Perform hand hygiene**~~
- ~~Enter SCA:~~
  - ~~Sanitize hands/wrists with alcohol-based hand sanitizer:~~
    - ~~Apply alcohol-based hand sanitizer to dry skin on one hand (volume determined by manufacturer)~~
    - ~~Rub hands together, covering all surfaces of fingers, hands, and wrists until hands are dry~~
  - ~~Don mask, head, and facial hair covers outside the perimeter line~~
  - ~~Sanitize hands/wrists with alcohol-based hand sanitizer~~
  - ~~Don gown~~
- ~~Inside the perimeter line of the SCA:~~
  - ~~Don shoe covers one foot at a time while stepping over the perimeter line~~
  - ~~Sanitize hands with alcohol-based hand sanitizer~~
  - ~~Don sterile gloves~~

4.7. [USP 797] Donning and doffing of garb will not occur in the perimeter line of the SCA at the same time.

~~4.8. **[USP 797]** Sterile gloves are never donned or doffed inside a Laminar Airflow System (LAFS) or Class II Biological Safety Cabinet (BSC) ISO Class 5 PEC.~~

~~4.9.~~4.8. [Conditional] Sterile gloves are donned and doffed inside a Restricted-Access Barrier System (RABS) ISO Class 5 PEC.

- Sterile gloves are worn over the gauntlet gloves that are attached to the RABS sleeve per manufacture specifications.

~~4.10.~~4.9. [Best Practice] Garbing for non-compounding staff or visitors:

- When it is necessary for non-compounding staff or visitors to enter the SCA to perform maintenance, cleaning procedures, inspections; the persons entering the area performs all proper hand hygiene and garbing per this policy.
  - Before entering the SCA, either change into hospital laundered lint free scrubs or don a fully enclosed non-shedding suit prior to following all above steps for preparing to enter the sterile compounding area.

~~4.11.~~4.10. [Best practice] Doffing of gown worn while compounding CSPs occurs within the perimeter of the SCA. Order of doffing garb worn during sterile compounding:

- Remove sterile gloves
- Remove gown

- [Conditional: if reuse of gowns allowed] For Category 1 CSPs gowns are stored within the perimeter of the SCA for reuse during the same shift only if the gown is not visibly soiled or torn.
- Leave the SCA perimeter line and remove and dispose of mask, facial hair cover, head cover, and shoe covers

5. Definitions

5.1. **Assigned Trainer (AT):** One or more individuals assigned by the Designated Person(s) to be responsible for directly providing the training, observation, and/or evaluation pf personnel for the preparation of CSPs

5.2. **ISO:** International Standards Organization

5.3. **Laminar Airflow System (LAFS):** A device or zone within a buffer area that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow. Examples of LAFS are Laminar Airflow Workbenches (LAFWs), Integrated Vertical Laminar Flow Zones (IVLFZs) and Biological Safety Cabinet, Class II (BSCs).

5.4. **Low-lint:** Material that exhibits few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from the material in a dry condition

5.5. **Perimeter Line:** A visible demarcation (such as a door, walls , or visible marking on the floor) that defines the SCA

5.6. **Primary Engineering Control (PEC)**: A device or zone that provides an ISO Class 5 air quality environment for sterile compounding

5.7. **Restricted-access Barrier System (RABS):** An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include Compounding Aseptic Isolators (CAIs) and Compounding Aseptic Containment Isolators (CACIs).

5.8. **Segregated Compounding Area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only

6. Related Policies, Documents, References

6.1. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 proposed version.

6.2. United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval (MM/YYYY)
Next review:	Month/year

7.1. Initial version published by Wolters Kluwer 2022.

7.2. Revised MM/YYY with the following key changes… OR… with no changes.

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Hand Hygiene and Garbing for Sterile Compounding in a Segregated Compounding Area	Policy #	PHARMXXXX
Responsible	Pharmacy Director	Revised/Reviewed	07/2023

I. PURPOSE

- This policy describes the requirements and procedures for hand hygiene and garbing where Compounded Sterile Preparations (CSP) are prepared within a Segregated Compounding Area (SCA) within Watsonville Community Hospital

- Personal hygiene and proper garbing are essential to minimizing microbial control of the sterile compounding environment. The human body sheds squamous cells at a rate of 106 or more per hour and these skin particles are covered in microorganisms. Touch contamination is the leading cause of CSP contamination. To minimize the risk of contamination into the sterile compounding environment, all persons who enter the sterile compounding environment must be properly garbed per this policy.

- This policy applies to the compounding of Category 1 CSPs only.

- This policy applies to compounding of only non-hazardous CSPs. Refer to USP <800> for additional Personal Protective Equipment (PPE) that may be required when compounding hazardous drugs.

II. POLICY

1. It is the policy that all persons who enter the SCA of Watsonville Community Hospital comply with all aspects of this Hand Hygiene and Garbing policy to maintain microbial control of the sterile compounding environment.
2. Individuals entering the SCA are properly garbed and maintain proper personal hygiene and hand hygiene to minimize the risk of contamination to the environment and/or CSPs.
3. Gloves worn in the SCA are always sterile.
4. Garb is replaced immediately if it becomes soiled or if the integrity is compromised.
5. All garb is stored away from the sink to avoid splashing onto clean garb and is stored in a way that minimizes contamination.
6. All personnel responsible for sterile compounding are trained in hand hygiene and garbing and have their competency evaluated. Competency in hand hygiene and garbing is assessed by the DP or an Assigned Trainer (AT) and by passing a gloved fingertip test.
7. All personnel who clean the SCA (excluding the PEC) are trained in hand hygiene and garbing and have their competency evaluated. Competency in hand hygiene and garbing is assessed by the DP or AT
8. Replace all garb that has become visibly soiled (e.g., becomes moist or wet due to splashing of cleaning agents and/or perspiration) after cleaning and prior to resuming compounding duties; at a minimum, repeat hand hygiene and replace sterile gloves before returning to compounding.

III. DEFINITIONS

- **Assigned Trainer (AT):** One or more individuals assigned by the Designated Person(s) to be responsible for directly providing the training, observation, and/or evaluation pf personnel for the preparation of CSPs
- **ISO:** International Standards Organization
- **Laminar Airflow System (LAFS):** A device or zone within a buffer area that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow. Examples of LAFS are Laminar Airflow Workbenches (LAFWs), Integrated Vertical Laminar Flow Zones (IVLFZs) and Biological Safety Cabinet, Class II (BSCs).
- **Low-lint:** Material that exhibits few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from the material in a dry condition
- **Perimeter Line:** A visible demarcation (such as a door, walls , or visible marking on the floor) that defines the SCA
- **Primary Engineering Control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding
- **Restricted-access Barrier System (RABS):** An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include Compounding Aseptic Isolators (CAIs) and Compounding Aseptic Containment Isolators (CACIs).
- **Segregated Compounding Area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only

IV. ROLES & REPONSIBILITIES

1. **The Designated Person(s) (DP):**
   - Oversees the personnel who enter the SCA and ensures they comply with all procedures in the Hand Hygiene and Garbing policy.
   - Evaluates if compounding personnel need to be excluded from sterile compounding based on individual special conditions. Special conditions include but are not limited to: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections
   - Ensures that any non-compounding staff or visitors who enter the SCA comply with all procedures in the Hand Hygiene and Garbing policy. These include but are not limited to: engineering, environmental services, stocking personnel, inspectors, or students.
2. **Compounding personnel:**
   - Maintain the sterile environment by performing hand hygiene and garbing procedures.
   - Inform the Designated Person (DP) if they have any conditions that could contaminate the sterile compounding environment. Examples of these conditions include but are not limited to: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.

3. **Non-compounding staff and visitors:**
   - Maintain the sterile environment by performing hand hygiene procedures.
   - Don appropriate garb according to facility SOP.

V. PROCEDURE

1. All personnel entering the SCA take appropriate steps to minimize microbial contamination of the environment and of the CSPs, including hand hygiene, garbing, and consideration of needed materials to be brought into the compounding area.
2. All individuals entering the SCA remove all items that are not easily cleanable or are not necessary for compounding. The DP may permit accommodations to the below list as long as the quality of the CSP and compounding area will not be affected, and accommodations are documented. At a minimum, individuals must:
   - Remove personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests)
   - Remove all cosmetics
   - Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing. Cover any jewelry that cannot be removed.
   - Remove earbuds and headphones
   - Individuals will not bring in electronic devices that are not necessary for compounding or other required tasks into the compounding area
   - Nails are clean and neatly trimmed. No nail products may be worn (all nail polish, artificial nails and extenders are not allowed)
   - If eyeglasses are worn, they are cleaned with an eyeglass wipe on the lenses and with a disinfectant wipe on the frames
   - Employees entering the sterile compounding area ensure exposed skin on legs are covered (e.g., will wear socks or shoe cover " booties" long enough to cover exposed skin on legs)
   - If street clothes are worn into the compounding area, or non- pharmacy employees need to enter the sterile compounding environment, individuals will don a full non-shedding suit over street clothes prior to performing hand hygiene and garbing steps.
3. Required garb for sterile compounding Category 1 CSPs include:
   - Low-lint gown with sleeves that fit snugly around the wrist and have an enclosed neck
     - Gowns with a thumb loop may be used, if available
   - Low-lint shoe covers
   - Low-lint face mask
   - Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair
   - Sterile powder-free gloves
   - [Conditional if using RABS] Disposable gloves are worn inside the gloves attached to the RABS sleeves. Sterile gloves are worn over the gloves attached to the RABS sleeve.
4. Any person entering the SCA must wash hands and forearms up to the elbows with soap and water before initiating compounding activities.
   - Steps for hand hygiene:
     - Remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner
     - Wash hands and forearms up to the elbows with soap and water for at least 30 seconds

- Dry hands and forearms up to the elbows completely with low-lint disposable towels or wipers
- Brushes and hand dryers are not used
- A non-refillable soap dispenser is located next to the sink

5. All garb for sterile compounding is stored outside the perimeter line of the SCA.
6. Order of hand hygiene and garbing is:
   (CONDITIONAL: If sink is located inside the room the SCA is located):
   - Outside of the SCA:
     - Tie long hair back
     - Clean eyeglasses
   - Enter SCA:
     - Don mask, head, and facial hair covers outside the perimeter line
   - Inside the perimeter line of the SCA:
     - Don shoe covers one foot at a time while stepping over the perimeter line
       - Perform hand hygiene (sink inside perimeter line)
       - Don gown
       - Sanitize hands/wrists with alcohol-based hand sanitizer:
   - Apply alcohol-based hand sanitizer to dry skin on one hand (volume determined by manufacturer)
   - Rub hands together, covering all surfaces of fingers, hands, and wrists until hands are dry
     Don sterile gloves
7. Donning and doffing of garb will not occur in the perimeter line of the SCA at the same time.

8. Sterile gloves are donned and doffed inside a Restricted-Access Barrier System (RABS) ISO Class 5 PEC.
   - Sterile gloves are worn over the gauntlet gloves that are attached to the RABS sleeve per manufacture specifications.
9. Garbing for non-compounding staff or visitors:
   - When it is necessary for non-compounding staff or visitors to enter the SCA to perform maintenance, cleaning procedures, inspections; the persons entering the area performs all proper hand hygiene and garbing per this policy.
     - Before entering the SCA, either change into hospital laundered lint free scrubs or don a fully enclosed non-shedding suit prior to following all above steps for preparing to enter the sterile compounding area.
10. Doffing of gown worn while compounding CSPs occurs within the perimeter of the SCA.
    Order of doffing garb worn during sterile compounding:
    - Remove sterile gloves
    - Remove gown
      - [Conditional: if reuse of gowns allowed] For Category 1 CSPs gowns are stored within the perimeter of the SCA for reuse during the same shift only if the gown is not visibly soiled or torn.
    - Leave the SCA perimeter line and remove and dispose of mask, facial hair cover, head cover, and shoe covers

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding-Sterile Preparations. 2022 proposed version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

VII. STAKEHOLDERS

N/A

{{Pharmacy/Organization Name}}Watsonville Community Hospital	**Responsibilities of Sterile Compounding Personnel**
Policy Number/ Version:	797-2022 version
Policy Start Date:	Initial policy version/implementation

HOW TO USE THIS DOCUMENT

- [USP 797] Language directly from the USP.
- [BEST PRACTICE] Best practice considerations
- [CONDITIONAL: If pharmacy personnel are…] Policy language that is depending the specific conditions of your organization.
- Details to be filled in by the Pharmacy are highlighted in {{brackets}}.
- Template tips are in *italics*, e.g., suggested language to include or additional clarifying information.

1. Overview and Scope

1.1. This policy describes the responsibilities and procedures for Compounding Personnel and individuals entering sterile compounding areas where Compounded Sterile Preparations (CSP) are prepared within {{**Pharmacy/Organization Name**}}.Watsonville Community Hospital.

1.2. Humans shed approximately 10^6 microbe-laden skin cells per hour and, as such, pose a significant risk to the cleanroom environment. Additionally, human touch contamination within the controlled areas is the most common cause of component and CSP contamination. Consequently, personal hygiene, proper hand washing and garbing, and appropriate conduct and work practices within a sterile environment help to reduce the introduction of contamination into the controlled environment and risk of touch contamination to sterile preparations.

1.3. Compounding personnel are essential in maintaining a state of control inside compounding areas and serve as the first line in the detection of deviations or failures of facilities, environmental controls, equipment, work processes, personnel conduct/behaviors, or entry of unauthorized personnel or visitors that could adversely impact the quality of the environment and, ultimately, patient safety. All compounding personnel have a responsibility to actively monitor the compounding environment and report any suspected or known issues in a timely manner to the Designated Person(s) or managing supervisor.

2. Policy

2.1. [USP 797] Compounding personnel are responsible to review, understand, and comply with all aspects of the {{**Pharmacy/Organization Name**}}Watsonville Community Hospital's sterile practice SOPs related to their job duties, including, but not limited to:

- Hand Hygiene and Garbing
- Personnel Training and Evaluations
- Materials Movement into Controlled Areas
- Aseptic Technique and Workflow
- Beyond-use Date (BUD) Determination & Stability Considerations

- Cleaning, Disinfecting, & Applying Sporicidal Agents
- Labeling
- Good Documentation Practices

2.2. [USP 797] All required sterile practice training, evaluations, and assessments are successfully completed:

- Prior to compounding independently or overseeing compounding activities initially and
- Per the required ongoing, role-based frequency as described in the Sterile Compounding Training and Competency Program and SOP
- Deviations from the required training and evaluation schedule and/or failures of any portion of an evaluation or assessment are reported to the Designated Person(s) as soon as known so appropriate accommodations, if appropriate, can be made and documented.

~~2.3. [BEST PRACTICE] *(Edit and amend the following statement to reflect your organization's garbing requirements outside of and prior to entry into the compounding area).* Institutionally provided or a freshly laundered scrubs and scrub jacket/coat are donned prior to entering controlled areas. Scrub jackets are worn fully buttoned at all times when outside of the controlled area. Dedicated shoes are donned/doffed immediately adjacent to the controlled area.~~

~~2.4.~~2.3. [USP 797] Illnesses, skin conditions, and noncompliant personal issues (e.g., unremovable jewelry) are reported to the Designated Person(s) (DP) prior to entering the compounding area at the beginning of each shift. The DP determines if accommodations are warranted and documents accommodations and/or reassignment of duties until the personal condition or situation is resolved (if possible).

~~2.5.~~2.4. [USP 797] Hand hygiene and garbing procedures are completed every time compounding personnel enter/reenter the compounding area.

~~2.6.~~2.5. [USP 797] Noncompounding personnel and visitors are observed and supervised when entering controlled areas and are required to perform hand hygiene and garbing. Deviations are reported to the DP (or supervising Pharmacist) immediately and unsupervised visitors are asked to exit the compounding area until proper oversight is available.

~~2.7.~~2.6. [USP 797] CSPs are labeled and assigned BUDs per policy. Reference appropriate resources, ~~such as~~including but not limited to the USP-NF Monograph ~~{{*list other stability resources used by your compounding personnel*}}~~ and MicroMedex,to validate (and document, if needed) stability issues necessitating a shortened BUD.

~~2.8.~~2.7. [USP 797] Cleaning, disinfecting, and sporicidal application responsibilities within compounding areas is completed and documented according to the schedule, frequency, and task descriptions per policy.

~~2.9.~~2.8. [USP 797] Known or suspected issues impacting the quality of the compounding area; functioning of equipment, faciltiies, or processes; or quality of the components and/or final compounded preparations are reported to the DP or supervising pharmacist in a timely manner. ~~(e.g., {{*same shift or immediately to ensure state of control of the compounding environment and integrity of CSPs*}}).~~

~~2.10.~~2.9. [USP 797] State and Federal licensures and certifications required for sterile compounding are kept current and in good standing.

3. Roles & Responsibilities

3.1 Designated Person(s):

- Ensure Compounding Personnel have education and training in the foundational knowledge and skills needed to perform sterile compounding job duties successfully.
- Provide immediate access to the SOPs and compounding resources needed to perform sterile compounding job duties successfully~~,~~ e.g., USP <797> and supporting Chapters, USP-NF Monographs and/or stability reference data~~; and other compounding resources needed to perform sterile compounding job duties successfully~~.
- Evaluate personnel illness, health conditions, and personal garbing situations to assess the impact and/or potential risks to the quality of the compounding environment, CSPs, and coworkers. Determine and document accommodations or job reassignment, if appropriate.
- Ensure the compounding facilities, environmental controls, and equipment are in good working order.
- Provide timely communication and education to compounding personnel on new and updated policies, procedures, equipment, formulations, systems, supplies, available components, etc.
- In partnership with pharmacy leaders, address behavior and conduct issues inconsistent with safe compounding practices and that potentially impact the quality of the environment.

3.2 Compounding personnel:

- Remain current and in good standing on all required sterile compounding training, evaluations, and assessments.
- Report any health conditions, personal garbing issues, or other circumstances that could impact the quality of the compounding area to the DP prior to entry into the compounding area.
- Take an active role in ensuring the quality of the compounding environment and patient safety by reporting suspected or known concerns with sterile compounding facilities, environmental controls, equipment, systems, personnel, supplies, components, etc. in a timely and appropriate manner.
- Ensure all non-compounding personnel and visitors entering the compounding area are properly supervised and successfully complete hand hygiene, garbing, and cleaning of necessary tools and supplies brought into the compounding area. Report concerns immediately.
- Perform advanced or specialized sterile practice job duties as assigned by the DP.

4. Procedures

4.1. Prior to entry into a classified compounding area

- ~~Don {{*freshly laundered / sterile*}} scrubs and scrub jacket {{*and shoes*}} in the {{*identify the changing area/locker room*}} and prior to entering the controlled area.~~
  - ~~Scrub jacket is worn fully closed (e.g., buttoned, zipped, snapped) at all times when outside of the controlled area.~~
  - ~~Replace scrub jacket before each shift or when {{*scrubs become visibly soiled, scrubs have been worn outside of the building or immediate area, etc.*}}~~

- Replace scrub jacket {{*at least once weekly, when visibly soiled, or when it has been worn outside of the building or immediate area, etc.*}}
- **[Conditional: If pharmacy allows undershirts/layers, insert allowance here]** {{*clean short sleeve cotton t-shirt/or under layer is allowed under the scrubs if needed for comfort*}}
- **[Conditional: If pharmacy requires dedicated shoes]:** Dedicated shoes are stored immediately adjacent to the compounding area and are only worn within the controlled areas. Dedicated shoes are cleaned {{*once weekly*}}.

- Wipe eyeglasses with a sanitizing agent that does not harm the lens or frames.
- Remove personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests) and store {{*in personal locker or other storage location outside of the controlled area*}}in appropriate area outside of segregated compounding area (SCA).
- Remove all cosmetics including false eyelashes and nail polish, artificial nails, or extensions. Ensure nails are kept clean and trimmed to avoid puncturing gloves.
- Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection) or otherwise increase the risk of contamination of the CSP
- Leave drinks, food, gum, mints, personal electronics outside of controlled areas.
- Attend to personal needs, such as visiting the restroom and fully hydrating, to minimize the need to exit and reenter the compounding area prior to assigned breaks or at the conclusion of compounding duties.
- Report current respiratory infections, fevers, flaking skin conditions, fresh tatooes, fresh or oozing wounds, unremovable jewelry, or similar to the DP or supervising pharmacist for determination if compounding personnel should be reassigned to duties outside of the compounding area until the current health condition is resolved.

4.2. [USP 797] Upon entry into the compounding area

- Follow the hand hygiene and garbing procedure and sequence when entering or reentering the compounding area.
  - **[Conditional: If sink used for hand hygiene is located outside of the ante room]:** Ensure alcohol-based hand gel is applied to hands just prior to initiating the garbing and hand hygiene process.
- Confirm all hair, including facial hair, is fully covered and hair and face coverings are positioned properly in mirror adjacent to the garbing area.
- During hand hygiene, ensure proper use of the nail pick, full lathering and washing of hands and forearms (to the elbows), and continue washing for at least 30 seconds (after use of the nail pick) each time hands are washed. Pat dry arms with a low-lint towel to minimize skin shell shedding.
- Following hand hygiene, immediately don compounding frock or gown without touching any other surfaces. Apply alcohol-based hand gel and allow to fully dry before donning sterile gloves, ensure ungloved hands do not touch any other surface during the process.

4.3. **[Conditional: If reuse of scrub jackets is allowed]** Upon exit of the compounding area

- Prior to exiting the compounding area for a break, ensure nonsoiled compounding jacket is stored properly inside the controlled area to allow for reuse during the same shift. Discard and do not reuse all other garbing elements during the doffing process.
- At the end of the shift, discard compound jacket during doffing process.

~~4.4.~~4.3. Conduct within compounding area

- Limit access to compounding areas to trained and qualified compounding personnel or supervised non-compounding personnel or visitors.
- Don and doff compounding gown immediately upon entry (just prior to exit) to minimize shedding from uncovered skin and scrubs. ~~[Conditional: if reuse of gowns allowed.]~~ Store gown appropriately for reuse during same shift.
- Minimize conversations to work-related communication only. Do not talk directly into a PEC, turn head away from PEC prior to speaking.
- When coughing or sneezing occurs, replace mask and, at a minimum, sanitize gloves with sIPA prior to resuming activities. Turn head or step away from PEC if coughing or sneezing occurs while compounding.
- Minimize touching of eyeglasses, face, or garb. Sanitize hands thoroughly with sIPA immediately and prior to resuming activities.
- Move through the compounding areas in at a controlled and deliberate pace to minimize particle shedding. Avoid congregating in traffic pattern areas.
- Do not eat, drink, chew gum or tobacco, spit, or similar in controlled areas.
- Keep clean side carts within compounding area at all times. If a clean side cart crosses the LOD, clean and disinfect the cart prior to reentry into the controlled area.
- ~~Do not prop open, block, or manually open doors or pass throughs within the controlled areas.~~
- ~~{{*Insert other conduct expectations*}}~~

~~4.5.~~4.4. Conduct within the ISO Class 5 PEC

- Prior to introducing items into the PEC:
  - Sanitize gloved hands and all components and supplies with sIPA just prior to intoduction in the PEC. Use both mechanical/manual (i.e., wiping) and chemical (i.e., wet contact time) clean action to fully sanitize all surfaces.
  - Resanitize gloved hands throughout the compounding process and, when removed from the PEC, prior to reentry.
  - Components or supplies in a sterile outer wrap do not need to be cleaned if removed from the sterile wrap as the item crosses into the PEC.
- Prior to compounding, wipe all critical sites with a sIPA wipe three times firmly in one direction or around the neck of an ampule. Allow the sIPA to fully dry prior to puncturing or entering the component.
- Perform compounding activities within the DCA and use aseptic technique during all compounding manipulations while ensuring first air on critical sites.
- Conduct aseptic manipulations at least 6 inches from the front sash and 3 inches from the deck of the PEC to ensure unidirectional airflow and first air.
- Label CSPs outside of the PEC and place all used components, supplies, and finished CSPs in an individual bin for final verification and reduce the risk of mix ups.
- Do not allow bare skin (e.g., hands or face/neck) to enter a PEC ~~{{*or buffer room (for Category 3 compounders)*}}~~.
- Adhere to required in-process quality control and release checks, as specified in the IVWS or MFR, and document results appropriately

~~4.6.~~4.5. Managing Power Outages or Disruptions

- Allow PECs to run continuously. If PEC is turned off or if a power disruption occurs:
  - Stop compounding activities and restore power to the PEC(s) as soon as possible.
  - Allow the PEC to run for ~~{{30 minutes}}~~30 minutes or for the timeframe stated by the manufacturer to restore the ISO Class 5 environment.
  - Fully clean and disinfect all interior surfaces of the PEC prior to resuming compounding activities and handle components and finished CSPs inside the hood at the time of the outage as follows: ~~*(Adjust per your facilities policy regarding cleaning requirements and product handling/destruction when power outages impacting the functioning of a PEC occurs):*~~

Outage Timeframe	Cleaning of PEC Interior ~~{{30 minutes}}~~30 minutes after Power Restored	Components	CSPs
< 1 Hour	*One-step disinfectant cleaner followed by sIPA to remove residue; observe dwell times* ~~{{One-step disinfectant cleaner followed by sIPA to remove residue; observe dwell times}}~~	Date, store, & use per component BUD policy Single use components: < 12 Hour BUD Multi-dose components: < 28 Days BUD	Completed: remove from hood and label; BUD unaffected Partially compounded individual CSPs: discard Uncompounded batched CSPs (components): move to another PEC or sanitize and compound after power is restored to PEC and it is cleaned
1 to 24 Hours	*Sporicidal disinfectant followed by sIPA; observe dwell times* ~~{{Sporicidal disinfectant followed by sIPA; observe dwell times}}~~		
> 24 Hours	Triple clean followed by sIPA; observe dwell times		

- If power to the SEC is disrupted (without impacting power to the PECs) or the SEC environmental controls fall outside of acceptable specifications (e.g., HVAC system, temperature, humidity, and/or pressure differentials), immediately consult with the DP or ~~Lead IV~~supervising ~~p~~Pharmacist. At a minimum, all CSPs inside of hoods at the time of the disruptions are dated with a < 12 Hour BUD.

~~4.7.~~4.6. Materials Movement into Compounding Areas

- Remove all supplies, medications, and components are from corrugated cardboard and outer shipping containers prior to introduction into ~~a classified areas~~Segregated Compounding Area (SCA) ~~*[and/or Segregated Compounding Area (SCA)].*~~ .
  - Smooth coated cardboard is allowed inside of the compounding area, however both the cardboard surface and contents (e.g., vials) are thoroughly cleaned and disinfected.
- Clean and disinfect all materials (e.g., equipment, furniture, supplies, medications, components) introduced into ~~the classified areas *[and/or SCA*~~SCA] upon entry/crossing the Line of Demarcation (LOD) with ~~{{*sterile 70% isopropyl alcohol (sIPA), EPA-registered one step disinfecting cleaner, or sporicidal cleaner*}}~~ *sterile 70% isopropyl alcohol (sIPA), EPA-registered one step disinfecting cleaner, or sporicidal cleaner* using both mechanical/manual (i.e., wiping motion) and chemical (e.g., dwell time or wet contact time) action.
  - [BEST PRACTICE] Thoroughly "pre-clean" furniture and equipment (e.g., ladders, inspection equipment, etc.) visibly dirty or that have been used outside of the building prior to introduction into the compounding area with a *hospital grade cleaner, one-step*

disinfectant cleaner, or sporicidal agent ~~{{*hospital grade cleaner, one step disinfectant cleaner, or sporicidal agent*}}~~.

- Transport materials within the compounding area on a "clean-side" dedicated cart or bin. Do not allow "dirty side" carts to cross LOD without thorough cleaning of entire cart and wheels.

~~4.8.~~4.7. Cleaning, Disinfecting, & Applying Sporicidal Agents

- Complete hand hygiene and don full garb prior to initiating cleaning activities.
  - Don appropriate protective eye gear and respiratory support (e.g., N-95, PAPR or full respirator) prior to and during use of sporicidal agents or other irritating cleaning solutions.
- Clean, disinfect, and apply sporicidal agents to PECs and SECs according to the frequency and procedures described in the **Cleaning & Disinfecting policy**, including:
  - Conduct and sequence cleaning activities from cleanest to dirtiest areas and, generally, from top to bottom (e.g., ceiling to floor).
  - Observe dwell times for all cleaning agents; apply sIPA to remove cleaning agent residue inside PECs.
  - If surfaces inside the PECs and/or SECs are visibly soiled or have dried residue, remove debris with sterile water prior to initiating cleaning process.
  - Use only sterile cleaning agents and supplies inside of PECs.
  - Do not spray or squirt cleaning agents inside of PECs; apply cleaning solution to a sterile low-lint wipe or use pre-saturated sterile cleaning wipes inside the PEC.
- Record completed cleaning activities ~~{{*on written logs or in electronic system*}}~~in electronic system (e.g., Simplifi) prior to returning to work to ensure timely and accurate recording of these tasks.
- Prior to returning to compounding activities, discard used garb and repeat the complete hand hygiene and garbing process with fresh garb.

5. Definitions

5.1. **Classified area**: An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).

5.2. **Cleaning agent**: An agent for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.

5.3. **Compounding area:** The area where compounding is occurring (i.e., a cleanroom suite or inside the perimeter of the SCA).

5.4. **Garb:** Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).

5.5. **IPA:** Isopropyl alcohol.

5.6. **Low-lint wiper**: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from, the wiper material in a dry condition.

5.7. **One-step disinfectant cleaner**: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.

5.8. **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.

5.9. **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

5.10. **Segregated compounding area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.

5.11. **Sporicidal disinfectant**: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms

5.12. **Triple clean:** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full wet contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA.

6. Related Policies, Documents, References

6.1. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding - Sterile Preparations. 2022 version.

6.2. United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health Care Settings. 2019 version.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval (MM/YYYY)
Next review:	Month/year

7.1. Initial version published by Wolters Kluwer 2022.

7.2. Revised MM/YYY with the following key changes…OR…with no changes.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Responsibilities of Sterile Compounding Personnel	Policy #	PHARMXXXX
Responsible	Pharmacy Director	Revised/Reviewed	08/2023

I. PURPOSE

1. This policy describes the responsibilities and procedures for Compounding Personnel and individuals entering sterile compounding areas where Compounded Sterile Preparations (CSP) are prepared within Watsonville Community Hospital.

2. Humans shed approximately 106 microbe-laden skin cells per hour and, as such, pose a significant risk to the cleanroom environment. Additionally, human touch contamination within the controlled areas is the most common cause of component and CSP contamination. Consequently, personal hygiene, proper hand washing and garbing, and appropriate conduct and work practices within a sterile environment help to reduce the introduction of contamination into the controlled environment and risk of touch contamination to sterile preparations.

3. Compounding personnel are essential in maintaining a state of control inside compounding areas and serve as the first line in the detection of deviations or failures of facilities, environmental controls, equipment, work processes, personnel conduct/behaviors, or entry of unauthorized personnel or visitors that could adversely impact the quality of the environment and, ultimately, patient safety. All compounding personnel have a responsibility to actively monitor the compounding environment and report any suspected or known issues in a timely manner to the Designated Person(s) or managing supervisor.

II. POLICY

1. Compounding personnel are responsible to review, understand, and comply with all aspects of the Watsonville Community Hospital's sterile practice SOPs related to their job duties, including, but not limited to:
   - Hand Hygiene and Garbing
   - Personnel Training and Evaluations
   - Materials Movement into Controlled Areas
   - Aseptic Technique and Workflow
   - Beyond-use Date (BUD) Determination & Stability Considerations
   - Cleaning, Disinfecting, & Applying Sporicidal Agents
   - Labeling
   - Good Documentation Practices
2. All required sterile practice training, evaluations, and assessments are successfully completed:
   - Prior to compounding independently or overseeing compounding activities initially and
   - Per the required ongoing, role-based frequency as described in the Sterile Compounding Training and Competency Program and SOP

- Deviations from the required training and evaluation schedule and/or failures of any portion of an evaluation or assessment are reported to the Designated Person(s) as soon as known so appropriate accommodations, if appropriate, can be made and documented.

3. Illnesses, skin conditions, and noncompliant personal issues (e.g., unremovable jewelry) are reported to the Designated Person(s) (DP) prior to entering the compounding area at the beginning of each shift. The DP determines if accommodations are warranted and documents accommodations and/or reassignment of duties until the personal condition or situation is resolved (if possible).
4. Hand hygiene and garbing procedures are completed every time compounding personnel enter/reenter the compounding area.
5. Noncompounding personnel and visitors are observed and supervised when entering controlled areas and are required to perform hand hygiene and garbing. Deviations are reported to the DP (or supervising Pharmacist) immediately and unsupervised visitors are asked to exit the compounding area until proper oversight is available.
6. CSPs are labeled and assigned BUDs per policy. Reference appropriate resources, including but not limited to the USP-NF Monograph and MicroMedex to validate (and document, if needed) stability issues necessitating a shortened BUD.
7. Cleaning, disinfecting, and sporicidal application responsibilities within compounding areas is completed and documented according to the schedule, frequency, and task descriptions per policy.
8. Known or suspected issues impacting the quality of the compounding area; functioning of equipment, facilities, or processes; or quality of the components and/or final compounded preparations are reported to the DP or supervising pharmacist in a timely manner.
9. State and Federal licensures and certifications required for sterile compounding are kept current and in good standing.

III. DEFINITIONS

- **Classified area:** An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).
- **Cleaning agent:** An agent for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
- **Compounding area:** The area where compounding is occurring (i.e., a cleanroom suite or inside the perimeter of the SCA).
- **Garb:** Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).
- **IPA:** Isopropyl alcohol.
- **Low-lint wiper**: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from, the wiper material in a dry condition.

IV. ROLES & RESPONNSIBILITIES

1. Designated Person(s):

- Ensure Compounding Personnel have education and training in the foundational knowledge and skills needed to perform sterile compounding job duties successfully.

- Provide immediate access to the SOPs and compounding resources needed to perform sterile compounding job duties successfully, e.g., USP <797> and supporting Chapters, USPNF Monographs and/or stability reference data.
- Evaluate personnel illness, health conditions, and personal garbing situations to assess the impact and/or potential risks to the quality of the compounding environment, CSPs, and coworkers. Determine and document accommodations or job reassignment, if appropriate.
- Ensure the compounding facilities, environmental controls, and equipment are in good working order.
- Provide timely communication and education to compounding personnel on new and updated policies, procedures, equipment, formulations, systems, supplies, available components, etc.
- In partnership with pharmacy leaders, address behavior and conduct issues inconsistent with safe compounding practices and that potentially impact the quality of the environment.

2. Compounding personnel:

- Remain current and in good standing on all required sterile compounding training, evaluations, and assessments.
- Report any health conditions, personal garbing issues, or other circumstances that could impact the quality of the compounding area to the DP prior to entry into the compounding area.
- Take an active role in ensuring the quality of the compounding environment and patient safety by reporting suspected or known concerns with sterile compounding facilities, environmental controls, equipment, systems, personnel, supplies, components, etc. in a timely and appropriate manner.
- Ensure all non-compounding personnel and visitors entering the compounding area are properly supervised and successfully complete hand hygiene, garbing, and cleaning of necessary tools and supplies brought into the compounding area. Report concerns immediately.
- Perform advanced or specialized sterile practice job duties as assigned by the DP.

V. PROCEDURE

1. Prior to entry into a classified compounding area
   - Wipe eyeglasses with a sanitizing agent that does not harm the lens or frames.
   - Remove personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests) and store in appropriate area outside of segregated compounding area (SCA).
   - Remove all cosmetics including false eyelashes and nail polish, artificial nails, or extensions. Ensure nails are kept clean and trimmed to avoid puncturing gloves.
   - Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection) or otherwise increase the risk of contamination of the CSP
   - Leave drinks, food, gum, mints, personal electronics outside of controlled areas.
   - Attend to personal needs, such as visiting the restroom and fully hydrating, to minimize the need to exit and reenter the compounding area prior to assigned breaks or at the conclusion of compounding duties.

- Report current respiratory infections, fevers, flaking skin conditions, fresh tattoos, fresh or oozing wounds, unremovable jewelry, or similar to the DP or supervising pharmacist for determination if compounding personnel should be reassigned to duties outside of the compounding area until the current health condition is resolved.

2. Upon entry into the compounding area
   - Follow the hand hygiene and garbing procedure and sequence when entering or reentering the compounding area.
   - Confirm all hair, including facial hair, is fully covered and hair and face coverings are positioned properly in mirror adjacent to the garbing area.
   - During hand hygiene, ensure proper use of the nail pick, full lathering and washing of hands and forearms (to the elbows), and continue washing for at least 30 seconds (after use of the nail pick) each time hands are washed. Pat dry arms with a low-lint towel to minimize skin shell shedding.
   - Following hand hygiene, immediately don compounding frock or gown without touching any other surfaces. Apply alcohol-based hand gel and allow to fully dry before donning sterile gloves, ensure ungloved hands do not touch any other surface during the process.
3. Conduct within compounding area
   - Limit access to compounding areas to trained and qualified compounding personnel or supervised non-compounding personnel or visitors.
   - Don and doff compounding gown immediately upon entry (just prior to exit) to minimize shedding from uncovered skin and scrubs. Store gown appropriately for reuse during same shift.
   - Minimize conversations to work-related communication only. Do not talk directly into a PEC, turn head away from PEC prior to speaking.
   - When coughing or sneezing occurs, replace mask and, at a minimum, sanitize gloves with sIPA prior to resuming activities. Turn head or step away from PEC if coughing or sneezing occurs while compounding.
   - Minimize touching of eyeglasses, face, or garb. Sanitize hands thoroughly with sIPA immediately and prior to resuming activities.
   - Move through the compounding areas in at a controlled and deliberate pace to minimize particle shedding. Avoid congregating in traffic pattern areas.
   - Do not eat, drink, chew gum or tobacco, spit, or similar in controlled areas.
   - Keep clean side carts within compounding area at all times. If a clean side cart crosses the LOD, clean and disinfect the cart prior to reentry into the controlled area.
4. Conduct within the ISO Class 5 PEC
   - Prior to introducing items into the PEC:
     - Sanitize gloved hands and all components and supplies with sIPA just prior to intoduction in the PEC. Use both mechanical/manual (i.e., wiping) and chemical (i.e., wet contact time) clean action to fully sanitize all surfaces.
     - Resanitize gloved hands throughout the compounding process and, when removed from the PEC, prior to reentry.
     - Components or supplies in a sterile outer wrap do not need to be cleaned if removed from the sterile wrap as the item crosses into the PEC.
   - Prior to compounding, wipe all critical sites with a sIPA wipe three times firmly in one direction or around the neck of an ampule. Allow the sIPA to fully dry prior to puncturing or entering the component.

- Perform compounding activities within the DCA and use aseptic technique during all compounding manipulations while ensuring first air on critical sites.
- Conduct aseptic manipulations at least 6 inches from the front sash and 3 inches from the deck of the PEC to ensure unidirectional airflow and first air.
- Label CSPs outside of the PEC and place all used components, supplies, and finished CSPs in an individual bin for final verification and reduce the risk of mix ups.
- Do not allow bare skin (e.g., hands or face/neck) to enter a PEC.
- Adhere to require in-process quality control and release checks, as specified in the IVWS or MFR, and document results appropriately

5. Managing Power Outages or Disruption
   - Allow PECs to run continuously. If PEC is turned off or if a power disruption occurs:
     - Stop compounding activities and restore power to the PEC(s) as soon as possible.
     - Allow the PEC to run for {{30 minutes}}30 minutes or for the timeframe stated by the manufacturer to restore the ISO Class 5 environment.
     - Fully clean and disinfect all interior surfaces of the PEC prior to resuming compounding activities and handle components and finished CSPs inside the hood at the time of the outage as follows:

<table>
<tr><th>Outage Timeframe</th><th>Cleaning of PEC Interior
30 minutes after Power Restored</th><th>Components</th><th>CSPs</th></tr>
<tr><td>< 1 Hour</td><td>One-step disinfectant cleaner followed by sIPA to remove residue: observe dwell times</td><td rowspan="3">Date, store, & use per component

BUD policy

<u>Single use components</u>:
<u><</u> 12 Hour BUD

<u>Multi-dose components</u>:
<u><</u> 28 Days BUD</td><td rowspan="3">Completed: remove from hood and label; BUD unaffected

<u>Partially compounded individual CSPs: discard</u>

<u>Uncompounded batched CSPs (components):</u> move to another PEC or sanitize and compound after power is restored to PEC and it is cleaned</td></tr>
<tr><td>1 to 24 Hours</td><td>Sporicidal disinfectant followed by sIPA; observe dwell times</td></tr>
<tr><td>> 24 Hours</td><td>Triple clean followed by sIPA; observe dwell times</td></tr>
</table>

- If power to the SEC is disrupted (without impacting power to the PECs) or the SEC environmental controls fall outside of acceptable specifications (e.g., HVAC system, temperature, humidity, and/or pressure differentials), immediately consult with the DP or supervising pharmacist. At a minimum, all CSPs inside of hoods at the time of the disruptions are dated with a < 12 Hour BUD.

6. Materials Movement into Compounding Areas
   - Remove all supplies, medications, and components are from corrugated cardboard and outer shipping containers prior to introduction into a classified areas Segregated Compounding Area (SCA).

- Smooth coated cardboard is allowed inside of the compounding area, however both the cardboard surface and contents (e.g., vials) are thoroughly cleaned and disinfected.

- Clean and disinfect all materials (e.g., equipment, furniture, supplies, medications, components) introduced into upon entry/crossing the Line of Demarcation (LOD) with sterile 70% isopropyl alcohol (sIPA), EPA registered one step disinfecting cleaner, or sporicidal cleaner using both mechanical/manual (i.e., wiping motion) and chemical (e.g., dwell time or wet contact time) action.
  - Thoroughly "pre-clean" furniture and equipment (e.g., ladders, inspection equipment, etc.) visibly dirty or that have been used outside of the building prior to introduction into the compounding area with a hospital grade cleaner, one-step disinfectant cleaner, or sporicidal agent.
- Transport materials within the compounding area on a "clean-side" dedicated cart or bin. Do not allow "dirty side" carts to cross LOD without thorough cleaning of entire cart and wheels.

7. Cleaning, Disinfecting, & Applying Sporicidal Agents
   - Complete hand hygiene and don full garb prior to initiating cleaning activities.
     - Don appropriate protective eye gear and respiratory support (e.g., N-95, PAPR or full respirator) prior to and during use of sporicidal agents or other irritating cleaning solutions.
   - Clean, disinfect, and apply sporicidal agents to PECs and SECs according to the frequency and procedures described in the Cleaning & Disinfecting policy, including:
     - Conduct and sequence cleaning activities from cleanest to dirtiest areas and, generally, from top to bottom (e.g., ceiling to floor).
     - Observe dwell times for all cleaning agents; apply sIPA to remove cleaning agent residue inside PECs.
     - If surfaces inside the PECs and/or SECs are visibly soiled or have dried residue, remove debris with sterile water prior to initiating cleaning process.
     - Use only sterile cleaning agents and supplies inside of PECs.
     - Do not spray or squirt cleaning agents inside of PECs; apply cleaning solution to a sterile low-lint wipe or use pre-saturated sterile cleaning wipes inside the PEC.
   - Record completed cleaning activities in electronic system (e.g., Simplifi) prior to returning to work to ensure timely and accurate recording of these tasks.
   - Prior to returning to compounding activities, discard used garb and repeat the complete hand hygiene and garbing process with fresh garb.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding - Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health Care Settings. 2019 version.

VII. STAKEHOLDERS

N/A

{{~~Pharmacy/Organization Name~~Watsonville Community Hospital}}	**Sterile Compounding Program Overview**
Policy Number/ Version:	797 – 2022 Version
Policy Start Date:	Initial policy version/implementation

HOW TO USE THIS DOCUMENT

- [USP 797] Language directly from the USP.
- [Best Practice] Best practice considerations
- [Conditional: If pharmacy personnel are…] Policy language that is depending the specific conditions of your organization.
- Details to be filled in by the Pharmacy are highlighted in {{brackets}}.
- Template tips are in *italics*, e.g., suggested language to include or additional clarifying information.

1. Overview and Scope

1.1. This policy provides an overview of {{~~Pharmacy/Organization Name~~}}Watsonville Community Hospital's Sterile Compounding Program which operates pursuant to the current version of USP <797>, related USP chapters, relevant Federal regulatory guidelines (e.g. FDA guidance), and in accordance with the {{~~*Insert Name of State(s) in which your organization has sterile compounding operations*~~}} California Board of Pharmacy State statutes governing sterile compounding practices. The Sterile Compounding Program outlines the following:

- Type of healthcare organization or practice(s) engaged in sterile compounding
- Type and location of compounding area(s) and ISO Class 5 hoods used
- Categories of CSP compounded
- Personnel performing sterile compounding
- General types of sterile preparations compounded
- Patient populations served

1.2. The overriding goal of the Sterile Compounding Program is to minimize harm, including death, to {{~~human and/or animal~~}}human patients that could result from:

- Microbial contamination [non-sterility]
- Excessive bacterial endotoxins
- Variability from the intended strength of correct ingredients
- Physical and chemical incompatibilities
- Chemical and physical contaminants, and/or
- Use of ingredients of inappropriate quality

1.3. [USP 797] Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication. While not an exhaustive list, the following CSPs are considered sterile preparations ~~{{Remember to remove sterile dosage forms from the following list that are not compounded at your facility}}:~~

- Injections
- Intravenous infusions

- Irrigations for internal body cavities (i.e., any space that does not normally communicate with the environment outside of the body, such as the bladder cavity or peritoneal cavity). [Note—Irrigations for the mouth, rectal cavity, and sinus cavity are not required to be sterile.]
- ~~Ophthalmic dosage forms~~
- ~~Aqueous preparations for pulmonary inhalation. [Note—Nasal dosage forms intended for local application are not required to be sterile.]~~
- ~~Baths and soaks for live organs and tissues~~
- ~~Implants~~
- ~~{{*Insert other sterile dosage forms or preparations compounded by your organization*}}~~

1.4. USP <797> defines CSP risk levels or categories of compounding that are primarily based on the state of environmental control under which the CSP is compounded, the probability for microbial growth during the time the CSP is stored, and the time period within which the CSP is to be used. USP <797> redefined CSP into the following categories:

- **Immediate Use CSPs** – compounded in less than ISO Class 5 conditions (e.g. bedside or countertop), with 3 or fewer sterile products, and a maximum BUD of 4 hours after the initiation of compounding.
- **Category 1 CSPs** – compounded in ISO Class 5 PEC located in a segregated compounding area with a maximum BUD of 12 hours when stored at room temperature or 24 hours when refrigerated.
- **Category 2 CSPs** – compounded in an ISO Class 5 PEC located within a classified sterile compounding facility and adhering to USP BUDs based on storage conditions, administration of CSP sterility testing, sterilization method, and sterility of starting components.
- **Category 3 CSPs** – compounded in an ISO classified sterile compounding facility with increased garbing, environmental monitoring, compounding oversight requirements, and CSP sterility and endotoxin testing requirements allowing for extended BUD assignments.

1.5. Administration of medication, preparation of allergenic extract prescription sets, blood-derived and other biological material processing that occurs physically removed from sterile compounding activities, and sterile radiopharmaceuticals ~~{{*insert any other compounding or related activities that fall outside of the scope of your USP 797 program*}}~~ is not in the scope of the Sterile Compounding Program and USP <797>.

2. Policy

2.1 The Sterile Compounding Program at ~~{{**Pharmacy/Organization Name**}}~~Watsonville Community Hospital is summarized in Appendix One. The Program includes the following type(s) of facilities and sterile compounding areas where sterile compounding of ~~{{*Category 1, 2, and/or 3*}}~~*Category 1* CSPs occurs:

[CONDITIONAL: Examples of healthcare facilities preparing CSPs include, but are not limited to, hospitals, other healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physicians or veterinary practice sites.]

[CONDITIONAL: Examples of sterile compounding areas where CSPs are prepared include all sterile compounding suites – non-hazardous only, hazardous only, or non-hazardous and hazardous; segregated compounding areas (SCAs), and other clinical practice sites where immediate use and/or Category 1, 2, and/or 3 CSPs are prepared]

- ~~{{Facility 1 / Geographic Location: Insert type(s) of healthcare facility(ies) and geographic/descriptive location of each facility}}~~Inpatient Pharmacy:
  - ~~Sterile Compounding Area 1 (within Facility 1) – CSP Category(ies) compounded onsite~~Segregated Compounding Area (SCA)
  - *Sterile Compounding Area 2 (within Facility 1) – CSP Category(ies) compounded onsite*
  - *Sterile Compounding Area 3 (within Facility 1) – CSP Category(ies) compounded onsite*
- *{{Facility 2 / Geographic Location}}*
  - *Sterile Compounding Area 1 (within Facility 2) – CSP Category(ies) compounded onsite*
  - *Sterile Compounding Area 2 (within Facility 2) – CSP Category(ies) compounded onsite*
  - *Sterile Compounding Area 3 (within Facility 2) – CSP Category(ies) compounded onsite*
- *{{Facility 3 / Geographic Location 3 and so on}}*
  - *Sterile Compounding Area 1 (within Facility 3) – CSP Category(ies) compounded onsite*
  - *Sterile Compounding Area 2 (within Facility 3) – CSP Category(ies) compounded onsite*
  - *Sterile Compounding Area 3 (within Facility 3) – CSP Category(ies) compounded onsite*

2.2 Personnel who compound or have direct oversight of compounding personnel are required to successfully complete and remain current in all Sterile Compounding Core Competencies. These personnel include:

[CONDITIONAL: Examples of personnel who perform sterile compounding: pharmacists, technicians, nurses, physicians, veterinarians, dentists, naturopaths, and chiropractors]

- ~~{{Personnel type 1}}~~Pharmacy Technicians
- ~~{{Personnel type 2}}~~Pharmacists
- *{{Personnel type 3}}*
- *{{Personnel type 4}}*

2.3 Personnel supporting, but not directly compounding, are required to successfully complete and remain current in selected Sterile Core Compounding Competencies directly related to their limited role(s). These personnel include:

[CONDITIONAL: Examples of personnel who provide indirect support to sterile compounding activities include, but are not limited to: decentralized pharmacists; centralized pharmacists not directly overseeing compounding activities; inventory and procurement personnel; investigational drug personnel; Environmental Services or similar external cleaning service personnel; quality assurance personnel.]

- ~~{{Personnel type 1}}~~Environmental Services (i.e., Housekeeping)
- *{{Personnel type 2}}*
- *{{Personnel type 3}}*
- *{{Personnel type 4}}*

2.4 **[BEST PRACTICE]** Personnel not involved in sterile compounding or visitors **{{certifiers, inspectors, vendors, students and other visitors}}** are escorted and overseen by the Designated Person(s) or designee and expected to comply with all aspects of the Sterile Compounding Program (e.g. hand hygiene, garbing, conduct, etc.).

2.5 Patient populations served by CSPs prepared under the Sterile Compounding Program include:

- ~~{{Inpatient, outpatient clinic, outpatient, or other}}~~Inpatients, Outpatients
- ~~{{Human, small animal veterinary, large animal veterinary, or other}}~~Human
- ~~{{Pediatric, adult, geriatric, or other special or specific patient population}}~~Adult, Neonate/Pediatric, Geriatric

- *{{Other general descriptions of patient populations}}*

2.6 General types of compounded sterile products prepared under the Sterile Compounding Program include:

- ~~*{{Non-hazardous CSPs, hazardous CSPs, chemotherapy CSPs}}*~~*Non-hazardous CSPs*
- ~~*{{Single patient, batched CSPs for single or multiple patients, repackaged CSPs}}*~~*Single patient, batched CSPs for single or multiple patients, repackaged CSPs*
- ~~*{{Sterile-to-sterile, nonsterile-to-sterile}}*~~*Sterile to sterile*
- ~~*{{Single use CSPs, multi-dose CSPs}}*~~*Single use CSPs, multi dose CSPs*
- ~~*{{Other high risk CSPs including, but not limited to intrathecal, epidural, and interventricular CSPs}}*~~*Other high risk CSPs including, but not limited to intrathecal, epidural CSPs*
- ~~*{{Other general descriptions of CSPs prepared}}*~~*Other CSPs not limited to parenteral nutrition*

2.7 Types of primary engineering controls used to compound sterile products prepared under the Sterile Compounding Program include:

- *{{LAFWs}}*
- *{{BSCs}}*
- ~~*{{CAI / CACI}}*~~*Restricted Access Barrier (RAB): CAI (Compounding Aseptic Isolator)*
- *{{IVFLZ}}*
- *{{Pharmaceutical Isolator / Contained Robotic Unit}}*
- *{{Other}}*

3. Roles & Responsibilities

3.1 The Designated Person(s) (DP): The DP is responsible for the Sterile Compounding Program and is accountable for the performance and operation of the sterile compounding facility and equipment; environmental monitoring and maintaining a state of microbial control within controlled areas; personnel competency qualification; and ongoing compliance with the Standard Operating Procedures.

4. Procedures

4.1 The Sterile Compounding Program is guided by policies and standard operating procedures, which are further outlined in this policy manual.

4.2. All Sterile Compounding Program policies and procedures are reviewed ~~every 12 months~~annually, at a minimum, by the Designated Person and relevant committees.

4.3 Any changes to Sterile Compounding Program policies and procedures are approved by the Designated Person and communicated to personnel in a manner commensurate with the degree of change.

5. Definitions

5.1. **Biological safety cabinet (BSC)**: A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.

5.2. **Classified area:** An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).

5.3. **Compounded sterile preparation (CSP):** A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance

5.4. **Compounding area:** The area where compounding is occurring (i.e., a cleanroom suite, inside the perimeter of the SCA, or AECA)

5.5. **Compounding aseptic containment isolator (CACI):** A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.

5.6. **Compounding aseptic isolator (CAI):** A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.

5.7. **Containment ventilated enclosure (CVE):** A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.

5.8. **Immediate-use CSP:** CSP aseptically compounded outside of ISO classified air for direct and immediate administration to a single patient with a maximum BUD of 4 hours after the initiation of compounding.

5.9. **Integrated vertical laminar flow zone (IVLFZ)**: A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns.

5.10. **Laminar airflow workbench (LAFW):** A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.

5.11. **Pharmaceutical isolator:** An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer.

5.12. **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.

5.13. **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

5.14. **Segregated compounding area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.

6. Related Policies, Documents, References

6.1 United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2 United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval (MM/YYYY)
Next review:	Month/year

7.1 Initial version published by Wolters Kluwer 2022.

Revised MM/YYY with the following key changes…OR…with no changes.

APPENDIX ONE: {{~~Pharmacy/Organization Name~~}}Watsonville Community Hospital's Sterile Compounding Program Overview

Healthcare Facility Type / Location	Description of Compounding Area(s)	Type of PECs Used	CSP Categories Compounded	Type of CSPs Prepared	Personnel Performing or Overseeing Compounding	Primary Patient Populations Served
Examples of healthcare facilities preparing CSPs include: hospitals, other healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physicians or veterinary practice sites	Examples include: sterile compounding suites – non-hazardous only, hazardous only, or non-hazardous and hazardous; segregated compounding areas (SCAs), and clinical practice sites where immediate use CSPs are prepared	LAFW, BSC, CAI, CACI, IVFLZ, Isolator	CSP Categories include: immediate use, Category 1, 2, and/or 3 CSPs	Examples of general types of CSPs: Non-hazardous, hazardous, chemotherapy; sterile-to-sterile, non-sterile-to-sterile; single use, multi-dose; intrathecal, epidural, intraventricular	Examples of personnel who perform sterile compounding: pharmacists, technicians, nurses, physicians, veterinarians, dentists, naturopaths, and chiropractors	Examples of general types of patient populations: inpatient, outpatient clinic, outpatient; human, veterinary; pediatric, adult, geriatric
{{~~insert~~}}Hospital: Inpatient Pharmacy	{{~~insert~~}}Segregated Compounding Area (SCA)	{{~~insert~~}}Compounding Aseptic Isolator (CAI)	{{~~insert~~}}Category 1, Immediate Use	{{~~insert~~}}Non-hazardous, sterile-to-sterile, epidural	{{~~insert~~}}Pharmacy technicians, pharmacists	{{~~insert~~}}Inpatients, outpatients, human, adult, neonate/pediatric, geriatric
{{insert}}	{{~~insert~~}}Clinical practice sites where immediate use CSPs are prepared	{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}
{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}
{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}
{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}
{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}
{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}	{{insert}}

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Sterile Compounding Program Overview	Policy #	PHARMXXX
Responsible	Pharmacy Director	Revised/Reviewed	07/2023

I. PURPOSE

1. This policy provides an overview of Watsonville Community Hospital's Sterile Compounding Program which operates pursuant to the current version of USP <797>, related USP chapters, relevant Federal regulatory guidelines (e.g. FDA guidance), and in accordance with the California Board of Pharmacy State statutes governing sterile compounding practices. The Sterile Compounding Program outlines the following:
   - Type of healthcare organization or practice(s) engaged in sterile compounding
   - Type and location of compounding area(s) and ISO Class 5 hoods used
   - Categories of CSP compounded
   - Personnel performing sterile compounding
   - General types of sterile preparations compounded
   - Patient populations served
2. The overriding goal of the Sterile Compounding Program is to minimize harm, including death, to human patients that could result from:
   - Microbial contamination [non-sterility]
   - Excessive bacterial endotoxins
   - Variability from the intended strength of correct ingredients
   - Physical and chemical incompatibilities
   - Chemical and physical contaminants, and/or
   - Use of ingredients of inappropriate quality
3. Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication. While not an exhaustive list, the following CSPs are considered sterile preparations
   - Injections
   - Intravenous infusions
   - Irrigations for internal body cavities (i.e., any space that does not normally communicate with the environment outside of the body, such as the bladder cavity or peritoneal cavity). [Note-Irrigations for the mouth, rectal cavity, and sinus cavity are not required to be sterile.]
4. USP <797> defines CSP risk levels or categories of compounding that are primarily based on the state of environmental control under which the CSP is compounded, the probability for microbial growth during the time the CSP is stored, and the time period within which the CSP is to be used. USP <797> redefined CSP into the following categories:
   - **Immediate Use CSPs** – compounded in less than ISO Class 5 conditions (e.g. bedside or countertop), with 3 or fewer sterile products, and a maximum BUD of 4 hours after the initiation of compounding.

- **Category 1 CSPs** – compounded in ISO Class 5 PEC located in a segregated compounding area with a maximum BUD of 12 hours when stored at room temperature or 24 hours when refrigerated.
- **Category 2 CSPs** – compounded in an ISO Class 5 PEC located within a classified sterile compounding facility and adhering to USP BUDs based on storage conditions, administration of CSP sterility testing, sterilization method, and sterility of starting components.
- **Category 3 CSPs** – compounded in an ISO classified sterile compounding facility with increased garbing, environmental monitoring, compounding oversight requirements, and CSP sterility and endotoxin testing requirements allowing for extended BUD assignments.

5. Administration of medication, preparation of allergenic extract prescription sets, blood-derived and other biological material processing that occurs physically removed from sterile compounding activities, and sterile radiopharmaceuticals is not in the scope of the Sterile Compounding Program and USP <797>.

II. POLICY

1. The Sterile Compounding Program at Watsonville Community Hospital is summarized in Appendix One. The Program includes the following type(s) of facilities and sterile compounding areas where sterile compounding of Category 1 CSPs occurs:
   - Segregated Compounding Area (SCA)
2. Personnel who compound or have direct oversight of compounding personnel are required to successfully complete and remain current in all Sterile Compounding Core Competencies. These personnel include:
   - Pharmacy Technicians
   - Pharmacists
3. Personnel supporting, but not directly compounding, are required to successfully complete and remain current in selected Sterile Core Compounding Competencies directly related to their limited role(s). These personnel include:
   - Environmental Services (i.e., Housekeeping)
4. Personnel not involved in sterile compounding or visitors are escorted and overseen by the Designated Person(s) or designee and expected to comply with all aspects of the Sterile Compounding Program (e.g. hand hygiene, garbing, conduct, etc.).
5. Patient populations served by CSPs prepared under the Sterile Compounding Program include:
   - Inpatients, Outpatients
   - Human
   - Adult, Neonate/Pediatric, Geriatric
6. General types of compounded sterile products prepared under the Sterile Compounding Program include:
   - Non-hazardous CSPs
   - Single patient, batched CSPs for single or multiple patients, repackaged CSPs
   - Sterile to sterile
   - Single use CSPs, multi dose CSPs
   - Other high risk CSPs including, but not limited to intrathecal, epidural CSPs
   - Other CSPs not limited to parenteral nutrition

7. Types of primary engineering controls used to compound sterile products prepared under the Sterile Compounding Program include:
    - Restricted Access Barrier (RAB): CAI (Compounding Aseptic Isolator)

III. ROLES & RESPONSIBILITIES

The Designated Person(s) (DP): The DP is responsible for the Sterile Compounding Program and is accountable for the performance and operation of the sterile compounding facility and equipment; environmental monitoring and maintaining a state of microbial control within controlled areas; personnel competency qualification; and ongoing compliance with the Standard Operating Procedures.

IV. DEFINITIONS

1. **Biological safety cabinet (BSC):** A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.
2. **Classified area:** An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class)
3. **Compounded sterile preparation (CSP):** A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance
4. **Compounding area:** The area where compounding is occurring (i.e., a cleanroom suite, inside the perimeter of the SCA, or AECA)
5. **Compounding aseptic containment isolator (CACI):** A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.
6. **Compounding aseptic isolator (CAI):** A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.
7. **Containment ventilated enclosure (CVE):** A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
8. **Immediate-use CSP:** CSP aseptically compounded outside of ISO classified air for direct and immediate administration to a single patient with a maximum BUD of 4 hours after the initiation of compounding.
9. **Integrated vertical laminar flow zone (IVLFZ):** A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns.
10. **Laminar airflow workbench (LAFW):** A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.
11. **Pharmaceutical isolator:** An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer.

12. **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
13. **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

14. **Segregated compounding area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.

V. PROCEDURE

1. The Sterile Compounding Program is guided by policies and standard operating procedures, which are further outlined in this policy manual.
2. All Sterile Compounding Program policies and procedures are reviewed every 12 months annually, at a minimum, by the Designated Person and relevant committees.
3. Any changes to Sterile Compounding Program policies and procedures are approved by the Designated Person and communicated to personnel in a manner commensurate with the degree of change.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

VII. STAKEHOLDERS

N/A

APPENDIX ONE: Watsonville Community Hospital's Sterile Compounding Program Overview

Healthcare Facility Type / Location	Description of Compounding Area(s)	Type of PECs Used	CSP Categories Compounded	Type of CSPs Prepared	Personnel Performing or Overseeing Compounding	Primary Patient Populations Served
Hospital: Inpatient Pharmacy	Segregated Compounding Area (SCA)	Compounding Aseptic Isolator (CAI)	Category 1, Immediate Use	Nonhazardous, sterile to sterile, epidural	Pharmacy technicians, pharmacists	Inpatients, outpatients, human, adult, neonate/pediatric, geriatric
	Clinical practice sites where immediate use CSPs are prepared					

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Sepsis Alert for Adults	Policy #	NUR4024
Responsible	Emergency Department Manager/Director	Revised/Reviewed	~~3/2021~~05/2023

I. PURPOSE

A. In an effort to reduce morbidity and mortality from sepsis, WCH will have a standardized process for early recognition and response to sepsis, severe sepsis, or septic shock. Care will be provided based upon evidence-based sepsis bundles. As management of these patients, and implementation of these bundles occur, communication amongst all members of the patient care team is essential for patient safety.

II. POLICY

A. This policy applies to inpatient and emergency department settings.
B. Sepsis Alerts should be called for patients meeting sepsis recognition criteria.
C. The Sepsis Bundle Checklist is strongly encouraged to be utilized for patients meeting sepsis recognition criteria to facilitate communication amongst all members of the patient care team.
D. Sepsis order set utilization is strongly encouraged to ensure physician orders comply with sepsis bundles of care.

III. DEFINITIONS

A. Bundles - a series of maneuvers that when applied concurrently have been shown to impact outcomes.
B. Sepsis criteria - exhibiting at least two of the following systemic inflammatory response syndrome (SIRS) signs and symptoms new to the patient AND suspicion or confirmed infection.
    1. Temp > 100.9 F or < 96.8 F (>38.3 C or < 36.0 C)
    2. Heart Rate > 90 beats per minute
    3. Respiratory rate > 20 breaths per minute
    4. WBC count> 12,000/mm3 or <4,000/mm3 or > 10% bands
C. Severe sepsis criteria – sepsis criteria plus signs of acute organ dysfunction.
D. Septic shock criteria – severe sepsis criteria plus persistent organ dysfunction.
E. Signs of Organ Dysfunction include:
    1. New Changes in mental status
    2. Lactic acid > 2.0 mml
    3. Acute oliguria (urine output < 0.5 ml/kg/hr for at least 2 hours despite adequate fluid resuscitation)
    4. Coagulation abnormalities (INR > 1.5 or aPTT > 60 s)
    5. Thrombocytopenia (platelet count< 100,000 µL-1)
    6. Hyperbilirubinemia (plasma total bilirubin > 4 mg/dL or 70 µmol/L)
    7. SBP down by 40
    8. MAP < 65
    9. SBP <90
    10. Creat>2
    11. PTT>60
    ~~1.~~12. MV NIPPV

IV. PROCEDURE

A. A nurse or physician who identifies a patient meeting sepsis recognition criterion will initiate sepsis response.
B. Primary RN will initiate the sepsis checklist (attachment A)
C. If indicated, a sepsis alert will be called by dialing 6-1-1
D. The following people, with the following roles, will respond to the location of a sepsis alert:
    1. Primary RN
        a. Initiate sepsis checklist
        b. Notify primary care MD
        c. Provide the patient history to the team
        d. Assist team in getting supplies as needed
        e. Reevaluate patient status and any need for rapid response to be called
            i. For unstable patients, call rapid response by dialing 6-1-1. See policy NUR2060 Rapid Response Team Standardized Procedure.
    2. Laboratory Phlebotomist
        a. Obtain blood cultures x 2 and lactic acid
        b. Obtain additional blood specimens as needed
    3. Nursing Supervisor
        a. Direct team members to the room
        b. Release unnecessary personnel
        c. Communicate with family
        d. Communicate with MD
        e. Arrange appropriate bed level with physician if necessary
    4. Primary MD (bedside or phoned)
        a. Team leader
        b. Initiate appropriate sepsis order(s)
            i. Sepsis order set(s)
            ii. Any additional physician orders
E. Documentation
    1. Primary RN to document interventions and response to interventions in E H R

~~I. PURPOSE~~

~~To provide early recognition and treatment of sepsis or septic shock using an evidence-based standardized approach for the management of infection, hemodynamic instability, and organ dysfunction.~~

~~II. POLICY~~

~~A. **Recognition Criteria:** Sepsis is defined as exhibiting at least two of the following signs and symptoms (SIRS) new to the patient with suspicion or confirmed infection.~~

~~1. Temp > 100.9 F or < 96.8 F (>38.3 C or < 36.0 C)~~

~~2. Heart Rate > 90 beats per minute~~

~~3. Respiratory rate > 20 breaths per minute~~

4. WBC count> 12,000/mm3 or <4,000/mm3 or > 10% bands

B. **Septic Shock** is defined as having hypotension (SBP <90), despite adequate fluid resuscitation and / or lactate ≥ 4.

III. DEFINITIONS

A. **Systemic Inflammatory Response (SIRS)**

1. Temperature > 100.9 F or < 96.8 F (>38.3 C or < 36.0 C)

2. Heart Rate > 90 beats per minute

3. Respiration > 20 breaths per minute

4. WBC count > 12,000/mm3 or <4,000/mm3or > 10% bands

B. **Septic shock:** Refractory hypotension (SBP<90) despite adequate IV fluids (30ml/kg bolus) requiring vasoactive medications to maintain MAP ≥ 65 mmHg and lactate > 2mmol/L.

Policy Title	Sepsis Alert for Adults	Policy #	NUR4024

~~Policy Title~~	~~Sepsis Alert~~	~~Policy #~~	~~NUR4024~~

~~C. **Signs of Organ Dysfunction**~~

~~1. New Changes in mental status~~
~~2. Lactic acid > 2.0 mml~~
~~3. Decreased capillary refill or skin mottling~~
~~4. Arterial hypoxemia (Pao2/Fio2 < 300)~~
~~5. Acute oliguria (urine output < 0.5 ml/kg/hr for at least 2 hrs despite adequate fluid resuscitation)~~
~~6. Creatinine increase> 0.5 mg/dl or 44.2 µmol/L~~
~~7. Coagulation abnormalities (INR > 1.5 or aPTT > 60 s)~~
~~8. Ileus (absent bowel sounds)~~
~~9. Thrombocytopenia (platelet count< 100,000 µL-1)~~
~~10. Hyperbilirubinemia (plasma total bilirubin > 4 mg/dL or 70 µmol/L)~~

~~IV. PROCEDURE~~

~~A. Any nurse, physician or allied health professional who identifies a patient meeting septic shock criteria (*refractory hypotension (SBP<90) despite adequate fluid resuscitation (30ml/kg bolus)* or lactate ≥ 4) will:~~

~~Any nurse physician or allied health professional who identifies a patient meeting sepsis recognition criteria will:~~

~~1. Dial 611 and instruct the operator to page a "Sepsis Alert" and indicate the patient location.~~

~~B. The following personnel will respond to the location of a Sepsis Alert:~~

~~1. Rapid Response RN~~
~~2. Primary RN~~
~~3. Respiratory Therapist~~
~~4. Laboratory phlebotomist~~
~~5. Nursing supervisor~~
~~6. Radiology tech~~
~~7. EKG tech.~~
~~8. 8.Primary MD bedside or phoned.~~

Policy Title	Sepsis Alert for Adults	Policy #	NUR4024

~~Policy Title~~	~~Sepsis Alert~~	~~Policy #~~	~~NUR4024~~

~~C. Sepsis Alert Team Roles:~~

~~1. The Rapid Response RN functions as the leader until a physician assumes responsibility of the patient and shall:~~

~~a. Identify him/herself~~
~~b. Assess the patient~~
~~c. Administer oxygen as appropriate~~
~~d. Ensure an adequate airway is maintained~~
~~e. Initiate cardiac monitoring~~
~~f. Ensure two patent IV sites~~
~~g. Initiate a 30ml/kg fluid bolus of LR or 0.9% NS, if not already given~~
~~h. Proceed with RRT Standardized Procedures~~
~~i. Accompany patient to appropriate unit~~
~~j. Document interventions~~

~~2. Primary Care RN~~

~~a. Initiate RRT and/or Sepsis Alert by dialing 611~~
~~b. Initiate Code Sepsis Worksheet~~
~~c. Notify primary care physician~~
~~d. Direct team members to the room~~
~~e. Move other patients out of room (if possible)~~
~~f. Provide the patients history to the team~~
~~g. Assist team in getting supplies as needed~~
~~h. Provide report to RN assuming care of patient~~
~~i. Reevaluate if Rapid Response needs to be called~~

~~3. Nursing supervisor~~

~~a. Arranges appropriate bed level with physician if necessary~~
~~b. Communicates with family~~
~~c. Releases unnecessary personnel~~
~~d. Communicate with MD~~
~~e. Direct team members to the room~~

~~4. Documentation~~

~~a. Primary RN to document interventions and response to interventions in EHR.~~

~~a. Ensures Code Sepsis Worksheet is initiated~~

~~5. Respiratory Therapist~~
~~a. Maintains airway~~
~~b. Initiates appropriate oxygen therapy or adjuncts as needed~~
~~c. Assist physician with advanced airway placement~~
~~d. Secure ventilator and/ or settings as ordered by physician~~
~~6. Laboratory Tech~~

~~a. Obtains sepsis panel and places lactate on ice~~
~~b. Ensures Obtains blood cultures x 2 are obtained~~

~~7. Radiology Tech~~

~~a. Brings portable machine for imaging as needed~~

V. ~~V.~~ REFERENCES

Chakraborty, R. K., & Burns, B. (2020). *Systemic Inflammatory Response Syndrome* PubMed; StatPearls Publishing. https://pubmed.ncbi.nlm.nih.gov/31613449/

Dellinger, RP, Levy, M, Rhodes, A. et al. (2013). Surviving Sepsis Campaign: International guidelines for management of severe sepsis and septic shock: 2012. Critical Care Medicine. (41) 580-637.

Levy, M. M., Evans, L. E., & Rhodes, A. (2018).The Surviving Sepsis Campaign Bundle. *Critical Care Medicine*, *46*(6),997 https://doi.org/10.1097/ccm.0000000000003119

VI. STAKEHOLDERS

~~N/A~~

Sepsis Presentation: suspected infection source AND two or more SIRS Criteria

Infection Assumed to be present-suspected or known			**Infection Source:**	
SIRS Criteria #1 (circle)	**T**>38.3/100.9	**T**<36/96.8	Time:	Date:
	HR>90	**RR**>20		
	WBC>12k	**WBC**<4k		
SIRS Criteria #2 (circle)	**T**>38.3/100.9	**T**<36/96.8	Time:	Date:
	HR>90	**RR**>20		
	WBC>12k	**WBC**<4k		

ED and In-patient: Notify MD of sepsis presentation and confirm need for sepsis alert. ***Sepsis Alert: Dial #6-1-1***

In-patient: For unstable patient. ***Call RRT: Dial #6-1-1***

MD Name_____ Alert called Yes___ No___ If no, rationale: _____

Time Zero (sepsis presentation criteria met): _____

To be *completed* by HOUR 3 from time zero

(3-hour End Time: _____)

	Bundle Component	Time Completed	Initials
1	Obtain lactate. ****If result is ≥ 4mmol/L, requires "shock re-assessment" within 6 hours. See #7 below****	**Draw Time:** **Value:**	
2	Draw Blood Cultures prior to antibiotic		
3	Initiate broad-spectrum IV Antibiotic		
4	30 mL/kg Fluid Bolus: ****Indicated if initial lactate ≥4 mmol/L or patient is hypotensive (2 readings of SBP<90 or MAP<65 with-in 3 hours of each other) **** **If not given, provider must note rational for not giving and amount administered instead**		

To be *completed* by HOUR 6 from time zero

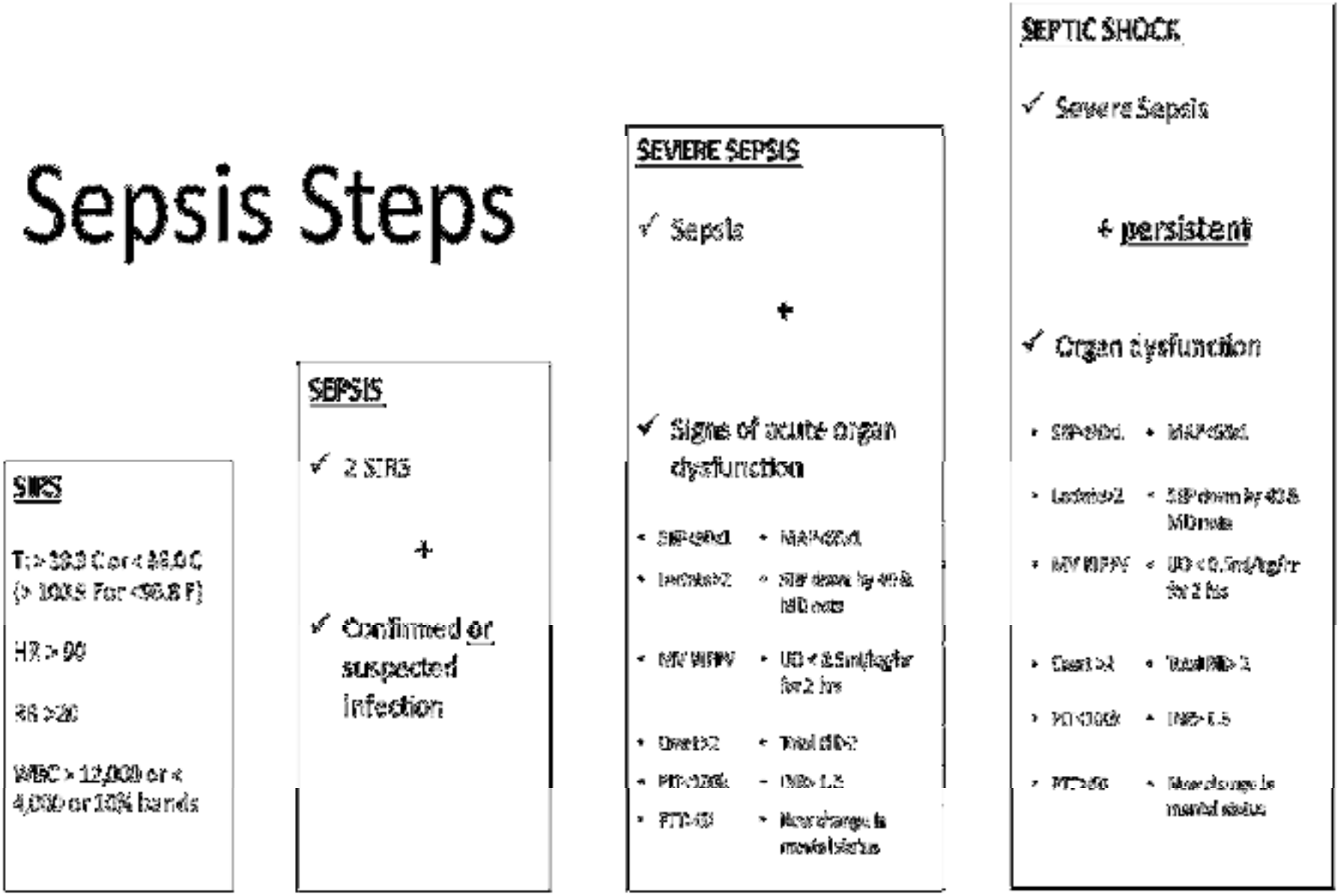
(6-hour end time: _____)

5	Repeat Lactate if initial > 2 mmol/L ****Within 4 hrs., but preferably 2 hrs. depending on fluid administration****	**Draw Time:** **Value:**	
6	For persistent hypotension complete "shock re-assessment" within 6 hours. See #7 below. ****persistent = SBP<90 or MAP < 65 after fluids & vasopressor****	**Shock Time:**	
7	**In the event of persistent hypotension OR initial lactate ≥ 4 mmol/L:** DOCUMENT "SHOCK RE-ASSESSMENT" **within 6 hours** using ONE of the following 3 options:		

Option 1: ASSESS AND DOCUMENT ANY **ONE** OF THE FOLLOWING FOUR:		
1) Measure ScVO2		
2) Measure CVP		
3) Bedside cardiovascular ultrasound		
4) Document dynamic assessment of fluid responsiveness with passive leg raise or fluid challenge (NICOM) "PLR or fluid challenge"		
Option 2: Provider documentation/attestation that a re-perfusion assessment has been performed or reviewed		
Option 3: Provider documentation indicating or attesting to performing or completing a review of *at least five* of the following eight parameters: SpO2, cap refill, cardiopulmonary assessment, peripheral pulses, shock index, skin color or condition, urine output, vital signs.		

Patient Label

Sepsis Steps



Sepsis Bundle Checklist
Form to remain in patient's chart until discharge.
HIM: Not part of the medical record, DO NOT SCAN. Send to Quality Department
09/23 (Rev.09/23)
Watsonville Community Hospital

Patient Label

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: August 30, 2023

Report Type: Discussion

Title: Finance Committee Member Appointments

Recommendation: Pass a **Motion** approving 1) Matko Vranjes, CEO (Senior Executive); 2) Julie Peterson, CFO (Senior Executive); and Jessica Dixon, Controller (Director/Manager) to serve on the Finance Committee.

Contact: Julie Peterson, Chief Financial Officer

Background

The Pajaro Valley Health Care District Hospital Corporation amended and restated bylaws were approved 01/25/2023.

Section 6.5(a) (excerpt)

Finance Committee. The Finance Committee shall consist of a minimum of two (2) Board members, with a total minimum of at least ten (10) persons including the Board Treasurer, two (2) senior executives; two (2) hospital directors or managers, two (2) providers with medical staff privileges at Watsonville Community Hospital i.e. physicians or advanced practice providers and two (2) hospital front line staff. The Finance Committee shall oversee all financial matters for PVHCDH including operating and capital budgets, borrowings and capital planning, audits, material contracts and leases, business plan development and implementation, and facilities and equipment.

Financial Impact: None.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: August 30, 2023
Report Type: Discussion

Title: Isom Advisors Survey Update

Recommendation: Receive and file information from Isom Advisors on survey/voter opinion polls which included: 1) preparing a voter survey to assist District to assess the feasibility of a voter approved funding measure in the District; 2) testing voter attitudes, specific project support, tax tolerances, and overall support for local district funding measure; 3) conducting telephone surveys with a not to exceed amount of 400 voters that match demographics of those voting on proposed election dates; and 4) and producing a written report of findings.

Contact: Matko Vranjes, Interim Chief Executive Officer

Analysis

On April 26, 2023, the Pajaro Valley Health Care District (PVHCD) board received information from Jon Isom, Isom Advisors, a Division of Urban Futures, Inc. on possible 2024 ballot measures for long term goals: 1) to purchase the land and the building from the property owner; and 2) to secure ongoing supplemental property taxes to support operations.

On July 26, the PVHCD passed **Motion 018-2023** approving an agreement with Isom Advisors to perform 1) survey/poll services 2) financial planning services, 3) financial advisory services and 4) Continuing Disclosure services and 5) Annual Debt Transparency Report and Isom Advisor agreeing to perform the Consulting Services pursuant to the terms and conditions of the agreement.

Financial Impact:

A bond issue could support 1) the acquisition of the land and buildings on the hospital site (saving the District ~$4 million per year); 2) the development of second floor space for alternative use (producing income for the District and PVHCDHC); 3) purchase and implementation of new electronic medical record system, 4) acquisition of new imaging equipment to improve quality and access; and 5) fund facility maintenance. Other than the direct costs of survey implementation and tabulation, Isom Advisors services are paid for through the bond financing itself.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: August 30, 2023
Report Type: Discussion

Title: Medical Committees Reports August 2023

Recommendation: Pass a **Motion** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of August 2023; 2) Updated Robotic Surgery Privilege Delineation List; 3) Order Sets: Empiric Sepsis Guidelines by Source, Sepsis Order, Inpatient Adult, ERAS Order Set, General Surgery and ERAS Order Set, Ortho Surgery

Contact: Clay Angel, M.D., Chief of Staff, Chair, Medical Executive Committee

Analysis

At each board meeting the board receives reports from the Medical Executive Committee including the Credentials Report and the Interdisciplinary Practice Credentials Report.

Financial Impact: None.

Attachments:

1-Medical Executive Committee Reports
2-Updated Robotic Surgery Privilege Delineation List
3-Order Sets

WATSONVILLE COMMUNITY HOSPITAL

Medical Executive Committee Summary – August 30, 2023
ITEMS FOR BOARD APPROVAL

Credentials Committee

INITIAL APPOINTMENTS: (7)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Anderson-Smith, Nicole, MD	Neonatology	Pediatrics	Neonatal / Perinatal Medicine, Sedation	08/31/2023 – 07/31/2025
Arodaki, Fadi, DO	Internal Medicine Hospitalist	Medicine	Internal Medicine, NonIntensivist Critical Care Medicine	08/31/2023 – 07/31/2025
Guan, Yuxi, DPM	Podiatry	Surgery	Podiatry, Fluoroscopy	08/31/2023 – 07/31/2025
Mohabir, Anthony, MD	Teleradiology	Medicine	Teleradiology	08/31/2023 – 07/31/2025
Patel, Lincoln, MD	Teleradiology	Medicine	Teleradiology	08/31/2023 – 07/31/2025
Thalken, Gregory, MD	Teleradiology	Medicine	Teleradiology	08/31/2023 – 07/31/2025
Torres, Rosalicia, MD	OB Family Medicine	OBGYN	Core Obstetric Family Medicine	08/31/2023 – 07/31/2025

REAPPOINTMENTS: (5)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Gowda, Alpana, MD	Pain Management / Courtesy	Surgery	Pain Management, Fluoroscopy, Sedation	09/01/2023 - 08/31/2025
Graham, Kyle, MD	OBGYN / Active	OBGYN	OBGYN	09/01/2023 - 08/31/2025
Haberlach, Marissa, DO	Emergency Medicine / Active	Emergency Medicine	Emergency Medicine & Sedation	09/01/2023 - 08/31/2025
Joye, James, DO	Cardiovascular Disease / Active	Medicine	Cardiovascular Disease, Sedation, Fluoroscopy	09/01/2023 - 08/31/2025
Nirady, Alan, DO	Hyperbaric Medicine / Active	Surgery	Hyperbaric Medicine	09/01/2023 - 08/31/2025

MODIFICATION / ADDITION OF PRIVILEGES: (0)

NAME	SPECIALTY / STATUS	Privileges
None		

STAFF STATUS MODIFICATIONS: (15)

NAME	SPECIALTY / DEPARTMENT	RECOMMENDATION
Ahn, Johan, MD	Radiology / Provisional	Release from Proctoring
Bi, Luke, MD	Gastroenterology / Provisional	Release from EGD and Colonoscopy Proctoring
Guzman, Jose, MD	Anesthesiology / Provisional	Release from Proctoring
Haberlach, Marissa, DO	Emergency Medicine / Provisional	Advance to Active Staff
Harmon, Liv, MD	General Surgery / Active	Release from Proctoring

Harkins, Andrew, MD	Pediatrics / Active	Release from Proctoring
Hotchkiss, John, MD	Teleradiology / Provisional	Release from Proctoring
Martin, Andrew, MD	Teleradiology / Provisional	Release from Proctoring; Advance to Telemedicine Staff
Riad, Shareef, MD	Teleradiology / Provisional	Release from Proctoring; Advance to Telemedicine Staff
Thompson, Gregory, MD	Anesthesiology / Provisional	Release from Proctoring; Advance to Active Staff
Wang, Eileen, MD	Pain Management / Provisional	Release from Proctoring
Yellin, Rachelle, DO	Emergency Medicine / Provisional	Release from Proctoring
Bixler, Christopher, MD	Teleneurology / Telemedicine	Voluntary Resignation, 07/20/2023
Frederiksen, Ryan, MD	Teleradiology / Telemedicine	Voluntary Resignation, 07/25/2023
Hashisho, Mazen, MD	Vascular Surgery / Active	Voluntary Resignation, 08/09/2023

TEMPORARY PRIVILEGES: (2)

NAME	SPECIALTY / DEPARTMENT	DATES
Haberlach, Marissa, DO	Emergency Medicine / Emergency Medicine	08/26/2023 - 08/31/2023
Guan, Yuxi, DPM	Podiatry / Surgery	08/11/2023 - 08/31/2023

INTERDISCIPLINARY PRACTICE CREDENTIALS REPORT

Initial Appointment: (2)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Gamble, Lisa, PA-C	Physician Assistant / Allied Health Professional	Emergency Medicine	PA Emergency Medicine	**08/31/2023 – 07/31/2025**
Weiner, Haley, PA-C	Physician Assistant / Allied Health Professional	Emergency Medicine	PA Emergency Medicine	**08/31/2023 – 07/31/2025**

REAPPOINTMENT: (0)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
None				

Temporary Privileges: (2)

NAME	SPECIALTY / DEPARTMENT	DATES
Gamble, Lisa, PA-C	Physician Assistant / Allied Health Professional	**08/14/2023 – 08/30/2023**
Weiner, Haley, PA-C	Physician Assistant / Allied Health Professional	**08/14/2023 – 08/30/2023**

STAFF STATUS MODIFICATIONS: (3)

NAME	SPECIALTY / DEPARTMENT	RECOMMENDATION
Cannon, Susan, CRNA	Nurse Anesthetist / Surgery	Release from Proctoring
Cobb, Katie, PA-C	Physician Assistant / Medicine	Voluntary Resignation, 05/02/2023
Lanes, Aaron, PA-C	Physician Assistant / Surgery	Voluntary Resignation, 07/31/2023

WATSONVILLE COMMUNITY HOSPITAL
DA VINCI SURGICAL ROBOTIC SYSTEM
DELINEATION OF PRIVILEGES
SPECIALTIES OF GENERAL SURGERY, OBSTETRICS & GYNECOLOGY AND UROLOGY

To be eligible for Da Vinci Surgical Robotic System privileges, the applicant must meet the following qualifications:

daVinci assisted case examples will follow the same breakdown as seen with General Surgery Laparoscopy Privileges.

Education and Training:
The physician must have completed an approved residency program in surgery or surgical specialty in an AOA or ACGME approved program. The physician must document certification or demonstrated equivalent competence by the certifying agency of the surgical specialty. The physician must have active privileges to perform the laparoscopic surgery (as described above) for the procedure being performed on the daVinci Surgical Platform.

AND
Must show evidence of training within the past 12 months by attendance at a hands-on training practicum in the use of the daVinci Surgical Platform of at least (8) hours duration with experience in a laboratory setting which includes a minimum of three (3) hours of personal time on the system during animate or cadaver models.

OR
Successful completion of a minimum of 10 computer-assisted robotic procedures within the past 24 months.

Proctoring:
Successful completion of a minimum of two (2) procedures proctored by an expert preceptor (defined as a surgeon who has met the above outlined qualifications for credentialing and has had practice experience in the successful use of the Platform). Additionally, the preceptor will be approved by the Department Chair. Need for additional proctoring, if any, to be recommended by the proctor. All robotic proctoring must be performed by a physician within the same specialty, unless the procedure is common to both specialties. The proctee is responsible to ensure the proper proctor is available and scheduled for the cases. ~~This requirement will be waived with evidence of the successful completion of a minimum 10 cases within the past 24 months.~~

Reappointment:
Regranting of privileges is based on unbiased, objective results of care according to individual departmental peer review mechanisms. The applicant must demonstrate that he/she has maintained competence in the use of the daVinci Surgical Platform during the two-year reappointment cycle with the performance of at least ten (10) procedures during the reappointment cycle.

OTHER CRITERIA:

(a) The performance of this procedure will be carefully monitored through the clinical quality improvement (CQI) process. Among other criteria, time to complete the procedure will be carefully considered in determining the continued eligibility of the surgeon, obstetrician-gynecologist or urologist to perform that procedure.

(b) Each operating surgeon, obstetrician-gynecologist or urologist shall be responsible for having a qualified assistant at the surgical procedure(s) when the operating surgeon, obstetrician-gynecologist or urologist determines, in accordance, with accepted standards of medical practice that surgical assistance is required. Based on the nature of the surgery, the operating surgeon, obstetrician-gynecologist or urologist shall determine the type of surgical assistant required: surgeon, obstetrician-gynecologist, other physician, physician assistant, nurse or technician.

Maintenance Criteria for Continued Privileges – Ongoing Professional Practice Evaluation

For any privileges that are granted during initial credentialing, the Practitioner must perform a minimum of ten (10) da Vinci Surgical Robot Surgical procedures, with acceptable outcomes, over a twenty-four (24) month period to be eligible to reapply for da Vinci Surgical Robot privileges. This will be reviewed at the time of reappointment.

~~W CH~~	REQUESTED	DA VINCI SURGICAL ROBOTIC SYSTEM	~~NUMBER~~ Denied	~~YEAR~~ Deferred	~~LOCATION~~ Approved
	~~DVSR 1~~ ☐	**Da Vinci Surgical Robotic System –** General Surgery			
	☐	Da Vinci Surgical Robotic System – OBGYN Surgery			
	☐	Da Vinci Surgical Robotic System – Urology Surgery			

PRIVILEGES REQUESTED BY:

I have requested only those privileges for which by education, training, current experience, and demonstrated performance I am qualified to perform, and that I wish to exercise at Watsonville Community Hospital, and;

I understand that:

(a) In exercising any clinical privileges granted, I am constrained by hospital and medical staff policies and rules applicable generally and any applicable to the particular situation.

(b) Any restriction on the clinical privileges granted to me is waived in an emergency situation and in such a situation my actions are governed by the applicable section of the medical staff bylaws or related documents.

_____ _____
Signature Date

_____
Print Name

Department Chair (Designee) recommendation

I have reviewed the requested clinical privileges and supporting documentation for the above-named applicant and:

❑ Recommend all requested privileges

❑ Recommend privileges with the following conditions/modifications:

_____

_____

❑ Do not recommend the following requested privileges:

_____

_____

Privilege condition/modification/explanation

_____

_____

Notes: _____

_____

Department Chair (Designee) signature _____ **Date** _____

FOR MEDICAL STAFF USE ONLY

Credentials Committee Action Date: _____

Medical Executive Committee Action Date: _____

Board of Trustees Action Date: _____

~~I have reviewed the requested clinical privileges and supporting documentation for the above named applicant and recommend action on the privileges as noted above.~~

_____ _____

~~Chair, Specialty of Surgery/OB-GYN~~ _____ ~~Date~~
~~Watsonville Community Hospital~~

Approvals:
Credentials: 11/13/15
Medical Executive Committee: 11/17/15
Board of Trustees: 11/18/15

Revised: 4/27/16

Community Acquired Pneumonia = CAP

CAP, LOW Pseudomonas Risk

- Ceftriaxone 2gm IV daily
- PLUS Azithromycin 500mg IV daily
  - or PLUS Levofloxacin 750mg IV daily
  - or PLUS Doxycycline 100mg IV Q12H

CAP, Pseudomonas Risk = immunocompromised, COPD with repeated corticosteroid therapy, structural lung disease or bronchiectasis, recent or repeated antibiotic therapy, and/or have extremes of age

- Azithromycin 500mg IV daily
  - or Levofloxacin 750mg IV daily
- PLUS Zosyn (Piperacillin/Tazobactam) 4.5gm IV Q6H
  - or PLUS Cefepime 2gm IV Q8H

CAP, Pseudomonas Risk w/Beta Lactam Allergy = patient w/known severe reaction to Penicillin or Cephalosporin (e.g., Anaphylaxis, Angioedema)

- Levofloxacin 750mg IV daily

MRSA Suspected (MRSA screen)

- PLUS Vancomycin 20mg/kg (WBD), Pharmacy to dose
  - or Linezolid 600mg IV Q12H … if documented failure or intolerance to Vancomycin or VRE

Critically Ill / Hospital Acquired Pneumonia / High Risk for Multi-Drug Resistant Pathogens

- Cefepime 2gm IV Q8H
  - or Zosyn (Piperacillin/Tazobactam) 4.5gm IV Q6H
    - PLUS Vancomycin 20mg/kg (WBD), Pharmacy to dose …if suspected MRSA
    - PLUS Levofloxacin 750mg IV daily … for "atypicals"
- Meropenem 1gm IV Q8H … if ESBL suspected
    - PLUS Vancomycin 20mg/kg (WBD), Pharmacy to dose …if suspected MRSA
    - PLUS Levofloxacin 750mg IV daily … for "atypicals"

Catheter / Line

- Vancomycin 20mg/kg (WBD), Pharmacy to dose
- PLUS Cefepime 2mg IV Q8H
  - PLUS … if high risk disseminated candida (already on antibiotics or hyperalimentation)
    - Micafungin 100mg IV daily
    - or Fluconazole 400mg IV daily

Urinary Tract Infection

REMINDER: de-escalate based on culture results

- Ceftriaxone 2gm IV daily
  - PLUS Gentamicin 5mg/kg (WBD) IV daily, Pharmacy to dose … if considering Pseudomonas and/or MDRO (e.g., SNF, catheter/stent, repeated antibiotics in past 3 months)
- Levofloxacin 750mg IV daily MONOTHERAPY … if no risk of MDRO
- Meropenem 1gm IV Q8H … if high risk of ESBL

Intra-abdominal

MONOtherapy:

- Zosyn (Piperacillin/Tazobactam) 4.5gm IV Q6H

COMBINATION therapy:

- Ceftriaxone 2gm IV daily
- PLUS Metronidazole 500mg IV Q6H

If severe Penicillin and Cephalosporin reaction (e.g., anaphylaxis):

- Aztreonam 2gm IV Q8H [NOTE: does not cover enterococci or Strep viridans]
- PLUS Metronidazole 500mg IV Q6H

Skin and Soft Tissue

Cellulitis (non-purulent, no wound)

- Cefazolin 2gm IV Q8H

Cellulitis (purulent, wound)

- Vancomycin 20mg/kg (WBD), Pharmacy to dose

Gangrene (diabetic or vascular)

- Vancomycin 20mg/kg (WBD), Pharmacy to dose
  - or Linezolid 600mg IV Q12H … if documented failure or intolerance to Vancomycin or VRE
- PLUS Zosyn (Piperacillin/Tazobactam) 4.5gm IV Q6H

Surgical wound

- Vancomycin 20mg/kg (WBD), Pharmacy to dose
- PLUS Cefepime 2gm IV Q8H

Necrotizing fasciitis

- Zosyn (Piperacillin/Tazobactam) 4.5gm IV Q6H
- PLUS Clindamycin 600mg IV Q8H
- PLUS Vancomycin 20mg/kg (WBD), Pharmacy to dose

Bacterial Meningitis

- Ceftriaxone 2gm IV Q12H
- PLUS Vancomycin 20mg/kg (WBD), Pharmacy to dose
- PLUS Ampicillin 2gm IV Q4H => if immunosuppressed, pregnant or > 50yo (add for Listeria)
- PLUS Acyclovir 10mg/kg IV Q8H => if encephalopathic and suspect HSV

Unknown

- Zosyn (Piperacillin/Tazobactam) 4.5gm IV Q6H – OR - Cefepime 2gm IV Q8H
- PLUS Vancomycin 20mg/kg (WBD), Pharmacy to dose

7/13/2023 JJ met w Dr Korz
Recommendations in blue

Screenshot of Current (Newly Revised) Adult Inpatient Order Set

ADULT- SEPSIS/SIRS

Use this order set in conjunction with General Admit or Critical Care Admit order set.

Start Date/Time Jun-14-2023 16:01

DEFINITIONS- GUIDE THERAPIES

Consider information below when choosing this order set

SIRS CRITERIA - 2 OR MORE

SEPSIS to be defined as probable or documented infection with 2 or more of the SIRS criteria

Temperature < 96.8 F (36 C) or > 100.4 F (38 C)

Heart rate > 90 BPM

Respiratory rate > 20 breaths per minute or PaCO2 below 32mmHg

WBC count > 12,000 or < 4,000, or > 10% bands

SEVERE SEPSIS CRITERIA

Lactate above upper limits lab normal (lactate 4mmol/L or greater)

Urine output < 0.5 mL/kg/hr for more than 2 hours with adequate fluid resuscitation

Sepsis induced hypotension (MAP less than 65 mmHg or SBP less than 90 mmHg)

Acute lung injury with PaO2/FiO2 less than 200 in the PRESENCE of pneumonia as infection source

Acute lung injury with PaO2/FiO2 less than 250 in the ABSENCE of pneumonia as infection source

Creatinine > 2 mg/dL

Bilirubin > 2 mg/dL

Platelet count < 100,000 (25 per cubic mm of blood)

Coagulopathy (INR > 1.5)

SEPTIC SHOCK

Sepsis with refractory hypotension or hypoperfusion abnormalities in the presence of adequate fluid resuscitation

NURSING

- [ ] CONTINUOUS CARDIAC MONITORING, CONT, Routine
- [ ] PULSE OX CONTINUOUS, ONCE, Routine
- [x] MEASURE WEIGHT, QDAY, Routine Modify
- [ ] MEASURE VITAL SIGNS, Q01H x 2 occ, Routine
- [ ] MEASURE VITAL SIGNS, Q01H x 4 occ, Routine
- [ ] URINARY CATHETER INSERTION & MGMT, CONT, Routine
- [x] MONITOR AND RECORD INTAKE AND OUTPUT EVERY SHIFT, QS, Routine Modify
- [x] NOTIFY PROVIDER FOR (SEE COMMENTS), ONCE, Routine Modify
- [ ] PERIPHERALLY INSERTED CENTRAL CATHETER (PICC) - INSERTION AND MANAGEMENT, ONCE, Routine
- [ ] INSERT 2 LARGE-BORE IVs, ONCE, Routine
- [ ] PLACE A SECOND PERIPHERAL IV, ONCE, Routine
- [ ] BED REST, ONCE ROUTINE, CONT, Routine

RESPIRATORY

Reminder to send home patient's own inhaler if using while an inpatieint

RESPIRATORY THERAPY ORDER SET

Enable

SEPSIS IV FLUID

Notify physician if SBP< 90mmHg or MAP <65mmHg Hold IV fluids and notify physician if patient develops shortness of breath, rales Sp02<92, or signs and symptoms of hypoxia

- [ ] SODIUM CHLORIDE 0.9% 250ML BOLUS, IV, NOW
- [ ] SODIUM CHLORIDE 0.9% 500ML BOLUS, IV, NOW
- [ ] SODIUM CHLORIDE 0.9% 1000ML BOLUS, IV, NOW
- [ ] LACTATED RINGERS SOLN 250ML BOLUS, IV, NOW
- [ ] LACTATED RINGERS SOLN 500ML BOLUS, IV, NOW
- [ ] LACTATED RINGERS SOLUTION 1000ML BOLUS, IV, NOW
- [ ] NS 1000ML@, IV
- [ ] NS W KCL 20MEQ/1000ML@, IV
- [ ] D5 1/2NS 1000ML@, IV
- [ ] D5 1/2NS W KCL 20MEQ/1000ML@, IV
- [ ] LACTATED RINGERS@, IV
- [ ] DEXTROSE 5%/LACTATED RINGERS@, IV

ANTIBACTERIAL AGENTS

Administer within 3 hours of arrival to hospital.

Encourage to confirm that cultures have been completed prior to the administration of antibiotics.

Administer appropriate and early treatment (eg, within 1 hour of presumptive diagnosis) with antibiotics

Narrow antibiotic therapy according to results of antimicrobial work-up and other test results

First dose of antibiotic to be given STAT if not already administered.

If a fmoroquinolone (e.g. Levofloxacin) is ordered, ensure EKG and LFT's ordered.

7/13/2023 Jg met ō Dr Kong
Recommendations below in blue

all Vancomycin's
Gent
should include
Pharmacy to dose

SUSPECTED SOURCE: PNEUMONIA

CAP-LOW PSEUDOMONAS RISK

If cefTRIAXone ADD (azithromycin OR doxycycline) OR Levofloxacin

- [ ] CEFTRIAXONE 2 GRAMS EVERY 24 HOURS, IV, Q24H
- [ ] aziTHROMYCIN (ZITHROMAX), 500 MG, ORALLY, Q24H
- [ ] AZITHROMYCIN 500 MG Q24 HOURS, IV, Q24H
- [ ] doxycycline (VIBRAMYCIN), 100 MG, ORALLY, Q12H
- [ ] DOXYCYCLINE 100 MG Q12 HOURS, IV, Q12H
- [ ] levoFLOXACIN (LEVAQUIN), 750 MG, ORALLY, Q24H
- [ ] LEVOFLOXACIN 750 MG PREMIX Q24H, IV, Q24H

CAP-PSEUDOMONAS RISK

Patients who are immunocompromised, have COPD with repeated corticosteroid therapy, structural lung disease or bronchiectasis, recent or repeated antibiotic therapy, and/or have extremes of age are considered high risk for pseudomonas infection

Recommendation: Select either cefepime OR Zosyn AND add azithromycin. OR Levofloxacin

- [ ] CEFEPIME 2G/NS 100ML Q8H, IV, Q8H
- [ ] LEVOFLOXACIN 750 MG PREMIX Q24H, IV, QAM
- [ ] PIPERACILLIN TAZOBAC 4.5GM/NS 100ML Q6H, IV, Q6H
- [ ] AZITHROMYCIN 500 MG Q24 HOURS, IV, Q24H

CAP-BETA LACTAM ALLERGY

For patients with known anaphylactic or severe reaction to penicillin or cephalosporin Recommendation: [illegible] levofloxacin monotherapy

- [ ] AZTREONAM 2 GRAMS EVERY 8 HOURS, IV, Q8H
- [ ] levoFLOXACIN (LEVAQUIN), 750 MG, ORALLY, Q24H
- [ ] LEVOFLOXACIN 750 MG PREMIX Q24H, IV, QAM

MRSA SUSPECTED

Recommendation: Add (vancomycin or linezolid) and order nasal MRSA screen if not already performed. Only use linezolid if documented failure or intolerance to vancomycin-resistant enterococci or vancomycin (VRE)

- [ ] VANCOMYCIN WBD (20 MG/KG) Q24H, IV, Q24H
- [ ] linezolid (ZYVOX), 600 MG, ORALLY, Q12H
- [ ] LINEZOLID 600MG/300ML Q12H, IV, Q12H

~~HIGH RISK MDRO~~

- [ ] ~~MEROPENEM 1000MG/NS100ML Q8H, IV, Q8H~~
- [ ] ~~AZITHROMYCIN 500 MG Q24 HOURS, IV, Q24H~~

CRITICALLY ILL/~~HCAP~~ HAP / MDRO risk

- [ ] CEFEPIME 2G/NS 100ML Q8H, IV, Q8H
- [ ] levoFLOXACIN (LEVAQUIN), 500 MG, ORALLY, Q24H
- [ ] LEVOFLOXACIN 500 MG PREMIX Q24H, IV, Q24H
- [ ] PIPERACILLIN TAZOBAC 4.5GM/NS 100ML Q6H, IV, Q6H
- [ ] VANCOMYCIN 1000 MG/NS 250 ML Q24 HOURS, IV, Q24H

move

Meropenem 1gm Wag²

¶ Cefepime or Zosyn (add levofloxacin to cover atypical; add Vancomycin if risk of MRSA)

¶ Meropenem if risk of ESBL

OTHER MEDICATIONS

- [ ] oseltamivir (TAMIFLU), 75 MG, ORALLY, BID
- [ ] gualFENesin (ROBITUSSIN), 200 MG/10 ML, 100 MG, ORALLY, Q6HPRN for COUGH

DM

SUSPECTED SOURCE:CATHETER/LINE

Vancomycin AND cefepime. (ADD micafungin OR fluconazole if patient was already on antibiotics or hyperalimentation)

- [ ] VANCOMYCIN WBD (20 MG/KG) Q24H, IV, Q24H
- [ ] ~~PIPERACILLIN TAZOBA 3.375GM/NS 100ML Q8H, IV, Q8H~~
- [ ] CEFEPIME 2G/NS 100ML Q8H, IV, Q8H
- [ ] FLUCONAZOLE 400MG/NS 200ML Q24H, IV, Q24H
- [ ] MICAFUNGIN 100MG/100ML Q 24 HOURS, IV, Q24H

or levofloxacin (if no risk of MDRO)

SUSPECTED SOURCE: UTI

Main choice ceftriaxone. If considering pseudomonas or MDRO then add gentamicin (i e SNF, catheter/stent) or repeated antibiotics in past 3 months

- [ ] CEFTRIAXONE 2 GRAMS EVERY 24 HOURS, IV, Q24H
- [ ] LEVOFLOXACIN 750 MG PREMIX Q24H, IV, QAM
- [ ] ~~PIPERACILLIN TAZOBA 3.375GM/NS 100ML Q6H, IV, Q6H~~
- [ ] GENTAMICIN WBD (5 MG/KG ADULT) Q24 HOURS, IV, Q24H
- [ ] ~~CEFEPIME 2GM/NS 100ML Q8H, IV, Q8H~~
- [ ] MEROPENEM 1000MG/NS100ML Q8H, IV, Q8H

OR Meropenem (if high risk ESBL)
Reminder: de-escalate based on culture results.

SUSPECTED SOURCE:INTRA-ABDOMIN

MONOTHERAPY

- [ ] PIPERACILLIN TAZOBAC 4.5GM/NS 100ML Q6H, IV, Q6H

COMBINATION THERAPY

If ceftriaxone ADD metroNIDAZOLE

CEFTRIAXONE/METRONIDAZOLE

- [ ] CEFTRIAXONE 2 GRAMS EVERY 24 HOURS, IV, Q24H
- [ ] METRONIDAZOLE 500 MG/100 ML Q8HOURS, IV, Q8H

AZTREONAM/METRONIDAZOLE

~~FOR PENICILLIN ALLERGY: AZTREONAM 2G IV Q8H AND METRONIDAZOLE 500MG IV Q8H~~

- [ ] AZTREONAM 2 GRAMS EVERY 8 HOURS, IV, Q8H
- [ ] METRONIDAZOLE 500 MG/100 ML Q8HOURS, IV, Q8H

NOTE: Aztreonam does not cover enterococci or Strep viridans

Reserved for patients at high risk of ~~For known anaphylactic or~~ severe reaction to penicillin or cephalosporin, such as anaphylaxis, SJS/TEN, hemolytic anemia, or DRESS syndrome

SUSPECTED SOURCE:SKIN/SOFT TIS

NON-PURULENT CELLULITIS

- (●) None
- ( ) CEFAZOLIN 2G 50ML, IV, Q8H

PURULENT CELLULITIS

- (●) None
- ( ) VANCOMYCIN WBD (20MG/KG), IV, NOW

SUSPECTED SOURCE:GANGRENE

Gangrene, diabetic or vascular wound

VANCOMYCIN/ZOSYN

- [ ] VANCOMYCIN 1G/NS 250ML, IV, Q24H
- [ ] PIPERACILILINL TAZO 4.5G/NS 100ML, IV, Q6H

OR

- (●) None
- ( ) linezolid (ZYVOX), 600 MG, ORALLY, Q12H
- ( ) LINEZOLID 600MG/300ML Q12H, IV, Q12H

only use linezolid if documented failure or intolerance to vancomycin or vancomycin-resistant enterococci (VRE)

SUSPECTED SOURCE:SURG WOUND

- [ ] VANCOMYCIN WBD (20 MG/KG) Q24H, IV, Q24H
- [ ] CEFEPIME 2G/NS100ML, IV, Q8H

SUSPECTED SOURCE:NECROTIZ FASC

ZOSYN/VANCOMYCIN/CLINDAMYCIN

Piperacillin-Tazobactam IV and Vancomycin IV and Clindamycin IV

- [ ] PIPERACILLIN TAZOBAC 4.5GM/NS 100ML Q6H, IV, Q6H
- [ ] VANCOMYCIN WBD (20 MG/KG) Q24H, IV, Q24H
- [ ] CLINDAMYCIN 900 MG EVERY 8 HOURS, IV, Q8H

- [ ] CEFEPIME/FLAGYL/VANCO/CLINDAMY

  Cefepime IV and Metronidazole IV and Vancomycin IV and Clindamycin IV

  - [ ] CEFEPIME 2G/NS 100ML Q12H, IV, Q12H
  - [ ] METRONIDAZOLE 500 MG/100 ML Q8HOURS, IV, Q8H
  - [ ] VANCOMYCIN WBD (20 MG/KG) Q24H, IV, Q24H
  - [ ] CLINDAMYCIN 900 MG EVERY 8 HOURS, IV, Q8H

- [ ] VANCO/AZTREO/FLAGYL/CLINDAMYCI

  Vancomycin IV and Aztreonam IV and Metronidazole IV and Clindamycin IV For severe panicillin and cephalosporin allergy that cannot be challenged

  - [ ] VANCOMYCIN WBD (20 MG/KG) Q24H, IV, NOW
  - [ ] AZTREONAM 2 GRAMS EVERY 8 HOURS, IV, Q8H
  - [ ] METRONIDAZOLE 500 MG/100 ML Q8HOURS, IV, Q8H
  - [ ] CLINDAMYCIN 900 MG EVERY 8 HOURS, IV, Q8H

BACTERIAL MENINGITIS

cefTRIAXone AND vancomycin ADD ampicillin if listeria suspected- Risk factors. AGE>50, PREGNANT or IMMUNOSUPPRESSED. Add acyclovir if suspect HSV.

- [ ] ~~CEFTRIAXONE 2 GRAMS EVERY 12 HOURS, IV, Q12H~~
- [ ] VANCOMYCIN WBD (20MG/KG), IV, NOW
- [ ] AMPICILLIN 2 GRAM EVERY 4 HOURS, IV, Q4H
- [ ] ACYCLOVIR 10 MG/KG (WBD) IV Q8 HOURS, IV, Q8H
- [ ] ~~dexamethasone (DECADRON), (0.15 mg/kg), IM, NOW~~
- [ ] dexamethasone (DECADRON), (0.15 mg/kg), IVP, ~~NOW~~ Q6° x 4 days

SUSPECTED SOURCE: UNKNOWN

(piperacillin-tazobactam OR cefepime) AND vancomycin

- [ ] PIPERACILLIN TAZOBAC 4.5GM/NS 100ML Q6H, IV, Q6H
- [ ] VANCOMYCIN WBD (20MG/KG), IV, NOW
- [ ] CEFEPIME 2G/NS 100ML Q8H, IV, Q8H

LABS

- [x] LACTIC ACID, ONCE, ASAP Modify
- [x] LACTIC ACID, Q03H x 2 occ, Routine Modify
- [x] CBC W/AUTO DIFF, ONCE, Routine Modify
- [ ] METABOLIC BASIC PANEL, ONCE, Routine
- [x] METABOLIC COMPREHENSIVE PANEL, ONCE, Routine Modify
- [ ] ABG LAB AND PUNCTURE
- [ ] CALCIUM, IONIZED, ONCE, Routine
- [ ] MAGNESIUM, BLOOD, ONCE, Routine
- [ ] PHOSPHOROUS, BLOOD, ONCE, Routine
- [ ] PROTIME PT INR, ONCE, Routine
- [ ] PTT, ONCE, Routine
- [ ] TYPE AND SCREEN, ONCE, Routine
- [ ] TROPONIN I, HIGH SENSITIVITY, ONCE, Routine
- [ ] BASIC NATRIURETIC PEPTIDE, BNP, ONCE, Routine
- [ ] PROCALCITONIN (INHOUSE), ONCE, Routine
- [ ] SEDIMENTATION RATE, ONCE, Routine
- [ ] C-REACTIVE PROTEIN, ONCE, Routine
- [ ] PREGNANCY/SERUM HCG, ONCE, Routine
- [ ] CK (CPK), ONCE, Routine

MICRO

- [ ] SPUTUM OR BRONCH CULTURE, ONCE x 1 occ, Routine
- [ ] CULTURE OTHER, ONCE x 1 occ, Routine
- [ ] GRAM STAIN, ONCE x 1 occ, Routine
- [ ] *BLOOD CULTURE X 2
- [ ] NASAL MRSA SCREEN, ONCE x 1 occ, Routine
- [ ] ~~CDIFF BY PCR, ONCE, Routine~~
- [ ] CDIFF TOXIN&GDH W/ RFX TO NAAT, ONCE, Routine
- [ ] RESPIRATORY PANEL PCR BIOFIRE (COVID), ONCE, Routine
- [ ] URINALYSIS/COMPLETE +CULT IF INDICATED, ONCE, Routine

DIAGNOSTIC IMAGING

- [ ] XR CHEST 1V (AP) PORTABLE, ONCE, STAT
- [ ] EKG, ONCE, STAT
- [ ] US ABDOMEN COMPLETE, ONCE, STAT
- [ ] CT ABDOMEN PELVIS W, ONCE, STAT
- [ ] CT ABDOMEN PELVIS WO, ONCE, STAT
- [ ] CT HEAD WO, ONCE, STAT

CONSULTS

- [ ] CONSULT TO CRITICAL CARE, ONCE, Routine
- [ ] CONSULT TO HOSPITALIST, ONCE, Routine
- [ ] CONSULT TO INFECTIOUS DISEASES, ONCE, Routine
- [ ] CONSULT TO NEPHROLOGY, ONCE, Routine
- [ ] CONSULT TO CARDIOLOGY, ONCE, Routine
- [ ] CONSULT TO PULMONOLOGY, ONCE, Routine
- [ ] CONSULT TO PALLIATIVE CARE, ONCE, Routine
- [ ] CONSULT TO CASE MANAGEMENT, ONCE, Routine

GENERAL Surgery Post-Op Order Set

GENERAL

- ☐ ADMIT TO INPATIENT, ONCE, Routine
- ☐ PLACE IN OBSERVATION, ONCE, Routine

CODE STATUS

✓ CODE STATUS FOR PATIENT, ONCE, Routine

Comment -Choice list within the order and it's a required field to select a choice

- ☐ LIMITED CODE, ONCE, Routine

When selecting LIMITED CODE option please select a Limited Code Type Below

- ☐ NO CHEST COMPRESSIONS, ONCE, Routine
- ☐ DO NOT DEFIBRILLATE, ONCE, Routine
- ☐ DO NOT INTUBATE, ONCE, Routine
- ☐ CHEMICAL CODE- MEDICATIONS ONLY, ONCE, Routine

NURSING

Comment – Modified Early Warning Score (MEWS) parameters used in VS orders. MEWS is used on nursing units to monitor patients for clinical deterioration.

VITAL SIGNS

✓ MEASURE VITAL SIGNS PER UNIT POLICY, CONT, Routine

Comment: Notify provider for Temp < 35 or > 38.4, HR < 50 or > 110, SBP < 90 or > 180, RR < 9 or > 24, O2 sat < 90 %

- ☐ MEASURE VITAL SIGNS, Q04H, Routine
  Comment - Notify provider for Temp < 35 or > 38.4, HR < 50 or > 110, SBP < 90 or > 180, RR < 9 or > 24, O2 sat < 90 %
- ☐ MEASURE VITAL SIGNS, Q08H, Routine
  Comment - Notify provider for Temp < 35 or > 38.4, HR < 50 or > 110, SBP < 90 or > 180, RR < 9 or > 24, O2 sat < 90 %

MONITORING

- ☐ ASSESS NEUROVASCULAR CHECKS DISTAL TO OPERATIVE SITE, Q08H, Routine
  Comment -Q08H x 48 hours, then QD.
  - ☐ ASSESS NEUROVASCULAR CHECKS DISTAL TO OPERATIVE SITE, QD, Routine (linked orders)

- ☐ PULSE OXIMETRY CONTINUOUS X24 HRS, CONT, Routine
  Comment -Pulse oximetry x 24 hours, then while asleep
  - ☐ PULSE OXIMETRY CONTINUOUS WHILE ASLEEP, QHS, Routine (linked orders)

ENHANCED RECOVERY PROTOCOL

✓ INITIATE ENHANCED RECOVERY PROTOCOL -CARE PLAN, CONT, Routine

****

This section will collapse.

Comment -Care Plan is inclusive of the following unless contraindicated

Delirium Precautions

- *DELIRIUM PRECAUTIONS -DAYTIME*

  Comment -Keep shades open, lights on, encourage normal routine and maximal mobility. Ensure hearing aids, glasses, and dentures are readily available.

- *DELIRIUM PRECAUTIONS -NIGHT TIME*

  Comment - Allow at least 4 hours of uninterrupted sleep between 2200-0600. Minimize noise, light, and consolidate patient care activities during this time.. Continue with all required medications and assessments.

Aspirations Precautions

- *ORAL CARE -BRUSH TEETH AFTER MEALS AND AT BEDTIME*
- *COUGH AND DEEP BREATHING EVERY 4 HOURS WHILE AWAKE*
- *INCENTIVE SPIROMETER 10 BREATHS EVERY HOUR WHILE AWAKE*
- *ELEVATE HOB UP 30 DEGREES AT ALL TIMES*
- *OOB TO CHAIR WITH MEALS, AT LEAST TWICE DAILY FOR 2 HOURS AS TOLERATED*

Activity

- *MOBILIZE PATIENT PER BEDSIDE MOBILITY ASSESSMENT TOOL (BMAT) ASSESSMENT WITHIN 12 HOURS OF OR EXIT*
- *PROGRESSIVE AMBULATION PER BMAT ASSESSMENT 3 X PER DAY*
- *CONTACT PROVIDER FOR PHYSICAL THERAPY CONSULT IF INDICATED PER BMAT*

****

INTAKE & OUTPUT

☐ MEASURE INTAKE & OUTPUT PER UNIT POLICY, CONT, Routine

✓ MONITOR FOR LOW URINE OUTPUT, Q08H, Routine

Comment - Notify provider if urine output less than 240 mL in 8 hours.

✓ INITIATE LOW URINE OUTPUT –NRSG CARE PLAN, CONT, Routine

****

This section will collapse.

Comment -Care Plan is inclusive of the following

BLADDER SCAN Instructions

- *Perform bladder scan if patient has any of the following*
  - *Void less than 240mL in past 8 hours*

- *Has not voided within 6 hours of indwelling catheter removal*
- *Has not voided within 4 hours post-operatively*
- *Symptoms – bladder distension, inability to void despite urge or discomfort, or new-onset incontinence*

- *For bladder scan volume less than 300mL*
  - *Encourage oral fluid intake (if allowed) and repeat bladder scan within 4 hours if patient has not voided*
  - *If patient still voids less than 240mL in 8 hours, notify provider*
- *For bladder scan volume 300mL to 500mL*
  - *If patient has no symptoms-*
  - *Encourage oral fluid intake (if allowed) and repeat bladder scan within 4 hours if patient has not voided (repeat sooner if symptoms develop)*
  - *If patient still voids less than 240mL in 8 hours, notify provider*

  - *If patient has symptoms – bladder distension, inability to void despite urge or discomfort, or new-onset incontinence*
  - *Perform Straight catheter in and out and repeat bladder scan within 4 hours if patient has not voided*
  - *Repeat Straight catheter x 1 if patient has not voided*
  - *If patient still has not voided after 2 straight catheterizations within 12 hours notify provider*

  - *For bladder scan volume greater than 500ml*
  - *Perform Straight catheter in and out and repeat bladder scan within 4 hours if patient has not voided*
  - *Repeat Straight catheter x 1 if patient has not voided*
  - *If patient still has not voided after 2 straight catheterizations within 12 hours notify provider*

****

WOUND CARE

- ☐ WOUND CARE- PHYSICIAN TO CHANGE FIRST POSTOPERATIVE DRESSING, REINFORCE PRN, ONCE, ROUTINE
- ☐ DRY DRESSING CHANGE STARTING ON POST-OP DAY 2, QD, Routine
  Comment -Once a day and as needed to keep wound clean and dry
- ☐ REINFORCE DRESSING, PRN, Routine
  Comment -As needed for saturation
- ☐ REPLACE DRESSING, PRN, Routine
  Comment -As needed for saturation
- ☐ WOUND DRAIN TO SUCTION -MEASURE AND RECORD OUTPUT, QSH, Routine
- ☐ WOUND DRAIN TO SUCTION – CLAMPING DRAIN, PRN, Routine
  Comment -Inclusive of the following

(1) WOUND DRAINAGE GREATER THAN 300 ML IN 3 HOURS

Comment -CLAMP DRAIN 1 HOUR AND RELEASE

(2) WOUND DRAINAGE GREATER THAN 300 ML IN 3 HOURS,

Comment - CLAMP DRAIN 2 HOURS AND RELEASE

(3) WOUND DRAINAGE GREATER THAN 300 ML IN 3 HOURS

Comment - CLAMP AND NOTIFY SURGEON

DIET

Comment -Patients should receive nutrition within 12 hours of OR exit time unless contraindicated. Please indicate diet type from the selection.

✓ PROVIDE NUTRITION WITHIN 12 HOURS OF OR EXIT TIME, ONCE, Routine

✓ JUVEN NUTRITIONAL SUPPLEMENT START POD 0, RECORD PERCENTAGE CONSUMED, BID, Routine

Comment -at Breakfast and Dinner

✓ ENSURE COMPACT BID, SERVE AT 10AM AND 2PM, RECORD PERCENTAGE CONSUMED, BID, Routine

- ☐ DIET REGULAR, ONCE, Routine
- ☐ DIET CARDIAC, ONCE, Routine
- ☐ DIET RENAL, ONCE, Routine
- ☐ DIET RENAL NO PROTEIN RESTRICT, ONCE, Routine
- ☐ DIET 2GM SODIUM, ONCE, Routine
- ☐ DIET GI SOFT, ONCE, Routine
- ☐ DIET MECH SOFT, ONCE, Routine
- ☐ DIET PUREE, ONCE, Routine
- ☐ DIET CLEAR LIQUID, ONCE, Routine
- ☐ DIET FULL LIQUID, ONCE, Routine
- ☐ DIET DIABETIC CARDIAC, ONCE, Routine
- ☐ DIET DIABETIC (CONSISTNT CARB), ONCE, Routine
- ☐ DIET DIABETIC 2GM SODIUM, ONCE, Routine
- ☐ DIET DIABETIC RENAL, ONCE, Routine
- ☐ DIET DIABETIC CLEAR LIQUID, ONCE, Routine
- ☐ DIET DIABETIC FULL LIQUID, ONCE, Routine
- ☐ DIET NPO, ONCE, Routine
- ☐ DIET NPO AFTER MIDNIGHT, ONCE, Routine

Comment -ENTER START DATE/TIME ON ORDER FOR NPO

- ☐ DIET NPO EXCEPT MEDICATIONS, ONCE, Routine

MEDICATIONS

INFECTION PREVENTION MEASURES

✓ RN TO CHECK THE TIME OF LAST DOSE OF ANTIBIOTICS ADMINISTERED IN PREOP/INTROP TO CONFIRM TIMING OF THE NEXT 2 DOSES, ONCE, Routine

Post-Op Antibiotics

☐ ceFAZolin (ANCEF), 1 GRAMS, IV, EVERY 8 HOURS X 2 DOSES
Comment – Enter start time of next dose (8 hours after pre-op dose)

✓ ceFAZolin (ANCEF), 2 GRAMS, IV, in Dextrose, EVERY 8 HOURS X2 DOSES,
Comment – Enter start time of next dose (8 hours after pre-op dose)

Post-Op Antibiotics for Patients With Cephalosporin or Severe Penicillin Allergy

☐ Clindamycin (CLEOCIN), 900 MG, IV, EVERY 8 HOURS X2 DOSES
Comment – Enter start time of next dose (8 hours after pre-op dose)

☐ Vancomycin (VANCOCIN), 1 GRAM, IV, EVERY 12 HOURS Every X1 DOSE
Comment – Enter start time of next dose (12 hours after pre-op dose)

POST OP VTE PROPHYLAXIS

Comments -Pharmacologic prophylaxis is recommended unless contraindicated. If contraindicated, then use mechanical prophylaxis and select the appropriate Reason Not Ordered below.

*Caution ordering Enoxaparin (LOVENOX)
-Spinal/epidural hematoma risk in patients with epidural, spinal, or lumbar puncture.
-Do not order if patient on heparin.

VTE EXCLUSION CRITERIA: duration of surgery less than or equal to 60 minutes, performed entirely by laparoscope, patient age less than 18 years, or hospital length of stay less than or equal to 3 days.

Mechanical VTE Prophylaxis

✓ APPLY SEQUENTIAL COMPRESSION DEVICE (SCD WHILE IN BED), CONT, Routine

☐ APPLY VENOUS FOOT PUMPS, CONT, Routine

Pharmacologic VTE Prophylaxis

Comments
-Single shot spinal or epidural do NOT give Lovenox for at least 4hrs of OR exit time
Use LOW DOSE Enoxaparin for patients with renal failure (creatinine clearance less than 30mL/min)

*For patient with epidural, order Heparin 5,000 Units SQ injection Q 12 hours
*For patient WITHOUT epidural order Heparin 5,000 Units SQ injection Q 8 hours

✓ Aspirin EC (ECOTRIN), 81 MG TBEC, 81 MG, ORALLY, BID
Comments -Start POD 1 at 0900

☐ Enoxaparin (LOVENOX), 30 MG/0.3 ML, 30 MG, SUBCUT, Q12H

Comment -Enter start time (Start within 24 hrs of OR start time)

☐ Enoxaparin (LOVENOX), 40 MG/0.4 ML, 40 MG, SUBCUT, Q24H
Comment -Enter start time (Start within 24 hrs of OR start time)

☐ Enoxaparin (LOVENOX), 30 MG/0.3 ML, 30 MG, SUBCUT, Q24H
Comment -for CrCl < 30 ml/min. Enter start time (Start within 24 hrs of OR start time)

☐ Warfarin (COUMADIN)[HD-1A], 7.5 MG, ORALLY, NOW

☐ Warfarin (COUMADIN)[HD-1A], 7.5 MG, ORALLY, BEDTIME
Comment: Pharmacy to adjust per protocol

☐ Heparin sodium (PORCINE), 5000 UNITS/ML, 5000 UNITS, SUBCUT, Q12H
Comment -For patient with epidural

☐ Heparin sodium (PORCINE), 5000 UNIT/ML, 5000 UNITS, SUBCUT, Q8H
Comment -For patient WITHOUT epidural

ANTIEMETIC MEDICATIONS

Concomitant Antiemetic

☐ Dexamethasone (DECADRON), 8 MG, IV, ONE UNSCHEDULED
Comment -if not already given in periop

First Line Antiemetic

✓ ondansetron (ZOFRAN)ODT, 4 MG, ORALLY, Q6HPRN for NAUSEA-VOMITING
Comment - May repeat X1

Second Line Antiemetic

☐ metoclopramide (REGLAN), 5 MG/ML, 10 MG, IVP, Q6HPRN for NAUSEA-VOMITING

Comment - Use only when first line medication is ineffective or not ordered.

☐ PRIORITY OF USE FOR ANTIEMETICS IF MORE THAN ONE ORDERED – ONDANSETRON FIRST THEN METOCLOPRAMIDE, CONT, Routine (linked order)

No Sedatives of Hypnotics for sleep

✓ DO NOT ADMINISTER SEDATIVE OR HYPNOTICS FOR SLEEP (unless clinically indicated as determined by the provider), CONT, Routine

PAIN CONTROL

Comment –
* Avoid ordering additional narcotics, sedative, or CNS depressants outside of this section* (Patients are considered opioid tolerant if they are taking the equivalent of ORAL Morphine 60 mg/day for at least 1 week).

For Opiate Tolerant patients: Resume home medication regimen.

*Acetaminophen (TYLENOL)
-Around the Clock (for patients age LESS than 65 years)
-DO NOT exceed cumulative 4,000 mg acetaminophen via any route (oral, rectal, IV) in 24 hours. Confirm the 24 hours amount of acetaminophen administered prior to ordering.
-Use caution in patients with liver disease as can cause severe hepatotoxicity.
-Use caution in patients with severe renal impairment (creatinine clearance 30 mL/min or Less).
-May administer via ORAL, NG or Feeding Tube.

✓ RN TO CHECK THE TIME OF LAST DOSE OF ACETAMINOPHEN ADMINISTERED TO CONFIRM TIMING OF THE NEXT DOSE, ONCE, Routine

✓ acetaminophen (TYLENOL), 500 MG TABS, 1000 MG, ORALLY, Q6H
Comment -start 6 hours after last dose.

☐ acetaminophen (TYLENOL), 500 MG TABS, 1000 MG, ORALLY, Q6H x 24 HOURS
Comment -For patient weight greater than 50 KG. *S*tart 6 hours after last dose.

☐ acetaminophen (TYLENOL), 500 MG TABS, 1000 MG, ORALLY, Q8H
Comment - Patient age GREATER than 65 years, liver disease or severe renal impairment. Start 8 hours after last dose. DO NOT exceed cumulative 3000 MG in 24 hours.

NSAIDs

Comments –
-Minimize the use of NSAIDs in patient age GREATER than 64 years or with decreased renal function.
-If only Aspirin for VTE prophylaxis, consider use of non-selective NSAIDs.
-Ketorolac is contraindicated in patients with advanced renal impairment or at risk for renal failure.

☐ ketorolac inj (TORADOL), 30 MG/ML, 15 MG, IVP, Q6H X 24 HOURS

Comment -for Elderly, Low Body Weight or Renal Insufficiency.
☐ Then ibuprofen (MOTRIN), 400 MG, ORALLY, Q6H (ATC) (linked order)

☐ ibuprofen (MOTRIN), 400 MG, ORALLY, Q6H (ATC)
Comment - for Elderly, Low Body Weight or Renal Insufficiency

☐ ketorolac inj (TORADOL), 30 MG/ML, 30 MG, IVP, Q6H X 24 HOURS
☐ Then ibuprofen (MOTRIN), 600 MG, ORALLY, Q6H (linked order)

☐ ibuprofen (MOTRIN), 600 MG, ORALLY, Q6H (ATC)

Mild Breakthrough Pain Management

✓NRSG CARE- APPLY ICE PACK, REPOSITIONING, MOBILIZATION AS NEEDED FOR MILD PAIN (scale 1-3), PRN, Routine

GENERAL Surgery Post-Op Order Set

Moderate Breakthrough Pain Medication

Comment - *Clinician to select one pain medication only with the preferred choice already pre-selected for Moderate and Severe Breakthrough Pain Medication sections.

Moderate Breakthrough Pain Medication (for Patient age LESS than 65 years and NO Delirium / Dementia Risk Factors)

✓ oxyCODONE ORAL 5 MG/5ML SOLN 5 ML, 5 MG, ORALLY, Q6HPRN

Comment -For moderate (scale 4-6) BREAKTHROUGH pain. (May administer via ORAL, NG, or Feeding Tube)

☐ morPHINE (PF), 2 MG/ML, 2 MG, IVP, Q2HPRN

Comment -For moderate (scale 4-6) BREAKTHROUGH pain.

- ☐ RN TO CALL PROVIDER IF 2 DOSES OF MORPHINE ARE ADMINISTERED WITHIN 8 HOURS TO RE-EVALUATE THE PAIN MEDICATION ORDER, CONT, Routine (linked order)

☐ HYDROmorphone (DILAUDID) PF 0.5 MG/ 0.5 ML SOLN 0.5 ML, 0.2 MG, IVP, Q2HPRN

Comment -For moderate (scale 4-6) BREAKTHROUGH pain.

- ☐ RN TO CALL PROVIDER IF 2 DOSES OF HYDROMORPHONE ARE ADMINISTERED WITHIN 8 HOURS TO RE-EVALUATE THE PAIN MEDICATION ORDER, CONT, Routine (linked order)

Moderate Breakthrough Pain Medication (for Patient age GREATER than 65 years and/or with Delirium / Dementia Risk Factors)

Comment- *ORAL OPIOIDS may be contraindicated with Tramadol

☐ traMADol HCL (ULTRAM), 50 MG, ORALLY, Q6HPRN

Severe Breakthrough Pain Medication (for Patient age LESS than 65 years and NO Delirium / Dementia Risk Factors)

Comment - *Clinician to select one pain medication only with the preferred choice already pre-selected for Moderate and Severe Breakthrough Pain Medication sections.

✓ oxyCODONE ORAL 5 MG/5ML SOLN 5 ML, 10 MG, ORALLY, Q6HPRN

Comment -For severe (scale 7-10) BREAKTHROUGH pain. (May administer via ORAL, NG, or Feeding Tube)

☐ morPHINE (PF), 4 MG/ML, 4 MG, IVP, Q2HPRN

Comment - For severe (scale 7-10) BREAKTHROUGH pain

- ☐ RN TO CALL PROVIDER IF 2 DOSES OF MORPHINE ARE ADMINISTERED WITHIN 8 HOURS TO RE-EVALUATE THE PAIN MEDICATION ORDER, CONT, Routine (linked order)

☐ HYDROmorphone (DILAUDID) PF 0.5 MG/ 0.5 ML SOLN 0.5 ML, 0.5 MG, IVP, Q2HPRN

Comment - For severe (scale 7-10) BREAKTHROUGH pain

- ☐ RN TO CALL PROVIDER IF 2 DOSES OF HYDROMORPHONE ARE ADMINISTERED WITHIN 8 HOURS TO RE-EVALUATE THE PAIN MEDICATION ORDER, CONT, Routine (linked order)

BOWEL CARE

- ✓ HOLD LAXATIVE FOR LOOSE STOOL, CONT, Routine

Scheduled Laxatives

- ☐ docusate sodium (COLACE) 100 MG CAPS, 100 MG, ORALLY, BID
- ✓ docusate sodium (COLACE) 250 MG CAPS, 250 MG, ORALLY, BID

  Comment -Start first dose today at 1800.
- ☐ polyethylene glycol (MIRALAX), 17 GM, ORALLY, Q24H
- ✓ SENNA, 8.6 MG TABS, 8.6 MG ORALLY, BID

AS NEEDED Laxatives

- ✓ PRIORITY OF USE IF MORE THAN ONE PRN LAXATIVE MEDICATION ORDERED, ADMINISTER MAGNESIUM HYDROXIDE (MOM) FIRST, IF INEFFECTIVE AFTER 24 HOURS, ADMINISTER LACTULOSE, THEN DULCOLAX), CONT, Routine
- ✓ magnesium hydrox (MOM) 7.75%, 400 MG/5 ML, 2400 MG, 30 ML, ORALLY, BIDPRN

  Comment -for CONSTIPATION. Caution in patients with renal impairment, hold for severe renal impairment.
- ✓ lactulose (CEPHULAC) 20 GM/30 ML SOLN, 30 ML, ORALLY, BIDPRN
  - ✓ Give as first line therapy Milk of Magnesia if lactulose is also ordered. If no bowel movement within 24 hours, give second line therapy if ordered, CONT, Routine. (linked order)
- ✓ DULCOLAX, 10 MG, REC, DAILYPRN for CONSTIPATION

  Comment -Give if no bowel movement for 2 days and other laxatives ineffective.

ORTHO Surgery Post-Op Order Set

GENERAL

- ☐ ADMIT TO INPATIENT, ONCE, Routine
- ☐ PLACE IN OBSERVATION, ONCE, Routine

CODE STATUS

- ✓ CODE STATUS FOR PATIENT, ONCE

Comment -Choice list within the order and it's a required field to select a choice

- ☐ LIMITED CODE, ONCE, Routine

When selecting LIMITED CODE option please select a Limited Code Type Below

- ☐ NO CHEST COMPRESSIONS, ONCE, Routine
- ☐ DO NOT DEFIBRILLATE, ONCE, Routine
- ☐ DO NOT INTUBATE, ONCE, Routine
- ☐ CHEMICAL CODE- MEDICATIONS ONLY, ONCE, Routine

NURSING

Comment – Modified Early Warning Score (MEWS) parameters used in VS orders. MEWS is used on nursing units to monitor patients for clinical deterioration.

VITAL SIGNS

- ✓ MEASURE VITAL SIGNS PER UNIT POLICY, CONT, Routine

  Comment: Notify provider for Temp < 35 or > 38.4, HR < 50 or > 110, SBP < 90 or > 180, RR < 9 or > 24, O2 sat < 90 %
- ☐ MEASURE VITAL SIGNS, Q04H, Routine
  Comment - Notify provider for Temp < 35 or > 38.4, HR < 50 or > 110, SBP < 90 or > 180, RR < 9 or > 24, O2 sat < 90 %
- ☐ MEASURE VITAL SIGNS, Q08H, Routine
  Comment - Notify provider for Temp < 35 or > 38.4, HR < 50 or > 110, SBP < 90 or > 180, RR < 9 or > 24, O2 sat < 90 %

MONITORING

- ☐ ASSESS NEUROVASCULAR CHECKS DISTAL TO OPERATIVE SITE, Q08H, Routine
  Comment -Q08H x 48 hours, then QD.
  - ☐ ASSESS NEUROVASCULAR CHECKS DISTAL TO OPERATIVE SITE, QD, Routine (linked orders)

- ☐ PULSE OXIMETRY CONTINUOUS X24 HRS, CONT, Routine
  Comment -Pulse oximetry x 24 hours, then while asleep
  - ☐ PULSE OXIMETRY CONTINUOUS WHILE ASLEEP, QHS, Routine (linked orders)

MOBILITY

- ✓ Consult to Physical Therapy

  Comment -evaluate and begin treatment on day of surgery, then twice a day

- ☐ Physical Therapy POD #1 – Anterior Approach
- ☐ Physical Therapy POD #1 – Posterior Approach

WEIGHT-BEARING

- ☐ LOG ROLL- DO NOT TURN TO AFFECTED SIDE, Q2H, ROUTINE, ROUT, Routine
- ☐ RLE WEIGHT BEARING AS TOLERATED, ROUTINE, ROUT, Routine
- ☐ RLE PARTIAL WEIGHT BEARING, ROUT, ROUTINE, ROUT, Routine
- ☐ RLE TOE TOUCH WEIGHT BEARING, ROUT, ROUTINE, ROUT, Routine
- ☐ RLE NON WEIGTH BEARING, ROUT, ROUTINE, ROUT, Routine
- ☐ LLE WEIGHT BEARING AS TOLERATED, ROUT, ROUTINE, ROUT, Routine
- ☐ LLE PARTIAL WEIGHT BERING, ROUT, ROUTINE, ROUT, Routine
- ☐ LLE TOE TOUCH WEIGHT BEARING, ROUT, ROUTINE, ROUT, Routine
- ☐ LLE NON-WEIGHT BEARING, ROUT, ROUTINE, ROUT, Routine
- ☐ PROVIDE OVERHEAD TRAZPEZE BAR, ROUT, ROUTINE, ROUT, Routine
- ☐ ELEVATE AFFECTED EXTREMITY ON PILLOW, ROUT, ROUTINE, ROUT, Routine
- ☐ APPLY ADDUCTION DEVICE, ROUT, ROUTINE, ROUT, Routine
- ☐ APPLY SLING, ROUT, ROUTINE, ROUT, Routine
- ☐ APPLY KNEE IMMOBILIZER, ROUT, ROUTINE, ROUT, Routine
- ☐ APPLY SHOULDER IMMOBILIZER, ROUT, ROUTINE, ROUT, Routine
- ☐ APPLY SPLINT, ROUT, ROUTINE, ROUT, Routine
- ☐ APPLY HEEL PROTECTORS, ROUT, ROUTINE, ROUT, Routine
- ☐ APPLY SACRAL PROTECTOR, ROUT, ROUTINE, ROUT, Routine
- ☐ BUCKS TRACTION- APPLY TO AFFECTED EXTREMITY USING 5LBS, ROUT, ROUTINE, ROUT, Routine
- ☐ POSTERIOR HIP DISLOCATION PRECAUTIONS, ROUT, ROUTINE, ROUT, Routine
- ☐ ANTERIOR HIP DISLOCATION PRECAUTIONS, ROUT, ROUTINE, ROUT, Routine
- ☐ GATCH FOOT OF BED TO FIRST DETENTE. UNGATCH WHEN GETTING IN AND OUT OF BED AND WHEN ELEVATION BECOMES UNCOMFORTABLE OR INTERFERES WITH SLEEP, ROUT, ROUTINE, ROUT, Routine
- ☐ DEVICE- CONTINUOUS PASSIVE MOTION (CPM), ROUT, Routine

ENHANCED RECOVERY PROTOCOL

✓ INITIATE ENHANCED RECOVERY PROTOCOL -CARE PLAN, CONT, Routine

****

This section will collapse.

Comment -Care Plan is inclusive of the following unless contraindicated

Delirium Precautions

- *DELIRIUM PRECAUTIONS -DAYTIME*

  Comment -Keep shades open, lights on, encourage normal routine and maximal mobility. Ensure hearing aids, glasses, and dentures are readily available.

- *DELIRIUM PRECAUTIONS -NIGHT TIME*

Comment - Allow at least 4 hours of uninterrupted sleep between 2200-0600. Minimize noise, light, and consolidate patient care activities during this time.. Continue with all required medications and assessments.

Aspirations Precautions

- *ORAL CARE -BRUSH TEETH AFTER MEALS AND AT BEDTIME*
- *COUGH AND DEEP BREATHING EVERY 4 HOURS WHILE AWAKE*
- *INCENTIVE SPIROMETER 10 BREATHS EVERY HOUR WHILE AWAKE*
- *ELEVATE HOB UP 30 DEGREES AT ALL TIMES*
- *OOB TO CHAIR WITH MEALS, AT LEAST TWICE DAILY FOR 2 HOURS AS TOLERATED*

Activity

- *MOBILIZE PATIENT PER BEDSIDE MOBILITY ASSESSMENT TOOL (BMAT) ASSESSMENT WITHIN 12 HOURS OF OR EXIT*
- *PROGRESSIVE AMBULATION PER BMAT ASSESSMENT 3 X PER DAY*
- *CONTACT PROVIDER FOR PHYSICAL THERAPY CONSULT IF INDICATED PER BMAT*

****

INTAKE & OUTPUT

☐ MEASURE INTAKE & OUTPUT PER UNIT POLICY, CONT, Routine

✓ MONITOR FOR LOW URINE OUTPUT, Q08H, Routine

Comment - Notify provider if urine output less than 240 mL in 8 hours.

✓ INITIATE LOW URINE OUTPUT –NRSG CARE PLAN, CONT, Routine

****

This section will collapse.

Comment -Care Plan is inclusive of the following

BLADDER SCAN Instructions

- *Perform bladder scan if patient has any of the following*
  - *Void less than 240mL in past 8 hours*
  - *Has not voided within 6 hours of indwelling catheter removal*
  - *Has not voided within 4 hours post-operatively*
  - *Symptoms – bladder distension, inability to void despite urge or discomfort, or new-onset incontinence*
- *For bladder scan volume less than 300mL*
  - *Encourage oral fluid intake (if allowed) and repeat bladder scan within 4 hours if patient has not voided*
  - *If patient still voids less than 240mL in 8 hours, notify provider*
- *For bladder scan volume 300mL to 500mL*
  - *If patient has no symptoms-*

- *Encourage oral fluid intake (if allowed) and repeat bladder scan within 4 hours if patient has not voided (repeat sooner if symptoms develop)*
- *If patient still voids less than 240mL in 8 hours, notify provider*

- *If patient has symptoms – bladder distension, inability to void despite urge or discomfort, or new-onset incontinence*
- *Perform Straight catheter in and out and repeat bladder scan within 4 hours if patient has not voided*
- *Repeat Straight catheter x 1 if patient has not voided*
- *If patient still has not voided after 2 straight catheterizations within 12 hours notify provider*

- *For bladder scan volume greater than 500ml*
- *Perform Straight catheter in and out and repeat bladder scan within 4 hours if patient has not voided*
- *Repeat Straight catheter x 1 if patient has not voided*
- *If patient still has not voided after 2 straight catheterizations within 12 hours notify provider*

****

WOUND CARE

- ☐ WOUND CARE- PHYSICIAN TO CHANGE FIRST POSTOPERATIVE DRESSING, REINFORCE PRN, ONCE, ROUTINE
- ☐ DRY DRESSING CHANGE STARTING ON POST-OP DAY 2, QD, Routine
  Comment -Once a day and as needed to keep wound clean and dry
- ☐ REINFORCE DRESSING, PRN, Routine
  Comment -As needed for saturation
- ☐ REPLACE DRESSING, PRN, Routine
  Comment -As needed for saturation
- ☐ WOUND DRAIN TO SUCTION -MEASURE AND RECORD OUTPUT, QSH, Routine
- ☐ WOUND DRAIN TO SUCTION – CLAMPING DRAIN, PRN, Routine
  Comment -Inclusive of the following

(1) WOUND DRAINAGE GREATER THAN 300 ML IN 3 HOURS

Comment -CLAMP DRAIN 1 HOUR AND RELEASE

(2) WOUND DRAINAGE GREATER THAN 300 ML IN 3 HOURS,

Comment - CLAMP DRAIN 2 HOURS AND RELEASE

(3) WOUND DRAINAGE GREATER THAN 300 ML IN 3 HOURS

Comment - CLAMP AND NOTIFY SURGEON

DIET

Comment -Patients should receive nutrition within 12 hours of OR exit time unless contraindicated. Please indicate diet type from the selection.

✓ PROVIDE NUTRITION WITHIN 12 HOURS OF OR EXIT TIME, ONCE, Routine

✓ JUVEN NUTRITIONAL SUPPLEMENT START POD 0, RECORD PERCENTAGE CONSUMED, BID, Routine

Comment -at Breakfast and Dinner

✓ ENSURE COMPACT BID, SERVE AT 10AM AND 2PM, RECORD PERCENTAGE CONSUMED, BID, Routine

- ☐ DIET REGULAR, ONCE, Routine
- ☐ DIET CARDIAC, ONCE, Routine
- ☐ DIET RENAL, ONCE, Routine
- ☐ DIET RENAL NO PROTEIN RESTRICT, ONCE, Routine
- ☐ DIET 2GM SODIUM, ONCE, Routine
- ☐ DIET GI SOFT, ONCE, Routine
- ☐ DIET MECH SOFT, ONCE, Routine
- ☐ DIET PUREE, ONCE, Routine
- ☐ DIET CLEAR LIQUID, ONCE, Routine
- ☐ DIET FULL LIQUID, ONCE, Routine
- ☐ DIET DIABETIC CARDIAC, ONCE, Routine
- ☐ DIET DIABETIC (CONSISTNT CARB), ONCE, Routine
- ☐ DIET DIABETIC 2GM SODIUM, ONCE, Routine
- ☐ DIET DIABETIC RENAL, ONCE, Routine
- ☐ DIET DIABETIC CLEAR LIQUID, ONCE, Routine
- ☐ DIET DIABETIC FULL LIQUID, ONCE, Routine
- ☐ DIET NPO, ONCE, Routine
- ☐ DIET NPO AFTER MIDNIGHT, ONCE, Routine

Comment -ENTER START DATE/TIME ON ORDER FOR NPO

- ☐ DIET NPO EXCEPT MEDICATIONS, ONCE, Routine

MEDICATIONS

NFECTION PREVENTION MEASURES

✓ RN TO CHECK THE TIME OF LAST DOSE OF ANTIBIOTICS ADMINISTERED IN PREOP/INTROP TO CONFIRM TIMING OF THE NEXT 2 DOSES, ONCE, Routine

Post-Op Antibiotics

- ☐ ceFAZolin (ANCEF), 1 GRAMS, IV, EVERY 8 HOURS X 2 DOSES

Comment – Enter start time of next dose (8 hours after pre-op dose)

✓ ceFAZolin (ANCEF), 2 GRAMS, IV, in Dextrose, EVERY 8 HOURS X2 DOSES

Comment – Enter start time of next dose (8 hours after pre-op dose)

Post-Op Antibiotics for Patients With Cephalosporin or Severe Penicillin Allergy

- ☐ Clindamycin (CLEOCIN), 900 MG, IV, EVERY 8 HOURS X2 DOSES
  Comment – Enter start time of next dose (8 hours after pre-op dose)
- ☐ Vancomycin (VANCOCIN), 1 GRAM, IV, EVERY 12 HOURS Every X1 DOSE
  Comment – Enter start time of next dose (12 hours after pre-op dose)

POST OP VTE PROPHYLAXIS

Comments -Pharmacologic prophylaxis is recommended unless contraindicated. If contraindicated, then use mechanical prophylaxis and select the appropriate Reason Not Ordered below.

*Caution ordering Enoxaparin (LOVENOX)
-Spinal/epidural hematoma risk in patients with epidural, spinal, or lumbar puncture.
-Do not order if patient on heparin.

VTE EXCLUSION CRITERIA: duration of surgery less than or equal to 60 minutes, performed entirely by laparoscope, patient age less than 18 years, or hospital length of stay less than or equal to 3 days.

Mechanical VTE Prophylaxis

- ✓ APPLY SEQUENTIAL COMPRESSION DEVICE (SCD WHILE IN BED), CONT, Routine
- ☐ APPLY VENOUS FOOT PUMPS, CONT, Routine

Pharmacologic VTE Prophylaxis

Comments
-Single shot spinal or epidural do NOT give Lovenox for at least 4hrs of OR exit time
-Use LOW DOSE Enoxaparin for patients with renal failure (creatinine clearance less than 30mL/min)

- ✓ Aspirin EC (ECOTRIN), 81 MG TBEC, 81 MG, ORALLY, BID
  Comments -Start POD 1 at 0900
- ☐ Enoxaparin (LOVENOX), 30 MG/0.3 ML, 30 MG, SUBCUT, Q12H
  Comment -Enter start time (Start within 24 hrs of OR start time)
- ☐ Enoxaparin (LOVENOX), 40 MG/0.4 ML, 40 MG, SUBCUT, Q24H
  Comment -Enter start time (Start within 24 hrs of OR start time)
- ☐ Enoxaparin (LOVENOX), 30 MG/0.3 ML, 30 MG, SUBCUT, Q24H
  Comment -for CrCl < 30 ml/min. Enter start time (Start within 24 hrs of OR start time)
- ☐ Warfarin (COUMADIN)[HD-1A], 7.5 MG, ORALLY, NOW
- ☐ Warfarin (COUMADIN)[HD-1A], 7.5 MG, ORALLY, BEDTIME
  Comment: Pharmacy to adjust per protocol

ANTIEMETIC MEDICATIONS

ORTHO Surgery Post-Op Order Set

Concomitant Antiemetic

☐ Dexamethasone (DECADRON), 8 MG, IV, ONE UNSCHEDULED
Comment -if not already given in periop

First Line Antiemetic

✓ ondansetron (ZOFRAN)ODT, 4 MG, ORALLY, Q6HPRN for NAUSEA-VOMITING
Comment - May repeat X1

Second Line Antiemetic

☐ metoclopramide (REGLAN), 5 MG/ML, 10 MG, IVP, Q6HPRN for NAUSEA-VOMITING

Comment - Use only when first line medication is ineffective or not ordered.

☐ PRIORITY OF USE FOR ANTIEMETICS IF MORE THAN ONE ORDERED – ONDANSETRON FIRST THEN METOCLOPRAMIDE, CONT, Routine (linked order)

No Sedatives of Hypnotics for sleep

✓ DO NOT ADMINISTER SEDATIVE OR HYPNOTICS FOR SLEEP (unless clinically indicated as determined by the provider), CONT, Routine

PAIN CONTROL

Comments –
Avoid ordering additional narcotics, sedative, or CNS depressants outside of this section
(Patients are considered opioid tolerant if they are taking the equivalent of ORAL Morphine 60 mg/day for at least 1 week).

For Opiate Tolerant patients: Resume home medication regimen.

*Acetaminophen (TYLENOL)
-Around the Clock (for patients age LESS than 65 years)
-DO NOT exceed cumulative 4,000 mg acetaminophen via any route (oral, rectal, IV) in 24 hours. Confirm the 24 hours amount of acetaminophen administered prior to ordering.
-Use caution in patients with liver disease as can cause severe hepatotoxicity.
-Use caution in patients with severe renal impairment (creatinine clearance 30 mL/min or Less).
-May administer via ORAL, NG or Feeding Tube.

✓ RN TO CHECK THE TIME OF LAST DOSE OF ACETAMINOPHEN ADMINISTERED TO CONFIRM TIMING OF THE NEXT DOSE, ONCE, Routine

✓ acetaminophen (TYLENOL), 500 MG TABS, 1000 MG, ORALLY, Q6H
Comment -start 6 hours after last dose.

☐ acetaminophen (TYLENOL), 500 MG TABS, 1000 MG, ORALLY, Q6H x 24 HOURS

Comment -For patient weight greater than 50 KG. *S*tart 6 hours after last dose.

☐ acetaminophen (TYLENOL), 500 MG TABS, 1000 MG, ORALLY, Q8H

Comment - Patient age GREATER than 65 years, liver disease or severe renal impairment. Start 8 hours after last dose. DO NOT exceed cumulative 3000 MG in 24 hours.

NSAIDs

Comments –

-Minimize the use of NSAIDs in patient age GREATER than 64 years or with decreased renal function.

-If only Aspirin for VTE prophylaxis, consider use of non-selective NSAIDs.

-Ketorolac is contraindicated in patients with advanced renal impairment or at risk for renal failure.

*Celecoxib - recommended dosing-

-Reduced dose of 200 mg DAILY for patients 66 to 80 years of age.

-Reduced dose of 100 mg DAILY for patients over 80 years of age.

-Celecoxib is NOT recommended for any patient with Serum Creatinine greater than 2.0 mg/dL.

-Celecoxib is intended only for inpatient use and not to be prescribed routinely upon discharge

✓ CELEcoxib (CeleBREX) 100 MG CAPS, 200 MG, ORALLY, QD X3 doses

Comment -Do not use with SULFA allergy. To be given with other analgesics ordered.

☐ ketorolac inj (TORADOL), 30 MG/ML, 15 MG, IVP, Q6H X 24 HOURS

Comment -for Elderly, Low Body Weight or Renal Insufficiency.

☐ Then ibuprofen (MOTRIN), 400 MG, ORALLY, Q6H (ATC) (linked order)

☐ ibuprofen (MOTRIN), 400 MG, ORALLY, Q6H (ATC)

Comment - for Elderly, Low Body Weight or Renal Insufficiency

☐ ketorolac inj (TORADOL), 30 MG/ML, 30 MG, IVP, Q6H X 24 HOURS

☐ Then ibuprofen (MOTRIN), 600 MG, ORALLY, Q6H (linked order)

☐ ibuprofen (MOTRIN), 600 MG, ORALLY, Q6H (ATC)

Mild Breakthrough Pain Management

✓NRSG CARE- APPLY ICE PACK, REPOSITIONING, MOBILIZATION AS NEEDED FOR MILD PAIN (scale 1-3), PRN, Routine

Moderate Breakthrough Pain Medication

Comment - *Clinician to select one pain medication only with the preferred choice already pre-selected for Moderate and Severe Breakthrough Pain Medication sections.

Moderate Breakthrough Pain Medication (for Patient age LESS than 65 years and NO Delirium /

Dementia Risk Factors)

✓ oxyCODONE ORAL 5 MG/5ML SOLN 5 ML, 5 MG, ORALLY, Q6HPRN

Comment -For moderate (scale 4-6) BREAKTHROUGH pain. (May administer via ORAL, NG, or Feeding Tube)

☐ morPHINE (PF), 2 MG/ML, 2 MG, IVP, Q2HPRN

Comment -For moderate (scale 4-6) BREAKTHROUGH pain.

- ☐ RN TO CALL PROVIDER IF 2 DOSES OF MORPHINE ARE ADMINISTERED WITHIN 8 HOURS TO RE-EVALUATE THE PAIN MEDICATION ORDER, CONT, Routine (linked order)

☐ HYDROmorphone (DILAUDID) PF 0.5 MG/ 0.5 ML SOLN 0.5 ML, 0.2 MG, IVP, Q2HPRN

Comment -For moderate (scale 4-6) BREAKTHROUGH pain.

- ☐ RN TO CALL PROVIDER IF 2 DOSES OF HYDROMORPHONE ARE ADMINISTERED WITHIN 8 HOURS TO RE-EVALUATE THE PAIN MEDICATION ORDER, CONT, Routine (linked order)

Moderate Breakthrough Pain Medication (for Patient age GREATER than 65 years and/or with Delirium / Dementia Risk Factors)

Comment- *ORAL OPIOIDS may be contraindicated with Tramadol

☐ traMADol HCL (ULTRAM), 50 MG, ORALLY, Q6HPRN

Severe Breakthrough Pain Medication (for Patient age LESS than 65 years and NO Delirium / Dementia Risk Factors)

Comment - *Clinician to select one pain medication only with the preferred choice already pre-selected for Moderate and Severe Breakthrough Pain Medication sections.

✓ oxyCODONE ORAL 5 MG/5ML SOLN 5 ML, 10 MG, ORALLY, Q6HPRN

Comment -For severe (scale 7-10) BREAKTHROUGH pain. (May administer via ORAL, NG, or Feeding Tube)

☐ morPHINE (PF), 4 MG/ML, 4 MG, IVP, Q2HPRN

Comment - For severe (scale 7-10) BREAKTHROUGH pain

- ☐ RN TO CALL PROVIDER IF 2 DOSES OF MORPHINE ARE ADMINISTERED WITHIN 8 HOURS TO RE-EVALUATE THE PAIN MEDICATION ORDER, CONT, Routine (linked order)

☐ HYDROmorphone (DILAUDID) PF 0.5 MG/ 0.5 ML SOLN 0.5 ML, 0.5 MG, IVP, Q2HPRN

Comment - For severe (scale 7-10) BREAKTHROUGH pain

- ☐ RN TO CALL PROVIDER IF 2 DOSES OF HYDROMORPHONE ARE ADMINISTERED WITHIN 8 HOURS TO RE-EVALUATE THE PAIN MEDICATION ORDER, CONT, Routine (linked order)

BOWEL CARE

✓ HOLD LAXATIVE FOR LOOSE STOOL, CONT, Routine

Scheduled Laxatives

☐ docusate sodium (COLACE) 100 MG CAPS, 100 MG, ORALLY, BID
✓ docusate sodium (COLACE) 250 MG CAPS, 250 MG, ORALLY, BID
Comment -Start first dose today at 1800.
☐ polyethylene glycol (MIRALAX), 17 GM, ORALLY, Q24H
✓ SENNA, 8.6 MG TABS, 8.6 MG ORALLY, BID

AS NEEDED Laxatives

✓ PRIORITY OF USE IF MORE THAN ONE PRN LAXATIVE MEDICATION ORDERED, ADMINISTER MAGNESIUM HYDROXIDE (MOM) FIRST, IF INEFFECTIVE AFTER 24 HOURS, ADMINISTER LACTULOSE, THEN DULCOLAX), CONT, Routine
✓ magnesium hydrox (MOM) 7.75%, 400 MG/5 ML, 2400 MG, 30 ML, ORALLY, BIDPRN

Comment -for CONSTIPATION. Caution in patients with renal impairment, hold for severe renal impairment.

✓ lactulose (CEPHULAC) 20 GM/30 ML SOLN, 30 ML, ORALLY, BIDPRN

✓ Give as first line therapy Milk of Magnesia if lactulose is also ordered. If no bowel movement within 24 hours, give second line therapy if ordered, CONT, Routine. (linked order)
✓ DULCOLAX, 10 MG, REC, DAILYPRN for CONSTIPATION

Comment -Give if no bowel movement for 2 days and other laxatives ineffective.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: August 30, 2023

Report Type: Discussion

Title: Update by Interim Chief Executive Officer (CEO)

Recommendation: Receive and file update from Matko Vranjes, Interim CEO

Contact: Matko Vranjes, Interim CEO

Analysis

At each board meeting the CEO provides the board and the public an oral update on various matters.

Financial Impact: None

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: August 30, 2023

Report Type: Discussion

Title: Chief Financial Officer (CFO) Monthly Financial Performance and Budget Update

Recommendation: Receive and file update from Julie Peterson, Chief Financial Officer

Contact: Julie Peterson, Chief Financial Officer

Analysis

At each board meeting the CFO provides the board and the public an update on Financial Performance.

Financial Impact: See attached report.

Attachments

A: Financial Performance Report

WATSONVILLE COMMUNITY HOSPITAL
2023 CONSOLIDATED TRENDED BALANCE SHEET
($ in 000's)

	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23
Assets							
Cash	$ 5,982	$ 6,078	$ 1,916	$ 3,958	$ 3,576	$ 2,081	$ 2,852
A/R	43,166	43,452	42,474	39,084	39,504	41,108	57,266
Less: Allowance for BD	(8,134)	(7,325)	(6,587)	(6,365)	(7,298)	(7,420)	(21,342)
Prior yr Cost Report Settlement							
Supplies	2,079	2,073	2,118	2,069	2,058	2,056	2,024
Prepaid Expenses	1,185	1,209	1,104	1,096	1,028	831	951
Other Current Assets	722	1,195	2,551	2,271	2,217	2,757	2,347
Total Current Assets	$ 45,000	$ 46,682	$ 43,576	$ 42,113	$ 41,085	$ 41,413	$ 44,098
Net PP&E	35,245	35,168	35,150	35,074	34,999	34,933	34,863
Operating Lease ROU, Net	1,676	1,634	1,491	1,449	1,408	1,367	1,326
Notes Receivable							
Deposits	5	5	5	5	5	5	5
Unamortized Loan Costs	50	50	50	50	50	50	50
Physician Recruitment Costs	-	-	-	-	-	-	-
Deferred MIS Charges	698	631	562	496	431	367	349
Goodwill (Placeholder)	(20,666)	(20,551)	(20,963)	(20,963)	(20,963)	(20,963)	(19,771)
Total Other Assets	$ (18,237)	$ (18,231)	$ (18,855)	$ (18,963)	$ (19,069)	$ (19,174)	$ (18,041)
Total Assets	$ 62,008	$ 63,619	$ 59,871	$ 58,224	$ 57,015	$ 57,172	$ 60,920
Liabilities and Equity							
Current maturities of LTD	$ (47)	$ (57)	$ (68)	$ (79)	$ (90)	$ (105)	$ (113)
Accounts Payable	6,622	7,194	7,009	7,361	6,855	7,478	9,746
Accrued Emp. Comp.	9,401	10,052	7,793	8,535	8,112	8,160	9,171
Operating Lease - Current	30	20	319	324	307	448	433
Other Accrued Liabilities	5,844	7,716	7,006	5,955	6,073	6,350	7,223
Total Current Liabilities	$ 21,850	$ 24,925	$ 22,059	$ 22,096	$ 21,257	$ 22,331	$ 26,460
Deferred Credits	6,935	6,880	6,405	6,318	6,133	6,116	6,131
Operating Lease Liabilities	1,693	1,655	1,194	1,159	1,124	940	904
Long Term Debt	39,836	39,847	40,358	40,369	40,379	40,388	41,686
Total Liabilities	$ 70,314	$ 73,307	$ 70,016	$ 69,942	$ 68,893	$ 69,775	$ 75,181
Stockholders' Equity	(8,306)	(9,688)	(10,145)	(11,718)	(11,878)	(12,603)	(14,261)
Total Liabilities and Equity	$ 62,008	$ 63,619	$ 59,871	$ 58,224	$ 57,015	$ 57,172	$ 60,920

Watsonville Community Hospital
Consolidated Income Statement
For The Month of July, 31, 2023

CURRENT PERIOD					YTD			
Jul-23	BUDGET	VARIANCE	% VARIANCE		ACTUAL	BUDGET	VARIANCE	% VARIANCE
				Operating Revenues				
31,875,150	31,780,363	94,787	0.3%	Inpatient Revenue	208,528,578	243,343,143	(34,814,565)	-14.3%
53,282,846	53,318,782	(35,936)	-0.1%	Outpatient Revenue	370,649,582	343,742,176	26,907,406	7.8%
85,157,996	**85,099,145**	**58,851**	**0.1%**	**Total gross patient revenue**	**579,178,160**	**587,085,319**	**(7,907,159)**	**-1.3%**
				Deductions From Revenue:				
61,469,873	73,690,518	(12,220,645)	-16.6%	Contractual Allowances	497,766,634	509,208,131	(11,441,497)	-2.2%
(1,599,179)	(1,599,179)		0.0%	QAF	(11,194,255)	(11,194,255)		0.0%
(128,059)	(128,059)		0.0%	Disproportionate Share DSH	(896,410)	(896,410)		0.0%
59,742,635	**71,963,280**	**(12,220,645)**	**-17.0%**	**Total Deductions From Rev**	**485,675,970**	**497,117,467**	**(11,441,497)**	**-2.3%**
25,415,361	**13,135,865**	**12,279,496**	**93.5%**	**Net Revenue**	**93,502,190**	**89,967,852**	**3,534,338**	**3.9%**
14,036,884	112,006	13,924,878	12432.3%	Provision for Bad Dbt	13,691,079	767,202	12,923,877	1684.5%
11,378,477	**13,023,859**	**(1,645,382)**	**-12.6%**	**Collectible Patient Revenue**	**79,811,111**	**89,200,650**	**(9,389,539)**	**-10.5%**
164,067	136,542	27,525	20.2%	Other Revenue	3,558,555	933,774	2,624,781	281.1%
11,542,544	**13,160,401**	**(1,617,857)**	**-12.3%**	**Total Net Operational Revenue**	**83,369,666**	**90,134,424**	**(6,764,758)**	**-7.5%**
				Operating Expenses				
6,352,968	5,556,685	796,283	14.3%	Salaries & Wages	41,106,915	40,539,096	567,819	1.4%
1,871,104	2,089,178	(218,074)	-10.4%	Benefits	11,791,145	14,369,691	(2,578,546)	-17.9%
769,969	500,000	269,969	54.0%	Contract Labor	4,202,225	3,856,000	346,225	9.0%
8,994,041	**8,145,863**	**848,178**	**10.4%**	**Subtotal Salaries Wages & Benefits**	**57,100,285**	**58,764,787**	**(1,664,502)**	**-2.8%**
703,725	857,399	(153,674)	-17.9%	Medical Spec Fees	4,681,542	5,879,716	(1,198,174)	-20.4%
701,648	873,505	(171,857)	-19.7%	Supplies	6,300,238	6,361,959	(61,721)	-1.0%
123,464	104,310	19,154	18.4%	Repairs & Maintenance	746,861	713,347	33,514	4.7%
192,281	167,041	25,240	15.1%	Utilities	1,552,280	1,141,384	410,896	36.0%
1,067,776	1,182,734	(114,958)	-9.7%	Purchased Services	8,261,616	9,884,451	(1,622,835)	-16.4%
150,733	216,799	(66,066)	-30.5%	Lease Cost and Rent	1,096,817	1,471,727	(374,910)	-25.5%
206,235	284,014	(77,779)	-27.4%	Prop Taxes & Ins	1,325,502	1,940,049	(614,547)	-31.7%
-	4,167			Marketing	-	29,167		
655,135	997,553	(342,418)	-34.3%	Other Operating Exp	4,574,101	6,920,226	(2,346,125)	-33.9%
12,795,038	**12,833,384**	**(38,346)**	**-0.3%**	**Total Operating Exp**	**85,639,242**	**93,106,812**	**(7,467,570)**	**-8.0%**
(1,252,494)	**327,017**	**(1,579,511)**	**-483.0%**	**EBITDA**	**(2,269,576)**	**(2,972,389)**	**702,813**	**-23.6%**
82,465	96,703	(14,238)	-14.7%	Depreciation and Amortization	617,089	675,281	(58,192)	-8.6%
323,883	402,538	(78,655)	-19.5%	Interest	2,646,699	2,813,805	(167,106)	-5.9%
406,348	**499,240**	**(92,892)**	-18.6%	**Total Other Expenses**	**3,263,788**	**3,489,085**	**(225,297)**	-6.5%
(1,658,842)	**(172,223)**	**(1,486,619)**	863.2%	**Net Income/Loss from Operations**	**(5,533,364)**	**(6,461,474)**	**928,110**	-14.4%

Watsonville Community Hospital
Income Statement
For The Month of July, 31, 2023

CURRENT PERIOD					YTD			
Jul-23	BUDGET	VARIANCE	% VARIANCE		ACTUAL	BUDGET	VARIANCE	% VARIANCE
				Operating Revenues				
31,875,150	31,780,363	94,787	0.3%	Inpatient Revenue	208,528,578	243,343,143	(34,814,565)	-14.3%
52,806,900	52,848,716	(41,816)	-0.1%	Outpatient Revenue	367,038,109	340,388,913	26,649,196	7.8%
84,682,050	**84,629,078**	**52,972**	**0.1%**	**Total gross patient revenue**	**575,566,687**	**583,732,056**	**(8,165,369)**	**-1.4%**
				Deductions From Revenue:				
61,175,782	73,434,268	(12,258,486)	-16.7%	Contractual Allowances	495,549,818	507,344,286	(11,794,468)	-2.3%
(1,599,179)	(1,599,179)		0.0%	QAF	(11,194,255)	(11,194,255)		0.0%
(128,059)	(128,059)		0.0%	Disproportionate Share DSH	(896,410)	(896,410)		0.0%
59,448,544	**71,707,030**	**(12,258,486)**	**-17.1%**	**Total Deductions From Rev**	**483,459,154**	**495,253,622**	**(11,794,468)**	**-2.4%**
25,233,506	**12,922,048**	**12,311,458**	**95.3%**	**Net Revenue**	**92,107,533**	**88,478,434**	**3,629,099**	**4.1%**
14,024,230	109,588	13,914,642	12697.3%	Provision for Bad Dbt	13,683,541	750,357	12,933,184	1723.6%
11,209,276	**12,812,460**	**(1,603,184)**	**-12.5%**	**Collectible Patient Revenue**	**78,423,992**	**87,728,078**	**(9,304,086)**	**-10.6%**
98,726	116,792	(18,066)	-15.5%	Other Revenue	3,076,757	798,703	2,278,054	285.2%
11,308,002	**12,929,252**	**(1,621,250)**	**-12.5%**	**Total Net Operational Revenue**	**81,500,749**	**88,526,781**	**(7,026,032)**	**-7.9%**
				Operating Expenses				
6,089,928	5,282,804	807,124	15.3%	Salaries & Wages	39,351,940	38,608,863	743,077	1.9%
1,829,222	2,037,256	(208,034)	-10.2%	Benefits	11,473,738	13,932,201	(2,458,463)	-17.6%
769,969	500,000	269,969	54.0%	Contract Labor	4,202,225	3,856,000	346,225	9.0%
8,689,119	**7,820,060**	**869,059**	**11.1%**	**Subtotal Salaries Wages & Benefits**	**55,027,903**	**56,397,064**	**(1,369,161)**	**-2.4%**
667,450	843,983	(176,533)	-20.9%	Medical Spec Fees	4,597,928	5,771,755	(1,173,827)	-20.3%
695,730	864,072	(168,342)	-19.5%	Supplies	6,253,994	6,314,986	(60,992)	-1.0%
123,464	104,189	19,275	18.5%	Repairs & Maintenance	746,719	712,521	34,198	4.8%
191,386	165,741	25,645	15.5%	Utilities	1,543,777	1,133,454	410,323	36.2%
1,033,775	1,148,399	(114,624)	-10.0%	Purchased Services	8,195,961	9,648,030	(1,452,069)	-15.1%
126,737	196,296	(69,559)	-35.4%	Lease Cost and Rent	927,999	1,342,411	(414,412)	-30.9%
191,476	272,329	(80,853)	-29.7%	Prop Taxes & Ins	1,263,833	1,862,379	(598,546)	-32.1%
-	-			Marketing	3,019	-	3,019	
-	-			Management Fees	-	150,000	(150,000)	-100.0%
649,311	995,363	(346,052)	-34.8%	Other Operating Exp	4,551,611	6,749,391	(2,197,780)	-32.6%
12,368,448	**12,410,432**	**(41,984)**	**-0.3%**	**Total Operating Exp**	**83,112,744**	**90,081,991**	**(6,969,247)**	**-7.7%**
(1,060,446)	**518,820**	**(1,579,266)**	**-304.4%**	**EBITDA**	**(1,611,995)**	**(1,555,210)**	**(56,785)**	**3.7%**
-	-			Depreciation and Amortization	-	-		
(8,333)	16,079	(24,412)	-151.8%	Interest	29,455	108,594	(79,139)	-72.9%
(8,333)	**16,079**	**(24,412)**	-151.8%	**Total Other Expenses**	**29,455**	**108,594**	**(79,139)**	-72.9%
(1,052,113)	**502,741**	**(1,554,854)**	-309.3%	**Net Income/Loss from Operations**	**(1,641,450)**	**(1,663,805)**	**22,355**	-1.3%

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: August 30, 2023
Report Type: Discussion

Title: Watsonville Community Hospital (WCH) Strategic Plan Approval

Recommendation: 1) Review the Strategic Plan with edits from July 26, 2023 and 2) Pass a **Motion** approving the mission, vision and values statements and Strategic Plan.

Contact: Matko Vranjes, Interim Chief Executive Officer (CEO)

Background:

The Pajaro Valley Health Care District (PVHCD) Hospital Board of Directors passed **Motion No. 011-2023** on January 20, 2023, a) approving the proposed engagement agreement with the Chartis Group for strategic planning; and b) directing the CEO to negotiate all possible cost savings with the vendor and request the Hospital Foundation to add Strategic Planning contract funding to their initiatives. Chartis will facilitate a strategic planning process including this workshop that elevates the hospital and healthcare district's health equity impact and preserves access to quality services for the community under a financially sustainable trajectory. The primary deliverable from this project will be a three-to-five-year strategic plan for Watsonville Community Hospital with the Pajaro Valley Health Care District's overall objectives and needs in mind. The strategic plan will include a clear articulation of organizational goals and metrics by which success will be defined.

Over the past months, Chartis has conducted one-on-one interviews with approximately 20 PVHCD Board members, WCH leaders, and community stakeholders to best understand strengths, needs, and opportunities, how they would like to see the organizations evolve, and what existing barriers may impact the success of this work. Chartis fielded an online survey in English and Spanish to identify themes, sentiments, and ideas that would inform WCH's new mission, vision and values, and received over 200 responses from employees and community members.

Chartis developed a current state assessment, synthesizing data about the PVHCD community, WCH, and regional health systems to allow WCH and PVHCD to articulate its desired role in the regional health care ecosystem, requirements for success and identify strategic implications.

Chartis used these sources of input to draft mission, vision, and value statements and developed strategies and tactics to prioritize and structure the organization's goals. These strategies and tactics inform the proposed clinical, financial, and operational impact over the next five years.

At the June 23,2023 PVHCDHC board meeting the board provided Chartis with 1) input on draft mission, vision and values statement; 2) validation on strategic priorities and tactics; and 3) feedback on clinical, financial and operational impact of strategies and tactics.

On July 26, 2023 the PVHCDHC the board provided Chartis: 1) Provide Chartis with input on: a) mission, vision, and values statements, and b) strategic priorities and tactics, and c) strategic plan roadmap and accountable leaders and 2) Passed **Motion No. 043-2023** approving the mission, vision and values statements and Strategic Plan as amended and directing staff to bring back for final approval on *August 30, 2023*.

Attachments:

A: Final Strategic Plan

CHARTIS

Watsonville Community Hospital & Pajaro Valley Healthcare District

MISSION, VISION, VALUES AND STRATEGIC PLAN SUMMARY

August 2023

WATSONVILLE COMMUNITY HOSPITAL

Mission, Vision and Values

Our Mission

We are the trusted, equitable healthcare partner and provider our diverse **families, friends and neighbors** deserve

Our Vision

To be our **community's champion and advocate for health and wellness** to **improve** the lives of our community **for generations to come**

Our Values

- **We put people first.** We put the health and wellbeing of people first in every decision and every experience.
- **We strive for excellence.** As stewards of our community's health, we commit to providing the highest quality of care and exceeding expectations.
- **We earn trust.** We work as a team to earn the trust of everyone we interact with.
- **We are family.** We embrace the family traditions, cultures and diversity of our community every day.

WCH and PVHCD Strategies

DISTRICT-FOCUSED STRATEGIES

Community Health & Advocacy

Expand **community partnerships,** serve as a trusted partner and advocate, and address health equity and social determinants of health

Provider Recruitment

Support **engaged, committed multi-specialty providers who practice at WCH and enable care closer to home**

HOSPITAL-FOCUSED STRATEGIES

Clinical Quality & Patient Experience

Improve clinical and operational processes and protocols to provide **high-quality care and excellent patient experience**

Talent & Culture

Retain, support, and recruit exceptional teams who advance a culture of trust, compassion, and integrity

Clinical Services & Access

Expand WCH clinical programs and partnerships to deliver **clinical services and sustainable and equitable access** for our community

Financially Sustainable Services

Ensure **effective operations and financial sustainability** to achieve our mission and ensure services for generations to come

Health Equity Across All Strategies