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, May 31, 2023-5:00 pm

(This meeting will begin after Closed Session)

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

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

Kathleen King Community Room - 85 Nielson Street, Watsonville

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Email: info@pvhcd.org
- Emailed documents may take up to 24 hours to be posted
- 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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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, May 31, 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.

Comments regarding items included on the Agenda will be heard before the item is discussed by the Board.

No action or discussion shall be taken on any item presented except that any Board Member may respond to statements made or questions asked or may ask questions for clarification. All matters of an administrative nature will be referred to staff. All matters relating to the Board will be noted in the minutes and may be scheduled for discussion at a future meeting or referred to staff for clarification and a report.

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: April 26, 2023**
   Recommendation: Pass a **Motion** approving the minutes of the April 26, 2023.
   Contact: Dawn Bullwinkel, Consultant Clerk of the Board, dbullwinkel@watsonvillehospital.com

2. **Policies/Policy Summary Approval: May 2023**
   Recommendation: Pass a **Motion** approving the Policies/Policy Summary.
   Contact: Sherri Torres, Chief Nursing Officer, Sherri_StoutTorres@Watsonvillehospital.com

Discussion

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

4. **Chief Financial Officer Monthly Financial Performance**
   Recommendation: Receive and file.
   Contact: Julie Peterson, Chief Financial Officer

5. **Line of Credit**
   Recommendation: Receive information regarding $5,000,000 Commercial Revolving Line of Credit, secured by external agency(s) funding presenting the opportunity for the Pajaro Valley Health Care District Hospital Corporation Board of Directors to provide the Hospital with short term working capital.
   Contact: Julie Peterson, Chief Financial Officer

6. **Medical Executive Committees Reports Report May 2023**
   Recommendation: Pass a **Motion** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of May 2023.
   Contact: Executive Sponsor-Dr. Angel, Chief of Staff, Medical Executive Committee

Adjournment

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 Report

Meeting Date: May 31, 2023
Report Type: Consent

Title: Minutes Approval: April 26, 2023

Recommendation: Pass a Motion approving the minutes for April 26, 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. April 26, 2023-Closed
B. April 26, 2023-Regular

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

Call to Order at 5:00 pm.

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

Closed Session Report- None

Agenda Modification Consideration-None

Public Comment on Matters Not on the Agenda

Public Comment on Matters on the Agenda

a) CEO Recruitment:
   i. Jennifer Ura Gavin
   ii. Fred Castillo

Adjourned to Closed Session at 5:10 pm.

1. **Conference with Labor Negotiators** (Government Code 54957.6)
   Agency Negotiator: Allyson Hauck; California Nurses Association (CAN)
   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

Approved: _____

John Friel, Chair

Attest: _____

Dawn Bullwinkel, Consultant Clerk of the Board

Pajaro Valley Health Care District Hospital Corporation
Minutes- Wednesday, April 26, 2023

Call to Order at 5:54 pm.

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

Closed Session Report- None

Agenda Modification Consideration-None

Public Comment on Matters Not on the Agenda -None

Comments from Board Members

a) Director Cox: Thanks to community organizations and engaging hospital community with art as a way to look to the future.
b) Director Pimentel: Thanks to community and pleased to announcement Salud Para La Gente's (Salud) appointment of Donna Young as next Chief Executive Officer (CEO).

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. **Minute Approval: March 2023**
   Action: Passed **Motion No. 26-2023** approving the minutes of the March 22, 2023 and March 29, 2023.
   Contact: Dawn Bullwinkel, Consultant Clerk of the Board, dbullwinkel@watsonvillehospital.com

2. **Policies/Policy Summary Approval: April 2023**
   Action: Passed **Motion No. 27-2023** approving the Policies/Policy Summary.
   Contact: Sherri Torres, Chief Nursing Officer, Sherri_StoutTorres@Watsonvillehospital.com

3. **Conflict of Interest Code**
   Action: 1) Passed **Resolution No. 003-2023** approving the Conflict of Interest Code pursuant to the Political Reform Act of 1974; and 2) direct the board clerk to forward the Conflict of Interest Code to the Fair Political Practice Commission for acceptance.
   Contact: Matko Vranjes, Interim Chief Executive Officer
   Matko_Vranjes@Watsonvillehospital.com

4. **Limited Authority Retirement Plan Amendments**
   Action: Passed **Resolution No. 004-2023** authorizing delegating limited "settlor: authority to the Chief Human Resources Officer (CHRO) to make certain types of plan amendments.
   Contact: Allyson Hauck, Chief Human Resources Officer

Discussion

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

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

7. **Medical Executive Committees Reports March 2023**
   Moved/Seconded:
   Yes: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

   Action: Passed **Motion No. 028-2023** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of April 2023; and 2) the Medical Executive Committee (MEC) action appointing Surgery Department Vice Chair – Sarah Brant, MD.

   Contact: A Janelle Rasi, M.D., Vice Chief of Staff Chair, Medical Executive Committee

Adjourn at 6:40 pm.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: May 31, 2023
Report Type: Consent

Title: Policy/Summaries May 2023

Recommendation: Pass a **Motion** approving the Policies and Summary Report of May 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 is provided for your approval.

Financial Impact: None.

Attachment A:
Reports

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOD

Reporting Period: May 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
Infection Prevention				
Human Infestations (Bed Bugs, Scabies, and Lice)	IP114	Revision of document. Title updated to Human Infestations (Bed Bugs, Scabies, and Lice) from Management of Bed Bug, Scabies, etc.	Regulary Scheduled Review	Author: IP Director 10/2022 QPSC: 10/2022 PTIC: 05/03/2023 CNO/VP.Sr Leader/CEO:05/2023 MEC: 05/16/2023 BOD:
Clostridiodes difficile: Prevention, Control and Management	IP0147	Added types of stool from Bristol stool chart (5,6 or7) that are appropriate for C. diff testing based on latest CDC guidance. If the stool conforms to the shape of the container is appropriate to test. Changed from only send stool types 6, 7. Added Nursing Standardized Procedure for C. diff testing upon admission.	Updated to latest evidence-based practice and CDC guidance. Nursing Standardized procedure updated to meet Title 22 requirements.	Author: IP Director 04/27/223 PTIC: 05/03/2023 IPD: 05/12/2023 CNOVP.Sr Leader/CEO: 05/2023 MEC: 05/16/2023 BOD:
Bloodborne PathogenExposure Control Plan (BBP/ECP)	IP0147	BBPE revised to provide guidance to manage all exposures, efficiently and consistently. Nursing Supervisor will facilitate exposed through emergency department; exception may be providers who may not have own work-comp and may order own lab draws.	Regulary Scheduled Review	Author: IP Director 05/01/223 PTIC: 05/03/2023 VP.Sr Leader/CEO: 05/2023 MEC: 05/16/2023 BOD:
PHARMACY (PHARM)				
Controlled Substances: OR/Anesthesia	PHARM0227	No Changes.	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO: 05/2023 VP/Sr.Leader/CEO: 05/16/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL		**Watsonville Community Hospital**		
		POLICY APPROVAL SUMMARY REPORT		
Committee: BOD				
Reporting Period: May 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**
Controlled Substances: Accountability of Waste	PHARM1879	III. Procedure: G=Wording Clarification	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO:05/2023 VP/Sr. Leader/CEO: 05/16/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:
Controlled Substances: Reporting Drug Diversion (including suspected theft)	PHARM1904	Added: III. Procedure: F.2 = wording directly from BPC 4107.5	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO:05/2023 PTIC: 05/03/2023 VP/Sr.Leader/CEO: 05/16/2023 MEC: 05/16/2023 BOD:
Controlled Substances: Audits	PHARM2003	DELETE: III. Procedure: A. 5= Drug Specific Audits(Not needed in this policy, covered w/Medication Utilization Reviews)	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO:05/2023 PTIC: 05/03/2023 VP/Sr.Leader/CEO: 05/16/2023 MEC: 05/16/2023 BOD:
Controlled Substances: Discrepancy Resolution	PHARM2024	No Changes.	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO:05/2023 PTIC: 05/03/2023 VP/Sr.Leader/CEO: 05/16/2023 MEC: 05/16/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOD

Reporting Period: May 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
Drugs Requiring Iventory Accountability in Acute Care Facilities	PHARM2705	No Changes.	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO:05/2023 VP/Sr.Leader/CEO: 05/16/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:
Controlled Subatance: Distribution	PHARM2706	No Changes.	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO:05/2023 VP/Sr.Leader/CEO: 05/16/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:
Controlled Substance: Pharmacy Licenses and Registrations	PHARM2707	DELETE: II. Policy: Reference to permits/licenses not required in CA	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO:05/2023 VP/Sr.Leader/CEO 05/16/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL		**Watsonville Community Hospital**		
		POLICY APPROVAL SUMMARY REPORT		
Committee: BOD				
Reporting Period: May 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**
Controlled Substance: Records	PHARM2708	Added: III. Procedure: D. 6. f= wording directly from CCR1715.65	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO:05/2023 VP/Sr. Leader/CEO: 05/16/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:
Controlled Substance: DEA Controlled Substance Odering System (CSOS)	PHARM2709	No Changes.	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO:05/2023 VP/Sr. Leader/CEO: 05/16/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:
Controlled Substance: Floor Stock Accountability	PHARM2710	No Changes.	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO:05/2023 Vp/sr. Leader/Ceo: 05/16/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL		**Watsonville Community Hospital**		
		POLICY APPROVAL SUMMARY REPORT		
Committee: BOD				
Reporting Period: May 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**
Controlled Substance: Prescription Forms (Pads and Paper)	PHARM2711	No Changes.	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO:05/2023 VP/Sr. Leader/CEO: 05/16/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:
Controlled Substance: Emergency Department Administration Reconciliation	PHARM2781	Archived/Retire (All areas reconciled monthly, covered in Policy#PHARM2003: Audits)	ARCHIVE/RETIRE: Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO:05/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:
Prescription Drug Disposal Program	PHARM003	ADD to Purpose= Clarification that WCH Outpatient Pharmacy Participates in the mail back program.	Regulary Scheduled Review	Author: Pharmacy Director 05/2023 CNO/VP Sr. Leader/CEO: 05/16/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:
Epidural Pain Management, Adult	PHARM0384	Collaboration between Nursing and Pharmacy to ensure clear process outlined for Nursing in management of patient on epidural.	Re-institution of previously archived policy	Author: Pharmacy Director 05/2023 CNO: 05/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:
PHARMACY: Annual Review of Compounding Policies				

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOD

Reporting Period: May 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
Compounded Sterile Products: End Product (Final) Examination	PHARM2726	Change post CA-Bop inspection in 2022*(PTIC 10/2022	Annual Review	Author: Pharmacy Director 05/2023 CNO:05/2023 PTIC: 05/03/2023 MEC: 05/16/2023 BOD:
Medical Staff				
Medical Staff Policy - Observers - Shadowers in Clinical Settings	MS POLICY	Amended Policy to reference health requirements. Amended Checklist to require attestation of current negative drug use instead of drug screen Removed N95 Testing. Observers will not go into rooms that require an N95	Shadow Observers are short term, no patient contact and always with their sponsor physician	Author: Medical Staff Director : 04/2023 MEC: 04/18/2023: BOD:
Medical Staff Policy Regarding Peer Review, Ongoing Professional Practice Evaluation (OPPE & (FPPE)	MS2842	Remove language on sharing external peer review reports and replace with wording that meets and protects confidentiality.	Updated to maintain compliance with California Evidence Code Section 1157	Author: Medical Staff MEC: 5/16/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL		**Watsonville Community Hospital**		
		POLICY APPROVAL SUMMARY REPORT		
Committee: BOD				
Reporting Period: May 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**

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Human Infestations (Bed Bugs, Scabies, and Lice)	Policy #	IP114
Responsible	Director of Infection Prevention & Control	Revised/Reviewed	10/10/2022

I. PURPOSE

To effectively assess, identify and address common infestations in order to provide early detection, treatment, and implementation of appropriate isolation (Contact Transmission-Based Precautions) and enact proper procedures to mitigate the risk of an infestation of a patient at Watsonville Community Hospital (WCH).

This policy deletes the previous steps for: "Call Material, who seals the room." There is no need to seal a room once a patient has been identified as having a possible bug infestation.

New Processes: Ensure all hospital linen has been secured in a plastic bag tied securely with a knot in the plastic bag before placing in the linen hamper, and that patient's personal clothing has also been placed inside of a tightly sealed plastic bag (this bag can stay with the patient), but it must remain sealed for a minimum of one week, unless the family can take the belongings home and follow washing instructions below. The door to the room is to be closed.

II. POLICY

All new patients should be carefully examined for suspicious skin rashes or evidence of parasitic infestation, even if characteristic signs or symptoms of scabies, lice or bed bugs are absent (e.g., itching).

For purposes of ensuring Pest Control treats with the correct pesticide … If possible attempt to obtain a photo or a specimen of the bug from the patient in a cup with a lid for Pest Control's identification.

SCABIES:

1. Prodromal Timeline: from exposure to symptoms: 4-8 weeks to develop after infested.
2. Spread by prolonged skin-to-skin contact with a person who has scabies. Persons who have had such contact should be evaluated by a physician and treated, if necessary.
3. Scabies mites do not survive more than 2-3 days away from human skin. Spraying or fumigating office or living areas is unnecessary.
4. Contain clothing and any other patient belongings in a plastic bag that is sealed tight and send home with patient's family. If left in the room, the patient is not to open the bag at any time while in the hospital.
5. Scabies treatment is recommended for members of the same household, particularly for those who have had prolonged skin-to-skin contact. All household members and other potentially exposed persons should be treated at the same time as the infested person to prevent re-exposure and reinfestation.
    - Items (bedding and clothing worn or used next to the infested person's should be machine washed using the hot water and hot dryer cycle or be dry cleaned. Items

that cannot be dry-cleaned can be disinfested by storing in a closed plastic bag for one week.

6. For non-crusted scabies, Follow the instructions on the treatment ordered. For non-crusted scabies, isolation can be discontinued 24 hours after the first treatment and after the patient has washed their hair and bathed, Clean linen is placed on the bed and the patient has clean clothing following their bath.

Crusted scabies (Norwegian scabies) are considered highly contagious and appropriate isolation procedures should be used to protect other persons from becoming infected (Contact Transmission-Based Precautions). A person with Norwegian "crusted" scabies can spread the infestation by brief skin-to-skin contact or by exposure to bedding, clothing, or even furniture that he/she has used.

- **PPE:** use Contact Precautions with protective garments, until patient has been successfully treated.

  Gowns,
  Disposable gloves
  Shoe covers

- Norwegian Scabies may not show the characteristic symptoms of scabies such as rash and itching (pruritus). The person with crusted scabies are infested with a very large number of mites, this increases the risk of transmission both from brief skin-to-skin contact and from contact with items such as bedding, clothing, furniture, rugs, carpeting, floors, and other fomites that can become contaminated with skin scales and crusts shed by a person with crusted scabies.
- Consult with a dermatologist (recommended).
- Scabies should be confirmed by skin scrapings
- Always wash hands thoroughly after providing care to any patient.
- Maintain contact precautions until skin scrapings from a patient with crusted scabies are negative. Treatment for Norwegian Scabies must be treated at least twice, a week apart; oral ivermectin may be necessary for successful treatment.
- Limit visitors for patients with crusted scabies; and visitors should use the same contact precautions and protective clothing as staff.
- Persons with crusted scabies and their close contacts should be treated rapidly and aggressively to avoid outbreaks.
- Rooms used with crusted scabies should be thoroughly cleaned and vacuumed after use. Environmental disinfestation using pesticide sprays or fogs generally is unnecessary and discouraged by the CDC.

LICE

- A parasitic insect that can be found on the head, eyebrows, and eyelashes of people
- Anyone who comes in head-to-head contact with someone who already has head lice is at greatest risk.
- Head lice feed on human blood several times a day and live close to the scalp. They are not known to spread disease.
- Head lice move by crawling; they cannot hop or fly.

- They are spread by direct contact with the hair of an infested person.
- It is uncommon for it to be spread by clothing (hats, scarves or coats) or personal items such as combs, brushes or towels used by an infested person.
- Head lice have three forms: the lice egg (nit), the nymph, and the adult.
- Head lice take about 8-9 days to hatch. Eggs that are likely to hatch are usually located no more than ¼ inch from the base of the hair shaft. A nymph is an immature louse that hatches from the nit. The nymph looks like an adult head louse, but smaller. Nymphs mature in 9-12 days.

Lice: Signs and Symptoms:

- Tickling feeling of something moving in the hair
- Itching caused by an allergic reaction to the bites of the head louse
- Irritability and difficulty sleeping, head louse are most active in the dark.
- Sores on the head caused by scratching. (these sores can become infected with bacteria found on the person's skin).

Lice: Diagnosis

- Best made by finding a live nymph or adult louse on the scalp or hair of a person; they are very small and move quickly and avoid light so can be difficult to find.
- Use a magnifying lens and a fine-toothed comb
- If lice are not seen, look for nits that are attached ¼ inch from the base of the hair shaft.
- Nits can be confused with dandruff, hair spray droplets, and dirt particles
- If no live nymphs or adult lice are seen, and the only nits found are more than ¼ inch from the scalp, the infestation is probably old and no longer active and does not need to be treated.

Life Span of Lice

- Head lice and their eggs (nits) soon perish if separated from their human host.
- Adult head lice can live only a day or so off the human head without blood for feeding, Nymphs can only live for several hours without feeding on a human. Nits (head lice eggs) generally die within a week away from their human host and cannot hatch at a temperature lower than that close of the human scalp.

Lice Treatment

- Do not use a combination shampoo/conditioner, or conditioner before using lice medicine. Do not re-wash the hair for 1-2 days after the lice medicine is removed.
- If a few live lice are still found after 8-12 hours after treatment, but are moving more slowly than before, do not retreat. Comb dead and any remaining lice out of the hair using a fine-toothed nit comb. Comb from the hair shaft.
- If after 8-12 hours of treatment, no dead lice are found and lice seem as active as before, the medicine may not be working. A different pediculicide may be necessary.
- Carefully follow all treatment instructions contained in the box or printed on the treatment label.
- For some drugs, retreatment is recommended routinely about a week after the first treatment (7-9 days,) depending on the drug) and for others only if crawling lice are seen during this period. Retreatment with lindane shampoo is not recommended.

Supplemental Measures:

- ✓ Machine wash and dry clothing, bed linens, and other items that the infested person wore or used during the 2 days before treatment using the hot water laundry cycle and the high heat drying cycle.
- ✓ Items that are not washable can be dry-cleaned or sealed in a plastic bag and stored for 2 weeks.

- ✓ The AAP recommends rinsing all topical pediculicides from the hair over a sink, rather than in the shower or bath to limit skin exposure and to use warm water rather than hot water to minimize absorption.

Bed Bugs

- Minimal symptomatic treatment and good hygiene to prevent itching and secondary infections are usually sufficient treatment for most cases of bed bug bites.

- Bed bugs are small, flat, parasitic insects that feed solely on the blood of people while they sleep. They are reddish brown in color, wingless and can live several months without a blood meal.

- Bed bug infestations usually hide during the day in places such as seams of mattresses, box springs, bed frames, headboards, dresser tables, inside cracks or crevices, behind wallpaper or any other clutter or objects around a bed. They tend to live within 8 feet of where people sleep.

- Bed bugs are not known to cause disease. Their presence can cause itching and loss of sleep.

Signs and Symptoms of Bed Bug Infestation

- Bite marks on the face, neck, arms, hands or other body parts while sleeping, however these bite marks may take as long as 14 days to develop in some people so look for other clues when determining if bed bugs have infested an area.
  - ✓ The bed bugs' exoskeletons after molting
  - ✓ Bed bugs in the fold of mattresses and sheets
  - ✓ Rusty-colored blood spots due to their blood-filled fecal material that they excrete on the mattress or nearby furniture, and
  - ✓ A sweet musty odor.
- Marks may not show up for one to several days after initial bite. Marks could be random or in a straight line, similar to a mosquito or a flea bite and may itch and be irritating.
- Physical symptoms of bed bug bites include insomnia, anxiety, and skin problems that arise from profuse scratching of the bites.
- Bed Bugs can be transported from place to place as people travel. They travel in the seams and fold of luggage, overnight bags, folded clothes, bedding, furniture, etc. These are called stow-away bugs as they travel from location to location.

Treatment for Bed Bugs

Insecticide spraying – contact the Environmental Services Director

III. DEFINITIONS

cdc.gov/parasites/bedbugs/index.html. September 22, 2020
Lice – Symptoms and Causes – Mayo Clinic. 6/30/2022
cdc.gov/parasites/scabies/index.html, November 2, 2010
mayoclinic.org/diseases-conditions/scabies-causes/syc-20377378 July 28, 2022.

IV. REFERENCES

N/A

V. STAKEHOLDERS

All healthcare staff working, leaders, and Infection Prevention & Control

C. DIFF COLLABORATIVE UPDATE

Gloria IP

Jenn Pharmacy

Susan Lab

Tracy, Kari Quality

Sherri, Anna Nursing

Initiated April 7th

Meets Q Friday 9am for 30 minutes

Report for PTIC May 3, 2023

WCH 3E/3W C. DIFF HOSPITAL ACQUIRED INFECTIONS(HAI)

February 2023 = 4 infections

3 of these infections we attributed as hospital acquired as we failed to send a specimen within the patient's first 3 days. This also delayed treatment for these infected patients.

WATSONVILLE COMMUNITY HOSPITAL

WE HAVE A C. DIFF PROBLEM, WHAT DO WE DO NOW?

WATSONVILLE COMMUNITY HOSPITAL

Form a Multidisciplinary Workgroup

New DRAFT to PITC 5/3

Review our Policy

Completed

Explore Evidence-Based Best Practices HSAG Review 4.28.23

3E Pilot Unit

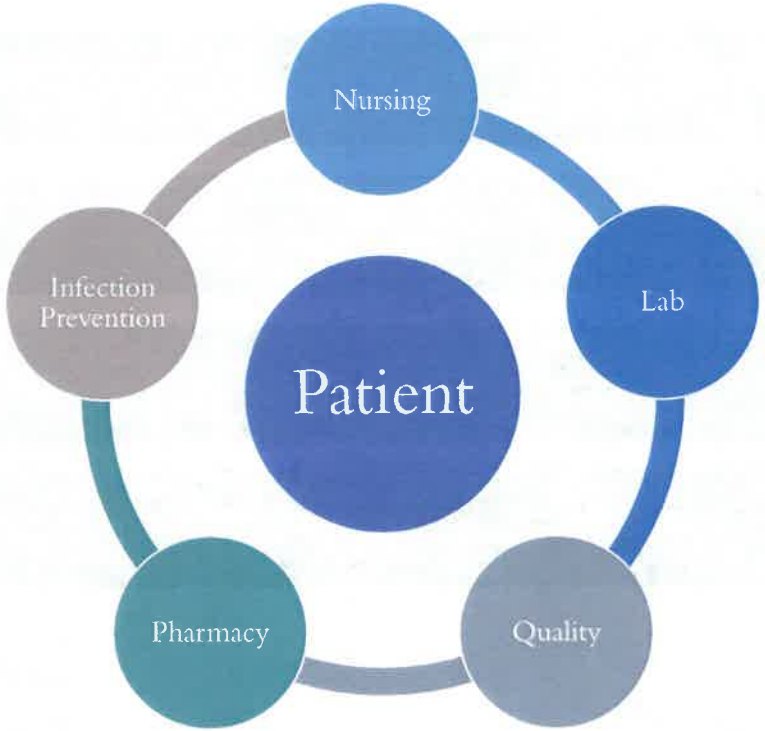
- 4/11 nursing education
- 4/27 specimen bag, placard pilot

Plan, Do, Study, Act

WCH C. DIFF MULTIDISCIPLINARY WORKGROUP

Goal: Reduce the incidence of hospital acquired C. difficile in 3W/3E as evidenced by Q2 2023 SIR ≤1.0 by December 30, 2023.

Method: Utilize a collaborative MTD workgroup exploring and implementing EBP across the domains of nursing, lab, pharmacy, quality and infection prevention.



WATSONVILLE COMMUNITY HOSPITAL

WCH PREVENTION OF CLOSTRIDIUM DIFF

Considerations:

If patient is on laxatives or stool softeners OR has formed stools DO NOT send specimen

DO NOT SEND

If patient is admitted with recent history of diarrhea-do not need to wait for 3rd loose sto

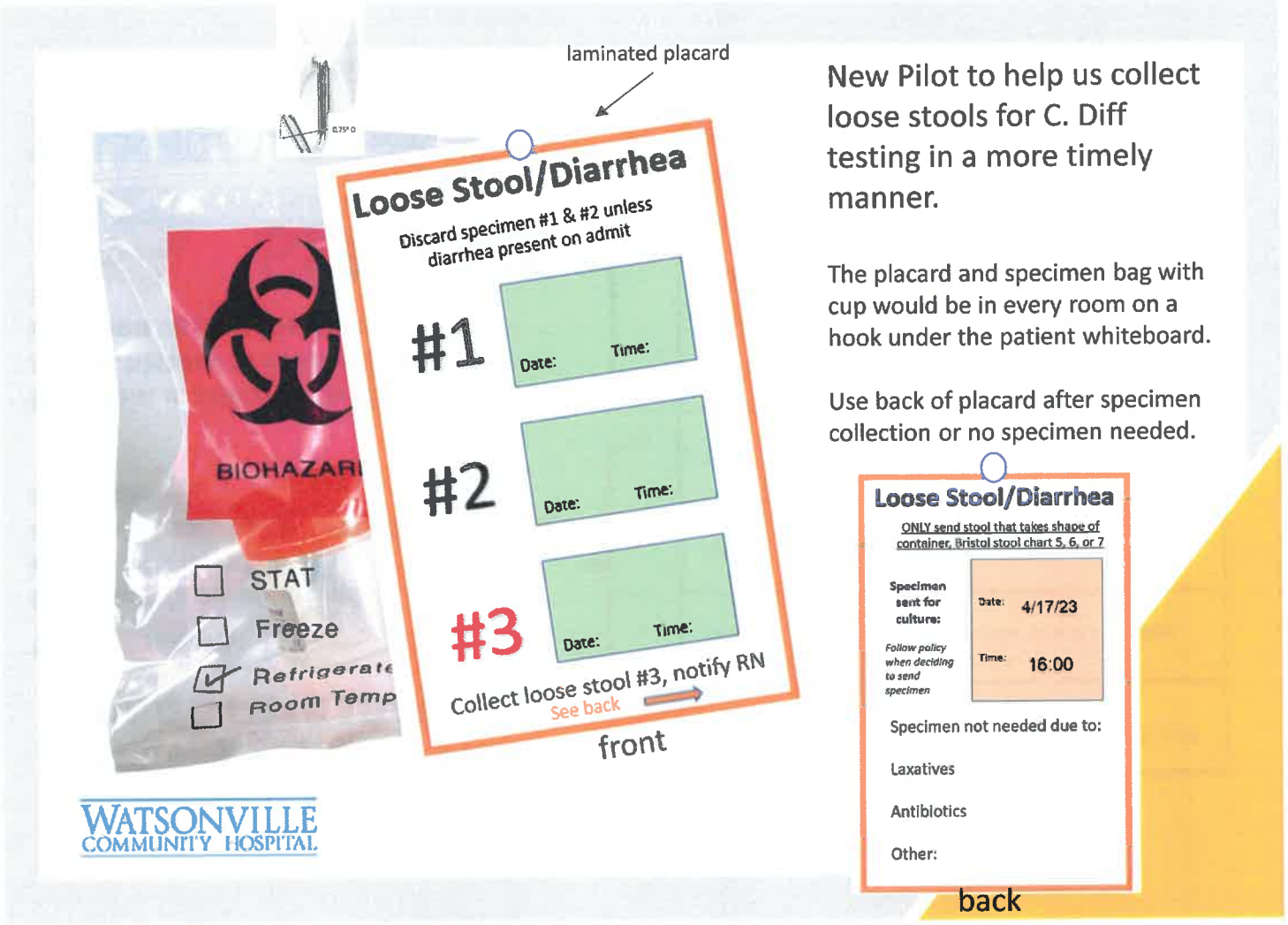
SEND ME

WATSONVILLE COMMUNITY HOSPITAL

Bristol Stool Chart

Type 1		Separate hard lumps, like nuts (hard to pass)
Type 2		Sausage-shaped but lumpy
Type 3		Like a sausage but with cracks on the surface
Type 4		Like a sausage or snake smooth and soft
Type 5		Soft blobs with clear-cut edges
Type 6		Fluffy pieces with ragged edges, a mushy stool
Type 7		Watery, no solid pieces, Entirely Liquid

3E Pilot
Launched
4/30/23



Laminated Placard

front

Loose Stool/Diarrhea

Discard specimen #1 & #2 unless diarrhea present on admit

#1 Date: Time:

#2 Date: Time:

#3 Date: Time:

Collect loose stool #3, notify RN

See back

back

Loose Stool/Diarrhea

ONLY send stool that takes shape of container, Bristol stool chart 5, 6, or 7

Specimen sent for culture:

Follow policy when deciding to send specimen

Date:

Time:

Specimen not needed due to:

Laxatives

Antibiotics

Other:

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Clostridioides difficile: Prevention, Control and Management	Policy #	IP115~~XXXX X~~
Responsible	Director, Infection Prevention & Control	Revised/Reviewed	~~02/25/2022~~ 04/27/2023

I. PURPOSE

To reduce the incidence of hospital-acquired C. difficile infection by implementing the most recent evidence-based bundles throughout Watsonville Community Hospital.

II. PROCEDURE

Until another alternate diagnosis can be made, immediately isolate any patient upon admission with recent history of diarrhea or assessed to have active diarrhea symptoms.

Initial Implementation of Isolation Precautions

a. Patient is placed in private room or with another patient who had a documented CDI infection
b. **Enteric Contact Signage** posted on patient's door
c. Duration of Enteric Contact Precautions should be initiated/maintained for entirety of admission. Patient's readmitted to the hospital within 90 days of previous CDI should also be placed in Enteric Contact Precautions.
d. Accessibility of personal protective equipment (PPE) should be stocked at the beginning of each shift and readily available. A sink should be easily accessible for washing hands immediately following care of patient.

Hospital and Staff Specific Precautions:

i. Prior to initially entering room of Enteric Contact patient: use ABHR, put on gown and gloves prior to entering room and gown should be tied;
ii. Perform hand hygiene before donning gloves – Use ABHR prior to donning gloves before going into the patient's room
iii. Getting ready to exit patient's room: Remove all PPE inside of patient's room prior to exiting being careful not to contaminate self with the outside of the contaminated gloves and gown.
iv. Perform hand hygiene with ABHR immediately after removing gloves inside of the patient's room (this can help to remove any of the younger spores that have not as yet developed the hard outer shell; but then immediately upon exiting room, find the nearest sink to wash hands with soap and water.

v. Disposable Equipment – when possible, disposable equipment (including stethoscopes) should be used; otherwise all equipment must be cleaned with an approved WCH sporicidal agent. Disposable equipment should be disinfected inside of the room immediately prior to exiting and left inside of the patient room.
vi. Use of Bristol Stool Chart when noting patient's who are frequent stooling. The stools can be noted as Type 5 through Type 7 and the timeframe when the stooling occurred. (See Appendix A)
vii. Stool specimen for C. difficile toxin is very unstable and can result in inaccurate results if left at room temperature in a two-hour timeframe. The stool specimen must be kept refrigerated and is to be taken to the laboratory within a reasonable time.

Transporting

1. When transferring patients, notify receiving unit or facilities about the patient's CDI status to ensure receiving patient or ancillary department maintains Contact Enteric Precautions at the patient's new locations.

Testing

Who Should be Tested

Adults:

Patients with diarrhea (greater than 3 unformed stools in the previous 24 hours), particularly those with risk factors and no other explanation for diarrhea.

Hospital admitted patients within the first 48 hours of admission with complaints of or any unexplained loose stools prior to admission.

Patients with a previous admission and treatment for CDI with prior resolution of symptoms who were readmitted after a 90- day discharge period.

Patients admitted within the first 3 days of admission (Day of Admission (DOA) is day one, no matter the time of day the patient is admitted). This 3-day time period ends the *Nurse Driven Protocol* for symptomatic testing of patients with diarrhea. Following this 3-day timeline period, the nurse is to notify the physician if the patient continues to have diarrhea stools and follows MD orders. Reports given to physician on diarrhea stool should include:

1. Using description from the Bristol Stool Chart,
2. Identifying the total number of times for diarrhea episodes and within what timeframe (i.e., previous 24 hours or few hours)
3. It is the physician's decision for testing beyond the 3-day time period.

Pediatrics Patients greater than or equal to 12 months with appropriate clinical findings (greater than or equal to 3 unformed stools in the previous 24 hours) particularly those with no alternative etiology for diarrhea.

Hospital admitted patient greater than 3 years within the first 48 hours of admission with complaints of or any unexplained loose stool prior to admission

Patient treated for CDI infection with resolution of symptoms who may have a new infection (stool episodes should be measured as 3 or greater unformed stools from patient's baseline bowel movements per day.

Who Should NOT be Tested

- Patients less than 12 months without appropriate clinical findings
- Patients on laxatives (and/or lactulose)
- Any admitted patient age greater than or equal to 3 years of age with less than 3 unexpected liquid/loose stools
- A patient who is still being treated for a recent CDI infection
- A patient who has had a previous C. diff test within the last 7 days
- Do not test for cure following CDI treatment

Nursing Standardized Procedure

a. A patient presenting with the following criteria may have stool collected and sent for c. diff testing by a registered nurse:
   i. Patient has been here for no more than 3 days, and;
   ii. Patient is 12 months of age or older, and;
   iii. Patient is not on laxatives, and;
   iv. Patient is not being treated for CDI, and;
   v. Patient has not had CDI test in the last 7 days, and;

vi. Patient has had 3 or more loose stools (Bristol chart 5-7) within the last 24 hours, or;

vii. Patient is within the first 48 hours of admission with complaints of or any unexplained loose stools prior to admission

b. Nursing will document all patient stools and the types of stools

c. Specimen will be sent for testing per laboratory protocol

d. RNs collecting these samples based on a standardized procedure will be deemed competent upon hire and annually

e. Annual education will be provided on C. Diff

Environmental Disinfection

1. During daily room cleaning and discharge terminal cleaning, it is best to leave the C. diff room patients cleaning for last
2. Environmental Services performs room cleaning using sporicidal approved product (use daily and at discharge with terminal cleaning).
3. Adequacy of room cleaning to be assessed by direct observations for cleaning practices and/or any other useful microbiologic culturing to ensure adequate cleaning of room.
4. Any healthcare worker must use the sporicidal disinfectant wipe to ensure consistent decontamination of high touch surface areas

Laboratory and other WCH Invested Programs

Laboratory Personnel

1. Implement laboratory procedures to ensure testing of only appropriate specimens (e.g., unformed stool) for C. difficile or its toxins; and conform to the specimen collection cup.
2. Report test results immediately to clinical care providers and infection control personnel through reliable means
3. Ensure consistent and appropriate testing is conducted.

Pharmacy / WCH Antimicrobial Stewardship Program

Assesses the appropriateness of prescribing antibiotics that pose the highest risk for CDI occurrence, especially fluoroquinolones, carbapenems, and 3rd and 4th generation cephalosporins

1. Develop WCH facility-specific treatment recommendations for common infections
2. Evaluate antibiotic treatment of conditions that commonly lead to high-risk antibiotic use, such as asymptomatic bacteriuria and common infections such as urinary tract infection and community-acquired pneumonia, to minimize the use of high-risk antibiotics
3. Ensure that patients receive the shortest effective duration of antibiotic therapy
4. Include inpatient antibiotic duration when determining post-discharge antibiotic

III. DEFINITIONS

ABHR: Alcohol Based Hand Rub
Clostridioides (formerly known as Clostridium) difficile infection

IV. REFERENCES

1. Stuart Johnson, Valéry Lavergne, Andrew M Skinner, Anne J Gonzales-Luna, Kevin W Garey, Ciaran P Kelly, Mark H Wilcox, Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of *Clostridioides difficile* Infection in Adults, *Clinical Infectious Diseases*, Volume 73, Issue 5, 1 September 2021, Pages e1029–e1044,
2. CDI Prevention Strategies: Centers for Disease Control and Prevention. cdc.gov/cdiff/clinicians/cdi-prevention-strategies.html. 12/17/2021
   Jacsson Musuuza, Ann Schoofs Hundt, Pascale Carayon, Karly Christensen, Caitlyn Ngam, Nicholas Haun, and Nasia Safdar. "Implementation of a Clostridioides difficile prevention bundle: Understanding common, unique, and conflicting work system barriers and facilitators for sub-process design." Infection Control Hospital Epidemiology. 2019 Aug: 40(8): 880-888.
3. APIC: Association for Professionals in Infection Control and Epidemiology. Guide to Preventing Clostridium difficile Infections (2013)

V. STAKEHOLDERS

Nursing, Physicians, Leadership, Quality & Safety, Infection Prevention & Control

APPENDIX A

Bristol Stool Chart

Bristol stool chart

Type 1		Separate hard lumps, like nuts (hard to pass)
Type 2		Sausage-shaped but lumpy
Type 3		Like a sausage but with cracks on its surface
Type 4		Like a sausage or snake, smooth and soft
Type 5		Soft blobs with clear-cut edges (passed easily)
Type 6		Fluffy pieces with ragged edges, a mushy stool
Type 7		Watery, no solid pieces, **Entirely liquid**

Bloodborne Pathogen Exposure (BBPE) Process (updated 5/3/2023)

STEPS	PURPOSE	BY WHOM	GUIDELINES
STEP 1	**Immediate First Aid** by "Exposed" (employee, contractor, practitioner) • Contact Nursing Supervisor (x5654, cell 831-234-2389)	• Employees • Contractors (e.g., travelers) • Practitioner • First Responders – will be accompanied by a Supervisor	• Lightly wash needlestick/cut exposed area with soap and water • Flush splashes to the nose, mouth, or skin with water • Irrigate eyes with clean water, saline, or sterile irrigation

STEP 2	**Identify if a BBPE has occurred?**
	 
	If NO BBPE has occurred, then the process can be STOPPED at this point.
	If YES, a BBPE has occurred, then proceed to STEP 3 testing below:
		Nursing Supervisor:
		• Notify (email or call):
		  ○ Human Resources (x1248)*
		  ○ Employee's manager
		• Assist employee in completing:
		  ○ Incident report (VERGE)
		  ○ BBPE paperwork
		* **Human Resources** notify for follow up:
		• Infection Prevention (x6014)
		  ○ Practitioner
		  ○ First responder
		• Employee Health (x1966)
		  ○ Employee
		  ○ Contractor
			What is considered to be a potential exposure to HIV, HBV, or HCV?
			For transmission of bloodborne pathogens (HIV, HBV and HCV) to occur, an exposure must include "both" of the following.
			1) **Infectious Body Fluid:** blood, semen, vaginal fluid, amniotic fluid, breast milk, cerebrospinal fluid, pericardial fluid, pleural fluid and synovial fluid can transmit HIV, HBV, and HCV.
			Note: Saliva, vomitus, urine, feces, sweat, tears and respiratory secretions do not transmit HIV (unless visibly bloody). Risk of HBV and HCV transmission from non-bloody saliva considered negligible.
			UCSF PEP-line (CDC experts on BBPE) does not recommend routine HIV, HBV or HCV surveillance testing following exposure or possible exposure to non-bloody saliva.
			2) **A portal of entry (percutaneous, mucous membrane, cutaneous with non-intact skin)**
			If both 1 and 2 above are not present, there is no risk of blood borne pathogen transmission and further evaluation is not required.

STEP 3	**Registration** of both Source and Exposed (Non-Source)	**Nursing Supervisor** facilitate registration: • Take "Exposed" to ED to register • Prompt for work comp information (contractor, practitioner, first responder) First Responder "Infectious Exposure Reporting Form" forward to Infection Prevention	**Source:** MRN# 6120156 Industrial billing account: • This account will NOT bill the patient/source • Update account number monthly (**Registration**) **Non-source ("Exposed"):** • Creates account in MedHost w/ Work-Comp as payor or plan • If Work-Comp information not known, select "MISC" Work-Comp payor or plan

Bloodborne Pathogen Exposure (BBPE) Process (updated 5/3/2023)

STEPS	STEP PURPOSE	BY WHOM	GUIDELINES
STEP 4	**Laboratory Baseline Testing** for "Source" & "Exposed" **If STAT Rapid HIV for "Source" is POSITIVE, then proceed to Step 5**	**ED Practitioner to be ordering provider for Labs:** • Employees • Contractors • First Responder ***NOTE: anyone using ED services will receive a bill from Vituity*** ✓ Practitioners can order lab work for self ("Exposed") and source **Nursing Supervisor**: • Facilitate blood draw for "Exposed" and "Source" • If practitioner orders own labs, call Lab x1237	**"Source" Person:** a) HIV Ag/Ab or HIV Ab (rapid HIV testing preferred if accessible)* Turnaround time should be no greater than 1-2 hours for initiation of PEP if needed. b) HCV Ab or HCV RNA ("HCV viral load") HBsAg (HBV surface antigen) or a hepatitis panel including HBsAg, HBsAb and HBcAb **Non-Source ("Exposed") Person:** a) HIV Ag/Ab or HIV Ab b) HCV Ab (if positive, follow-up with HCV RNA testing) c) HBV testing: Depends on immunization status.
STEP 5	**HIV PEP indicated** ***(rapid HIV is positive)*** Note: Is a rapid HIV test accurate enough to decide on whether to give PEP? Rapid HIV tests are generally very sensitive and specific and can be used to determine whether to offer PEP. A positive rapid HIV test should be preliminarily considered a true positive for the purposes of initial PEP decision-making. A negative rapid test should be considered a true negative. Investigation of whether a source might be in the "window period" is unnecessary for determining whether HIV PEP is indicated unless acute HIV is clinically suspected.	**ED Practitioner:** • Consult (review for drug interactions) • Dispense HIV PEP (3 day supply) **ED RN:** • Remove HIV PEP from ED Fast Track Pyxis	First dose should be given as soon as possible. Optimal time is within hours of exposure, rather than days. Do not wait for SP test results (unless results will be available within an hour or two) to proceed with a PEP decision and initiation, when indicated. PEP-line considers 72 hours post-exposure as the outer limit of opportunity to initiate PEP; however, delay of that scale is believed to compromise PEP efficacy. Consultation with the PEP-line or an expert in post-exposure prophylaxis is recommended if considering PEP initiation beyond 72 hours. **Nursing Supervisor to send the following information to Inpatient Pharmacy ASAP:** ✓ Patient information/face sheet; ✓ Medication prescription and work comp information

Bloodborne Pathogen Exposure Control Plan (BBP/ECP)
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Bloodborne Pathogen Exposure Control Plan (BBP/ECP)
Table of Contents

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Bloodborne Pathogen Exposure Control Plan (BBP/ ECP)	Policy #	0147
Responsible	Director of Infection Prevention & Control	Revised/Reviewed	Revised 5/1/2023

I. PURPOSE

Watsonville Community Hospital (WCH) is committed to providing a safe and healthy work environment for all staff. In pursuit of this goal, the following bloodborne pathogen / exposure control plan (BBP/ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA Standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." Employees at WCH are at risk for occupational exposure to bloodborne pathogens.

The ECP includes:

1. Determination of employee exposure
2. Implementation of various methods of exposure control. Included in this document are:
    - Standard Precautions
    - Engineering and work practice controls
    - Personal protective equipment
    - Housekeeping
    - Hepatitis B vaccination
    - Post-exposure evaluation and follow-up
    - Recordkeeping
    - Procedures for evaluating circumstances surrounding exposure incidents

In addition to its internal healthcare workers, WCH includes in this policy the Division 2.5, California Health and Safety Code Sections for Emergency Medical Services System and the Prehospital Emergency Medical Care Personnel Act (Code Section 1797), which is a follow-up to the Federal Ryan White HIV/AIDS Program legislation that was first enacted in 1990 and amended and reauthorized four times (1996, 2000, 2006, and 2009). Not all sections of this document are relevant to the Ryan White Act. Sections that are relevant will outline initial guidelines and procedures specific for EMS personnel. The goal of including EMS into this document is:

1. To meet Federal and State guidelines to protect "First Responders" from a communicable bloodborne pathogen or other communicable disease infection, and
2. To evaluate and report suspected exposures to the Santa Cruz County Public Health Division's Communicable Disease Unit. (Reported to Infection Prevention & Control who then reports the EMS BBPE to the County's authorized representative).

DEFINITIONS

Occupational Exposure: reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or OPIM that may result from the performance of an employee's duties.

Parenteral Contact – piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

OPIM – Other Potentially Infectious Material includes various contaminated human body fluids, unfixed human tissues or organs (other than skin), and other materials known or reasonably likely to be infected with human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) through cells, tissues, blood, organs, culture mediums or solutions.

II. POLICY

Infection Prevention & Control and Employee Health Services (IC/EHS) are responsible for the implementation of the BBP/ECP. The two departments will collaboratively maintain, review, and update the BBP/ECP annually, and whenever necessary to include new or modified tasks and procedures. The BBP/ECP will be reviewed and approved by all units directly and/or indirectly involved in the processes involved with determining and treating bloodborne pathogen exposures. Once all involved units have approved the processes, the policy will go through all hospital committees; initially through Antimicrobial Stewardship/Infection Prevention & Control Committee, Quality & Safety, and Medical Executive Board for approval. Physicians are also involved directly through their votes at the various multidisciplinary meetings.

Other categorized employees (non-WCH employees & Medical Staff) who have had an occupational exposure to blood or OPIM must comply with the procedures and work practices outlined in this ECP. Medical Staff's initial work-up will be completed, but further treatment and follow-up will be provided by the individual's authorized Worker's Compensation company. Infection Prevention & Control and/or Supervisor will follow-up with practitioners and/or contracted employees after normal business hours, holidays and weekends (initial steps, and laboratory test results).

1. Basic Guidelines for Exposures ~~during Normal and After Normal Business Hours~~.
    - After immediate first aid by employee, Nursing Supervisor will be contacted to facilitate BBPE Process
    - Nursing Supervisor will identify whether or not a BBPE has occurred. If a BBPE has occurred, Nursing Supervisor shall notify Human Resources and Employee manager, and assist "Exposed" in completing necessary paperwork (e.g., incident report and any additional [e.g., work comp] paperwork).
    - Infection Prevention & Control (IP&C) will follow up on ~~be notified of the~~ Practitioners and First Responder's BBPE ~~immediately for Normal Business Hours and House Supervisor for After Normal Business Hours~~
    - Employee Health (EH) will ~~be notified of the~~follow up on contracted employee's and WCH employee's BBPE ~~immediately for Normal Business Hours. All healthcare worker's BBPE After Normal Business Hours will be called to the House Supervisor.~~

- Nursing Supervisor shall facilitate registration process via ED Registrar. Exception: if "Exposed" is provider and the provider requests not registering for an ED visit, provider can order lab work for self ("Exposed") and "Source"
- ~~IP&C, EH and House~~Nursing Supervisor will ensure that initial steps have been completed ("SOURCE" patient's blood is drawn and "EXPOSED" individual's initial bloodwork is drawn)
- ~~For after normal business hours BBPE, the House Supervisor will notify the HCW of the "SOURCE" HIV results.~~ If "SOURCE" HIV is negative (no exposure for HIV has occurred), WCH staff will be directed for further follow-up with WCH contracted clinic through Employee Health and/or practitioner's independent worker's compensation group during normal business hours. All First Responders' BBPE will be called to the authorized County representative for both after and normal business hours.
- Hepatitis B and Hepatitis C are not rapid turnaround tests and the exposed will be notified when the results are known. The "EXPOSED" individuals will be informed dependent upon their contractual agreements of employment.
- If "SOURCE" HIV is positive ~~after normal business hours, holidays or weekends~~, then the ~~healthcare workers and First Responders~~ "Exposed" will be referred to the Emergency Department for initial consult and discussion on PEP. During Normal Business Hours, Employee Health will arrange an appointment with the outside contracted clinic for WCH Healthcare Workers and Contracted Employees. Practitioners will decide if they prefer to go to the Emergency Department for initial treatment, otherwise, they will be given the UCSF BBPE Guidelines and can order the testing and medications recommended, and/or can call UCSF during normal and after business hours.

Human Resources will be responsible for establishing and implementing reporting procedures to ensure all incidents involving the presence of blood or OPIM are reported via In-House Reporting and to Employee Health within 24-hours of the exposure. The incident report will include the names of all staff who provided assistance, whether personal protective equipment was used and shall give specific details on the exposure incident, including the date and time and initial First Aid taken.

Employee Health Services (EHS) will establish and maintain a Sharps Injury Record of each exposure incident involving a sharp. Human Resources will be responsible for recording exposure incidents on the Sharps Injury Record within 14 working days of the date the incident is reported to the employer. Sharps Injury Log will contain the following:

- Type & brand of device involved in the incident
- Location of incident
- Description of incident
- Contact location/phone number

Distribution and Environmental Services (EVS) stock and maintain all necessary personal protective equipment (PPE), and engineering controls (e.g., sharps containers), labels, and red bags as required

by this Standard. Adequate supplies of the aforementioned equipment will be readily available in appropriate sizes at all times for staff safety.

Infection Prevention & Control, Employee Health Services, and Human Resources will be responsible for ensuring that all medical actions required by this Standard are completed and that appropriate employee health and OSHA records are maintained.

Human Resources, Employee Health (EH), Infection Prevention & Control, and Education will be responsible for training, documentation of training, and ensure the written BBP/ECP is available to employees, OSHA, and NIOSH representatives.

House Supervisors ~~(for after business hours, weekends, and holidays)~~ will assist with the initial steps in the BBPE process (lab work for the "Exposed" and "Source," directing staff to Emergency Department if "Source" HIV is positive for initial consultation, assisting practitioners with the first steps in the BBPE process and of the initial HIV "Source" results, and notifying First Responders' authorized representative.

III. PROCEDURE

A. Employee Exposure Determination (Please see **Appendix A**) attached. This is a listing of job classifications in which employees at WCH could have occupational exposure. Included is a list of tasks and procedures, in which occupational exposure may occur for these individuals.

B. Methods of Implementation and Control:

1) Standard Precautions: All employees will adhere to Standard Precautions with patients at all times

2) Exposure Control Plan: Employees covered under WCH's bloodborne pathogens standard will receive an explanation of the ECP during their onboarding training session. It will also be reviewed during the annual refresher training. All employees can review this plan at any time during their work shifts by contacting Human Resources. If requested, WCH will provide an employee with a copy of the ECP free of charge and within 15 days of request.

Communication on bloodborne pathogen exposure policy for ~~Licensed Independent Contractors (LIP)~~practitioiners will occur through Committees, written communication and at time of their initial appointment to WCH.

Infection Prevention & Control and Employee Health in consultation with other hospital units directly involved with WCH's ECP Plan will be responsible for reviewing and updating the ECP annually or more frequently, if necessary, to reflect any new or modified tasks and procedures that affect occupational exposure, to reflect new or revised employee positions with occupational exposure, and/or make changes consistent with newly revised standards.

C. Engineering Controls and Work Practices:

a. Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens. Some of the engineering controls and work practice controls used are listed in **Appendix B.** Engineering and work practice controls are intended to eliminate or isolate hazards and promote a safer workplace.

b. Sharps disposal containers are inspected and maintained or replaced by a contractor or Environmental Services staff (EVS) when the contractor is not on site. The contracted company picks up waste daily, and are on site daily for sharps pick- up. EVS replaces full red sharp containers during the times and days (weekend) when the contracted company is not on site to prevent overfilling. The procedure for handling sharps disposal containers is located in **Appendix C**.

Contaminated sharps are discarded immediately or as soon as possible in containers that are closeable, puncture resistant, leak proof on sides and bottoms, and appropriately labeled or color coded. Sharps disposable containers are available in strategic areas on patient care units: patient rooms~~, WOWs~~, medication room, procedure room, surgical department areas and anywhere sharps might be used during patient care or other type of work processes.

c. WCH identifies the need for changes in engineering controls and work practices regularly through Employee Health OSHA records, employee interviews, event reporting, routine assessment via practice drills, and supplier information. WCH also has a regularly scheduled Hospital Environment of Care Committee (with multi-disciplinary members) whose members review and participate in the decision-making process to approve changes.

d. WCH evaluates new procedures and new products regularly through the Products Committee (multi-disciplinary members) and has established guidelines for policy and procedure review, revision, or amendment.

e. Both front-line workers and management staff are involved in the approval process in the following manner: Nursing Governance Board reviews nursing policies submitted to them from the unit Directors and/or specific specialty Director. Through input of employees, practitioners, and County (for First Responders) to BBPE from their experience with the process.

f. Chief Nursing Officer and/or Quality & Safety Director is responsible for ensuring recommendations are implemented.

D. Personal Protective Equipment (PPE)

PPE is provided to our employees at no cost to them. Training in the use of the appropriate PPE for specific tasks, procedures or isolation is provided by Infection Prevention & Control and Education Department. A listing of PPE available to employees are listed in **Appendix D**.

PPE is stored in Central Distribution and stocked levels are maintained on the patient care units. The units are stocked routinely at a specific stock level but when needed, the units can call Central Distribution to restock, replace and/or supply the unit with an item that is normally stocked or not stocked.

All employees using PPE must observe the following precautions:

1. Wash hands immediately or as soon as feasible after removing gloves or other PPE
2. Remove PPE after it becomes contaminated and before leaving the work area.
3. Used/disposable PPE may be disposed of in a trash receptacle with a lid (trash waste).
4. Wear appropriate gloves when it is reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated items or surfaces; replace gloves if torn, punctured or contaminated, or if their ability to function as a barrier is compromised.
5. Utility gloves (Engineering, etc.) may be decontaminated for reuse following manufacturer guidelines if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
6. NEVER wash or decontaminate disposable gloves for reuse. NEVER REUSE DISPOSABLE ITEMS.
7. Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eyes, nose, or mouth.
8. Remove PPE immediately or as soon as feasible if contaminated by blood or OPIM. The person removing the PPE should do so in a manner to avoid contact with the OPIM on oneself. The procedures for handling used PPE is located in **Appendix E**.

E. Housekeeping

Regulated Waste is placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded (see the following section "labels"), and closed prior to removal to prevent spillage or protrusion of contents during handling. The procedure for handling other regulated waste is located in **Appendix F.**

Cleaning and Decontamination: Re-useable bins and pails (e.g., wash or emesis basins) are cleaned and decontaminated as soon as feasible after visible contamination by the nursing staff, but are discarded after patient is discharged.

Broken glassware that may be contaminated is only picked up by mechanical means, such as a brush and dustpan.

Laundry

The following contaminated articles will be laundered by WCH's contracted company.
Staff will follow the following laundry requirements:

- Handle contaminated laundry as little as possible, with minimal agitation
- Place wet contaminated laundry in leak-proof, labeled or color-coded containers before transport. Use bags for this purpose only.
- Wear the following PPE when handling and/or sorting contaminated laundry: gown, gloves, and surgical mask while handling to sort or place into another laundry bag when using any type of agitation to loosen laundry.

Labels
The following labeling methods are used in this facility:
Equipment to be labeled and label type can be found in **Appendix G.**

Environmental Services Department is responsible for ensuring that warning labels are affixed or red bags are used as required if regulated waste or contaminated equipment is brought into the facility. Employees are to notify their direct Supervisor if they discover regulated waste containers, refrigerators containing blood or OPIM, contaminated equipment, etc., without proper labels.

F. Hepatitis B Vaccination

WCH's contracted employee health clinic will provide training to employees on Hepatitis B vaccination, addressing safety, benefits, efficacy, methods of administration, and availability.

The Hepatitis B vaccination series is available at no cost after initial employee training and within 10 days of initial assignment to all employees identified in the exposure determination section of this plan. Vaccination is encouraged unless:

1) Documentation exists that the employee has previously received the series,
2) Antibody testing reveals that the employee is immune, or
3) Medical evaluation shows that vaccination is contraindicated.

However, if an employee declines the vaccination, the employee must sign a declination form. Employees who decline may request and obtain the vaccination at a later date at no cost. Documentation of refusal of the vaccination is kept in the employee's Employee Health file.

Following a new hire's medical evaluation, a copy of the healthcare professional's written opinion will be obtained and provided to the employee within 15 days of the completion of the evaluation. It will be limited to whether the employee requires the hepatitis vaccine and whether the vaccine was administered.

G. Post Exposure Evaluation and Follow-Up

When an exposure incident occurs, staff should contact their unit supervisor immediately. A confidential medical evaluation will be completed by WCH's contacted clinic as soon as possible for employees who have had an exposure incident. However, if the Source person's HIV is negative, and it is on a weekend, holiday, or after hours, the time to schedule an appointment may not be made until the next business day.

The **Exposed person's** first step is the initial first-aid (cleaning of the wound, flush eyes, or other mucous membrane, etc.).

After the initial first-aid (cleaning of the wound, flush eyes or other mucous membrane), the Nursing Supervisor will be contacted to coordinate and facilitate the following activities ~~will be performed~~:

1) An **Event Report** will be completed noting route of exposure and how the exposure occurred.
2) Identify and document the **Source Individual** ~~to the Unit Supervisor~~.
3) **Order blood laboratory testing for the Source** as soon as possible to determine HIV, HCV and HCB infectivity.
    - If the SOURCE's BBPE blood test is already known for HIV, HCV, and/or HBV as a result of a current admission, or a positive HIV for a Source has resulted and the patient is known to have HIV/AIDS, then the testing does not need to be performed in this situation. The current results from the patient's chart can be used.

    - If the SOURCE cannot be located, is not known. Then the exposed person's risk should be treated as if the source has HIV. Consultation with the EXPOSED person should be conducted to inform them of the high-risk determination process, and then determine if the EXPOSED wants to pursue the HIV PEP in the absence of source testing. UCSF notes that outer limits to initiate PEP for HIV is beyond 72 hours.

    - If the Discharged Patient had blood drawn while a patient at WCH, the Lab holds blood from a hematology draw for 2 days and from other types of lab work drawn for 7 days. Please ask Laboratory if they have enough blood on hold from the discharged patient to perform the needed tests.

4) Ensure the "Exposed" is provided with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
5) ~~Infection Prevention & Control will provide the Practitioner and First Responders' Worker's Compensation representative with test results. Employee Health will notify the contracted staff member's Worker's Compensation authorized representative of the BBPE and follow their guidance on their worker's next steps.~~
6) Collect "Exposed" employee's blood as soon as feasible after the exposure incident, and test blood for HIV, HCV and HBV serological status. (the information is used only for follow-up physician or clinic visits to aid in the BBPE treatment for follow-up).
7) If the "Source" person's rapid HIV returns negative, then the House Supervisor and/or Infection Prevention & Control will speak to the Exposed person to discuss the next steps (A negative HIV result means that the Exposed person is not exposed to HIV as the Source does not have HIV). There is no necessity to give the Exposed Post Exposure Prophylaxis (PEP) as the Exposed HCW is not at risk. However, all Exposed HCWs will need to do further follow-up:

    - If a WCH employee, follow up with Employee Health / Pinnacle (this process is put into action by Employee Health on behalf of the employee). If the BBPE occurs during normal business hours when Employee Health is open then the Exposed HCW will be sent to the contracted clinic ASAP. If it occurs after normal business hours, holidays, or weekend, then the employee will be scheduled to visit the contracted clinic on the next

business day. If after normal business hours and the "Source" HIV result is positive, then the employee will be sent to the Emergency Department for initial consultation regarding PEP.

- If Exposed HCW is a contracted HCW, then Employee Health will contact their employer's representative for continued follow-up per each individual Company policy. However, if after normal business hours and the "Source" is HIV positive, the contracted healthcare worker will be sent to the Emergency Department for initial consultation on PEP.
- If "Exposed" is a Practitioner, orders can be written by the ~~person~~practitioner for lab work and PEP prescription, OR can be seen in the Emergency Department.
- If a County "First Responder" is the "Exposed" person, either Infection Prevention & Control and/or House Supervisor will speak with the County's authorized Worker's Compensation representative after lab results are known.

ADMINISTRATION OF POST-EXPOSURE EVALUATION AND FOLLOW-UP

Employee Health ensures that healthcare professionals are given a copy of WCH's bloodborne pathogen policy.

Employee Health ensures that the health care professional evaluating an employee after an exposure incident collects the following information:

- A description of the employee's job duties relevant to the exposure incident
- Route(s) of exposure
- Circumstances of exposure
- If possible, results of the source individual's blood test
- Relevant employee medical records, including vaccination status
- Employee Health provides the employee with a copy of the evaluating health care professional's written opinion within 15 days after completion of the evaluation.

PROCEDURES FOR EVALUATING THE CIRCUMSTANCES SURROUNDING AN EXPOSURE INCIDENT

Individuals who evaluate the circumstance of an exposure incident should determine in the report specific questions related to the BBPE (for purposes of this policy~~),~~); this MUST be completed for all WCH staff (whether a WCH employee and/or contracted employee, First Responders and/or Licensed Independent Practitioners.

- Engineering controls in use at the time of the exposure
- Work practices followed
- A description of the device being used (including type and brand)
- Protective equipment or clothing that was used at the time of the exposure incident
- Location of the incident (OR, ED, patient room, etc.)
- Procedure being performed when the incident occurred
- Employee's training

Employee Health/Human Resources will record all percutaneous injuries from contaminated sharps in a Sharps Injury Log.

H. EMPLOYEE TRAINING

All employees who have occupational exposure to bloodborne pathogens receive initial and annual training conducted Employee Health.

All employees who have occupational exposure to bloodborne pathogens receive training on the epidemiology, symptoms, and transmission of bloodborne pathogen diseases. In addition, the training program covers at a minimum, the following elements~~.~~:

- A copy and explanation of the OSHA bloodborne pathogen standard
- An explanation of our ECP and how to obtain a copy
- An explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident.
- An explanation of the use and limitations of engineering controls, work practices, and PPE.
- An explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE.
- An explanation of the basis for PPE selection
- Information on the Hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge.
- Information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM
- Information on the post-exposure evaluation and follow-up that the employer is required to provide for the Exposed HCW following an exposure incident.

I. RECORDKEEPING

Training records are completed for each employee upon completion of training. These documents will be kept for at least three years in ~~the HealthStream System. Transcript is completed for individuals or it can run a report for the Rapid Regulatory I and II modules per year for completions.~~employee's education file.

The training includes:

- The dates of the training sessions
- The contents or a summary of the training sessions
- The names and qualifications of persons conducting the training
- The names and job titles of all persons attending the training sessions.

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to Human Resources.

a) **MEDICAL RECORDS**: maintained for each employee with occupational exposure in accordance with 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records."

i. The Workers' Compensation Insurance Company is responsible for maintenance of the required medical records. These confidential records are kept in for at least the duration of the staff member's employment plus 30 years.

ii. Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to Human Resources.

b) **OSHA RECORDKEEPING:** An exposure is evaluated to determine if the case meets OSHA's Recordkeeping requirements (29 CFR 1904). This determination and the recording keeping activities are done by Employee Health.

c) SHARPS INJURY LOG: In addition to the 1904 Recordkeeping Requirements, all percutaneous injuries from contaminated sharps are also recorded in a Sharps Injury Log. All incidences must include at least:

- Date of the Injury
- Type and brand of the device involved (syringe, suture needle)
- Department or work area where the incident occurred
- Explanation of how the incident occurred

This log is reviewed as part of the annual program evaluation and maintained for at least five years following the end of the calendar year covered. If a copy is requested by anyone, it must have any personal identifiers removed from the report.

d) **HEPATITIS B VACCINE DECLINATION SIGNED FORM (MANDATORY)**

REFERENCES

1. Model Plans and Programs for the OSHA Bloodborne Pathogens Exposure Control Plan (OSHA 3186-O6R 2003)
2. Department of Industrial Relations Cal/OSHA Consultation Service Education Unit. "Exposure Control Plan for Bloodborne Pathogens." Published 2001 by the California Department of Industrial Relations.
3. Medical Waste Management Act. California Health and Safety Code, Sections 117600 – 118360. January 2017.

STAKEHOLDERS

All Leaders, Human Resources, Infection Prevention & Control, County Public Health Department and healthcare workers at WCH

APPENDIX A

JOB CLASSIFICATIONS at WCH in WHICH All employees have Occupational Exposure

Anesthesiologists	Intubation and close direct contact and exam of patients who could have a host of viral and/or bacterial infections. BBPE from invasive procedures, needle stick injuries and OPIM splashes
Central Processing Staff	Processing all types of dirty medical equipment and instruments
Certified Nursing Assistants	Involved in direct patient care; inadvertent needle stick injury
Dietary Employees	Handling food contaminated with vomit, blood or OPIM
EMT Personnel	Falls under Ryan White Act (Federal & State)
Emergency Department Staff	Unknown specifics when patients walk into door, invasive procedures, patient care contact with blood and possible OPIM
Plant Operations Engineers	Conducting maintenance/repairs on systems or equipment, containment and clean-up of spills for blood, OPIM, or containing used sharps
Environmental Services Staff	Handling regulated waste, cleaning up spills or equipment
Firefighters	Falls under Ryan White Act (Federal & State)
Hemodialysis Staff	Invasive procedures with blood
Labor & Delivery	Direct patient care contact with blood and possible OPIM, as well as other viral and bacterial OPIM
Laboratory Staff	OPIM of all types
Biomed Staff	Maintenance & Repairs on medical equipment contaminated with blood/OPIM
Nurse Practitioners	Invasive procedure and direct patient care
Phlebotomist	Direct blood draw
Physicians	Invasive procedures; direct patient care of patients with possible viral and/or bacterial OPIM
Physical Therapy Staff	Conducting exams, providing patient therapy
Police Officers	Fall under Ryan White Act (Federal & State)
Registered Nurses	Multiple scenarios whereby nursing staff is exposed to all types of OPIM from invasive procedures, needle sticks, and direct patient care
Security Services	Responding to incidents or emergencies
Surgeons	Invasive procedures and working with sharp instruments
Radiological Technicians	Patient contact activities; attaching/handling/cleaning diagnostic equipment
Wound Care Center Physicians and Nurses	Open wounds, intake of patients and close patient contact

APPENDIX B

Engineering and Work-Practice Controls

ENGINEERING CONTROLS	
	Sharps Disposal Containers
	Self-Sheathing Needles
	Sharps Needleless Systems
	Isolation Practices
	Intake Ventilation – local or dilution
	Exhaust Ventilation
	Using non-lead paint;
	Using power tools equipped with dust collection shrouds
	Other type of dust removal through HEPA vacuum system
	Chemical stripping
	Demolition work using mobile hydraulic shears in place of cutting torch
WORK PRACTICE CONTROLS	
	Needle recapping is prohibited by a two-handed technique
	Splash Guards
	Good Housekeeping, especially in connection with exposure conditions; dust on workplace surfaces must be maintained as free as practicable of accumulations to prevent traffic, vibration or random air currents from making the dust airborne. Regularly scheduled clean up to prevent the build-up of dust. Vacuuming or other method of entrapping dust from becoming airborne (i.e., microfiber cloths). Vacuum equipment with high-efficiency particulate air (HEPA) filters.
	Use of appropriate personal hygiene practices
	Routine inspection and maintenance of process and control equipment (i.e., AIIR)
	Use of proper procedures to perform a task
	Supervision of procedures performed
	Use of administrative controls.
	Blowing with compressed air prohibited from general housekeeping unless used with a ventilation system designed to capture the airborne dust
	Where feasible, debris and contaminated items accumulated for disposal should be wet-misted before handling (especially during construction). Material must be collected and placed into sealed impermeable bags or other closed impermeable containers.
	Bags and containers labeled to indicate that they contain lead-containing waste.
	Facility Engineer employees are not to enter lunchroom facilities or eating areas while wearing protective work clothing or equipment while working in dusty areas (like vents, etc.).
	All employees must wash their hands prior to eating or drinking.
	In Specialty areas (Surgery), work clothing is laundered by WCH and is only to be worn during their normal work hours.
	Periodic inspection and maintenance of process equipment and control equipment such as ventilations systems to detect abnormal conditions that can cause hazardous exposures.
	Construction: abatement to be done by wetting surfaces with water mist prior to sanding, scraping, or sawing.
	Supervision of all work practices

APPENDIX C

Handling Sharps Disposal Container (Biohazardous Waste)

1. Sharps containers are to be leak-resistant, puncture-resistant and designed to withstand the rigors of everyday use before being shipped to RCRA-permitted facilities for compliant processing and disposal. The containers are appropriately color-coded red to warn everyone that the contents are hazardous.

2. When the container has reached the manufacturer's full line indicated on the sharps waste container, the container shall be tightly closed or taped shut to prevent loss of contents prior to disposal. It is to be removed from WCH within the sharps holding time, this is dependent upon WCH's total poundage of sharp's waste. (20 pounds or more of both biohazardous and sharps waste per month, it shall be removed within seven calendar days of closing the container) (WCH at less than 20 pounds combined per month, the sharps containers shall be picked up within 30 calendar days of sealing the containers).

3. WCH has contracted an outside vendor to close full containers, remove, and replace with empty containers that are at the full line. The contracted vendor is on site daily Monday through Friday and also at other times. The contracted vendor transports the containers to a treatment facility for processing and disposal.

4. When the contracted vendor is not on site, (i.e., after hours (holidays), weekends, etc.) the Environmental Services team will close containers, place in the Sharp's holding area and replace an empty container from the site where the full container was removed. The full container will be in a locked position and placed in the holding area for the contracted vendor. Sharps containers are segregated from other types of waste containers and placed on the floor of the storage area for the medical waste transporter.

5. If a container becomes full and is not yet picked up, WCH staff will notify the EVS team to pick up the container and replace with empty container.

6. Any syringe, ampule, carpuject or other sharp which still contains medication shall be disposed of in approved waste container (blue for medical waste non-hazardous).

7. WCH maintains a medical waste tracking document for all non-RCRA hazardous waste, which tracks the waste from the time it leaves the generator's institution until it receives final treatment. This document shall be provided to WCH by the transporter and reviewed for accuracy and maintained for a minimum of three years. The tracking document shall include categories specific to the California Medical Waste Management Act.

APPENDIX D

Personal Protective Equipment Available to staff at WCH

Personal Protective Equipment
Gowns / Aprons
Gloves
Mask (N95 Respirators; CAPRs/PAPRs; surgical masks)
Faceshields
Safety Goggles and Glasses
Shoe Covers
Lead Aprons

APPENDIX E

Handling Used Personal Protective Equipment (PPE) **DOFFING PPE**

The type of PPE used WCH will vary based upon the infectious agent's transmission route to others, beginning with Standard, in addition to Contact, Droplet, and Airborne precautions.

SAFE WORK PRACTICES for protection that limits the spread of contamination

1. Keeps hands away from face
2. Limit surfaces touched
3. Change gloves when torn or heavily contaminated
4. Perform hand hygiene
5. All PPE is removed inside of an isolation room near door prior to exiting with the exception of N95 mask and/or respirators (PAPRs) which is discarded in an ante room or in corridor after the closing the door to a patient with airborne contaminants

GLOVES:

1. Outside of glove is contaminated
2. Grasp outside of glove with opposite gloved hand; peel off
3. Hold removed glove in gloved hand
4. Slide fingers of ungloved hand under remaining glove at wrist
5. Peel glove off over first removed glove
6. Discard gloves in waste container (if inside of patient room; inside of room closest to the door before exiting)
7. Gloves can also be removed with the gown at the same time, but being meticulous not to contaminate self during the process.

GOGGLES OR FACESHIELD:

1. Outside of goggles or face shield is contaminated
2. To remove, handle by head band or ear pieces
3. Place on clean towel if being reprocessed/disinfected for reuse, or in waste container inside of room by door before exiting

GOWN:

1. Gown front and sleeves are contaminated
2. Unfasten ties
3. Pull away from neck and shoulders, touching inside of gown only
4. Turn gown inside out
5. Fold or roll into a bundle and discard
6. See #7 above under GLOVES.

MASK or RESPIRATOR:

1. Front of mask /respirator is contaminated – DO NOT TOUCH
2. Grasp bottom, then tope ties or elastics and remove
3. Discard in waste container outside of room immediately after closing door behind you

APPENDIX F

Handling Regulated Waste

- Regulated medical waste, clinical waste, or biomedical waste that is a waste or reusable material derived from the medical treatment of a human that is suspected by the practitioner of being infected with a pathogen that is also infectious to humans. The regulated waste is suspected of containing a highly communicable disease.

- Regulated medical waste describes how the medical waste generated at the facility shall be segregated, handled, stored, packaged, treated, or shipped for treatment, as applicable.

- All healthcare and contracted staff who generate and dispose of regulated waste receive training in regulated waste management procedures upon hire and annually thereafter. Training records are maintained for a period of a minimum of two years.

APPENDIX G

Labeling

Warning labels are affixed to containers of regulated waste, refrigerators and freezers containing blood or OPIM, and other containers used to store, transport, or ship blood or OPIM. The warning labels are affixed as close as is feasible to the containers by string, wire, or adhesive (or other methods) to prevent their loss or unintentional removal.

The term "biohazard" for the purpose of this symbol is defined as "those infectious agents presenting a risk or potential risk to the well-being of man, either directly through his infection or indirectly through disruption of his environment."

The warning labels:

(1) are predominantly fluorescent orange or orange-red;

(2) have lettering and symbols in contrasting colors; and

(3) have the following words: BIOHAZARD (with the international biohazard symbol) or in the case of regulated waste BIOHAZARDOUS WASTE or SHARPS WASTE

BLOODBORNE PATHOGEN BLOOD DRAW PANEL FOR BOTH SOURCE AND EXPOSED

Use the following Bloodborne Laboratory Panel tests for:

TYPE OF EMPLOYEE	LAB WORK ORDERING PHYSICIAN
WCH Payroll Employees	~~Dr. Jacobs~~ED Practitioner
Contracted Employees	~~Dr. Jacobs~~ED Practitioner
~~Licensed Independent Contractors (LIP)~~Practitioner (e.g., physicians, PA's)	ED Practitioner or Can Self Order
Emergency Medical Staff - All EMTs in the community	~~Dr. Kaufmann (County)~~ED Practitioner

Please see and use both #1 (Source, if known) and #2 (Exposed)

I. Blood Draw for BBPE Panel: SOURCE
USE INDUSTRIAL ACCOUNT FOR WCH PAYROLL EMPLOYEE, CONTRACTED EMPLOYEES, LIP

1. HBsAG
2. HCV RNA/PCR
3. HIV Rapid Testing

II. Blood Draw for BBPE Panel: EXPOSED
REGISTER UNDER WORKMAN'S COMPENSATION ACCOUNT, ALL BUT EMTs

1. HBsAB
2. HCV RNA/PCR
3. HIV

EMSIA OF SANTA CRUZ COUNTY
EMERGENCY MEDICAL SERVICES INTEGRATION AUTHORITY

Hospital Worksheet
Infectious Exposure Reporting For Fire/EMS

Name _____ Department: _____ Sex_____ DOB_____

Date of Incident_____ Contact Number _____ Supervisor Name: _____

Supervisor Contact Number_____ Secure Fax # for Lab Results_____

MRN: _____

Workman's Comp Carrier/Contact Information_____

_____

Name of Source Patient: _____ Sex: _____ DOB: _____

MRN: _____

Brief description/explanation of exposure/possible exposure:_____

_____

_____

Exposure Yes
Exposure No

Post Exposure Prophylaxis Yes No If yes, following prescribed: _____

Source Patient Testing: Yes No If yes, HIV Hep B SAg Hep C Ab Other _____

Source Patient Test Results:_____

Exposed Patient Testing HIV Hep B SAb Hep C Ab Other _____

Exposed Patient Test Results:_____

Results Faxed to Supervisor Yes No

Supervisor Notified Yes No

Hospital Contact_____

Hospital Contact Phone Number_____

This document faxed to Supervisor Yes No Date/Time _____

Leave a copy of this document at Watsonville Community Hospital, Attn: Infection Preventionist

WATSONVILLE
COMMUNITY HOSPITAL

To: Committees: P&T, MEC, BoT **Date:** 3 May 2023
From: Jennifer Ura Gavin, Director of Pharmacy
Re: Controlled Substance Policies (14)

Every 3 year review of Controlled Substance Policies …

Minor or no "content" changes.

Minor changes clarifying practice and/or adding reference back to Board of Pharmacy documentation.

- P#0227: OR / Anesthesia – no change
- P#1879: Accountability of Waste – III.G = wording clarification
- P#1904: Reporting Drug Diversion (including suspected theft)
  - ADD III.F.2 = wording directly from BPC 4107.5
- P#2003: Audits
  - DELETE III.A.5 = Drug Specific Audits (not needed in this policy, covered w/Medication Utilization Reviews)
- P#2024: Discrepancy Resolution – no change
- P#2705: Drugs Requiring Inventory Accountability in Acute Care Facilities – no change
- P#2706: Distribution – no change
- P#2707: Pharmacy Licenses and Registrations
  - DELETE reference to permits/licenses not required in CA
- P#2708: Records
  - ADD III.D.6.f = wording directly from CCR 1715.65
- P#2709: DEA Controlled Substance Ordering System (CSOS) – no change
- P#2710: Floor Stock Accountability – no change
- P#2711: Prescription Forms (Pads and Paper) – no change
- P#2781: Emergency Department Administration Reconciliation
  - ARCHIVE (all areas reconciled monthly, covered in P#2003: Audits)
- P#Prescription Drug Disposal Program
  - ADD to Purpose – clarification that WCH Outpatient Pharmacy participates in mail back program

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Controlled Substances: OR / Anesthesia	Manual Location	Provision of Care		
Policy/Procedure #	0227	Effective	10/03	Page	1 of 2
Department Generating Policy	Pharmacy	Revised	3/2020		

I. PURPOSE:

To establish a collaborative process involving the OR (e.g., Surgery, Labor & Delivery) and Pharmacy Departments to accurately account for controlled substances.

II. POLICY:

- Controlled substances administered in the OR (Operating Room) areas must comply with federal and state statutes, as well as all Watsonville Community Hospital (WCH) policies related to controlled substance accountability.
- All controlled substance use and waste will be accurately documented by Anesthesia and verified by Pharmacy Department to assure accountability.
- Selected non-controlled drugs* may require additional control measures. See policy#2705: *Controlled Substances: Drugs Requiring Inventory Accountability in Acute Care Facilities.*

III. PROCEDURE:

A. Anesthesia:

1. Anesthesiologist will vend all pre-procedure controlled substances and select non-controlled drugs* for patients directly from the Pyxis units (e.g., MedStation or Pyxis Anesthesia System [PAS]).
2. No anesthesia provider shall give access or permission to a nurse or other personnel (e.g., anesthesia technicians) to obtain or transport controlled substances for the provider.
   a. An exception may be granted during an emergent situation which requires immediate drug retrieval, the primary anesthesia provider cannot leave the patient, and another anesthesia provider cannot obtain the drug for the primary provider.
   b. In such a situation, a nurse or other licensed personnel with authority to obtain controlled substances may obtain and deliver drug products to an anesthesia provider.
   c. The transfer of the drug to the anesthesia provider and acceptance of responsibility for the drug shall be documented in the patient's medical record, on the Anesthesia Proof-of-Use-Record, or in an automated dispensing cabinet (ADC, Pyxis).
3. Controlled substance return procedure:
   a. At the end of the procedure the Anesthesiologist will place any unused controlled substances in a labeled, capped syringe.
   b. Anesthesiologist will attach the printed Pyxis documentation to the anesthesia chart record.
   c. Anesthesiology Controlled Substance Record (ACSR) will be included, if utilized.
   d. The syringe(s) along with the anesthesia chart record and Pyxis slip (and ACSR, if utilized) will be placed in a plastic bag and deposited in the designated Controlled Substance Drop Box (CSDB).
   e. Even if there is no waste product for the patient, the Anesthesiologist will place the anesthesia chart record and Pyxis slip in the CSDB, for reconciliation.

4. All documentation and product waste must be completed before leaving work for the day.
5. No controlled substances or the selected non-controlled drugs* may be wasted in the OR.
   a. However, unused and unopened vials may be returned via Controlled Substance Drop Box.
6. All waste from surgery, anesthesia, and special procedures, when vended and administered to patient directly by anesthesia provider, shall be returned to pharmacy for accountability and proper disposal.

B. Pharmacy Reconciliation Procedure:
1. Pharmacy staff (Pharmacist or Technician) will retrieve the previous day's anesthesia chart record, Pyxis slip (ACSR, if utilized), and waste from CSDB (Controlled Substance Drop Box) daily
2. The anesthesia chart record, Pyxis slip (ACSR, if utilized), and waste will be brought to the Pharmacy for reconciliation by Pharmacy staff.
3. Each transaction will be totaled. The amount removed from Pyxis less the amount wasted must equal the amount charted by the Anesthesiologist.
4. Controlled substance waste shall be documented on "Controlled Substances Waste Verification Audit Form" (Form 100-RX-2401), or equivalent.
5. Pharmacist will verify the documentation.
6. Pharmacist verifying waste will randomly check waste via an applicable method to verify syringe content.
7. All returned controlled substances to be wasted will be discarded and witnessed by two Pharmacists.

C. Propofol and Dexmetomidine (Precedex®):
1. The control and accountability of propofol and dexmetomidine (Precedex®) shall follow all policies and procedures associated with controlled substances.

REFERENCE:

- Joint Commission Standards: LD.04.01.01 EP 1 – 3 MM.03.01.01 EP 2 – 6
- Anesthesia Proof of Use Record (100-RX-3104)
- Anesthesia Print-over Template (available in Pharmacy FORMS library)

Reviews:		**1st**	**2nd**	**3rd**	**4th**	**5th**
	Date:	9/1/09	1/19	5/2023		
	By:	J. Gavin	J.Gavin	J.Gavin		
Revised:		**1st**	**2nd**	**3rd**	**4th**	**5th**
	Date:	04/10	12/12	12/13	5/15	3/2020
	By:	J. Gavin	J. Gavin	J. Gavin	J. Gavin	J.Gavin

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Controlled Substances: Accountability of Waste	Manual Location	Provision of Care		
Policy/Procedure #	1879	Effective	6/04	Page	1 of 2
Department Generating Policy	Pharmacy & Nursing	Revised	~~3/2020~~5/2023		

I. PURPOSE:

To ensure accountability and compliance with Federal, State, & local statutes regarding wasting of controlled substances.

II. POLICY:

All waste of controlled substances (CS) and drugs requiring additional inventory accountability* shall be witnessed, accurately documented, and destroyed within 5 business days of the drug being returned to the Pharmacy, in compliance with all Federal, State, and local statutes.

- * Refer to policy #2705 : *Drugs Requiring Inventory Accountability in Acute Care Facilities*

III. PROCEDURE

A. Individuals handling controlled substance waste for analysis/destruction (e.g., fentanyl patches, waste returned from the OR) must do so while wearing protective gloves to prevent incidental absorption of the drug through the skin.

B. Anesthesia / OR waste:
   1. All controlled substance waste vended and administered by an anesthesiologist (e.g., from the OR) must be returned to the Pharmacy for reconciliation, analysis, and destruction.
   2. Refer to policy #0227: *Controlled Substances: OR / Anesthesia* for detail of process.

C. Large Volume CS waste:
   1. All large volume controlled substance waste must be returned to the Pharmacy for reconciliation, analysis, and destruction.
   2. Large volume CS waste includes, but is not limited to: PCA's, epidurals, propofol infusions

D. Fentanyl patch:
   1. Used fentanyl (Duragesic®) topical patches must be returned to the Pharmacy in clear plastic bags labeled with patient name for proper destruction.
   2. Fentanyl patches returned to the Pharmacy shall be wasted with a witness prior to appropriate disposal in compliance with DEA regulations.
   3. Documentation of waste shall be recorded on the "Controlled Substance Waste Verification Audit Form", or equivalent, by two licensed professionals, one of whom shall be a pharmacist.

E. Analysis of Waste:
   1. Waste will be analyzed using approved validation methods, including reference lab testing.

F. Waste of partial doses of controlled substance medication in patient care areas (other than the OR) must be witnessed and documented in Pyxis by two licensed personnel.
   1. This waste must be destroyed in compliance with DEA and state regulations and placed in the pre-determined, drug-specific waste stream.
   2. Partial dose waste may be randomly sampled for analysis by the Pharmacy.

~~G. Waste returned to the Pharmacy will be analyzed according to Policy# 2003: *Controlled Substances: Audits.*~~

G. Any w~~W~~aste returned to Pharmacy must be witnessed and destroyed (in compliance with DEA regulations) by two licensed personnel.

H. Propofol and Dexmetomidine (Precedex®) – non-infusion doses:

1. Non-surgical Patient Care Areas:
   a. Documentation of waste of propofol and dexmetomidine (Precedex®) in non-surgical, patient care areas should follow the same waste documentation as other controlled substances.
   b. It is not necessary and is not required to return non-infusion waste to Pharmacy, unless deemed necessary by the facility, in a large volume infusion container (e.g., 100ml).
2. Surgery, Anesthesia, and Special Procedural Areas:
   a. The control and accountability of propofol and dexmetomidine (Precedex®) waste used in anesthesia, surgery, and special procedures areas shall follow all policy and procedures associated with controlled substances.

I. All waste of all sizes of containers or syringes from surgery, anesthesia, and special procedures, when vended and administered to patient directly by anesthesiology provider, shall be returned to Pharmacy for accountability and proper disposal.

REFERENCE:

- Joint Commission Standards: LD.04.01.01 EP 1 – 3 MM.03.01.01 EP 1 - 6
- Controlled Substance Waste Verification Audit Form (100-RX-2401)

	1st	2nd	3rd	4th	5th
Reviewed Date:	11/06				
By:					
	1st	**2nd**	**3rd**	**4th**	**5th**
Revised Date:	04/10	1/12	12/12	5/15	2/16
By:	J. Gavin	J. Gavin	J. Gavin	J. Gavin	J.Gavin
	6th	**7th**	**8th**	**9th**	**10th**
Revised Date:	1/19	3/2020	5/2023		
By:	J.Gavin	J.Gavin	J. Gavin		

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Controlled Substance: Reporting Drug Diversion (including suspected theft)	Manual Location	Provision of Care		
Policy/Procedure #	1904	Effective	8/05	Page	1 of 7
Department Generating Policy	Pharmacy	Revised	4/20225/2023		

I. PURPOSE:

To require proper documentation and reporting of all drug thefts and/or significant losses (collectively, herein "diversions") of controlled substances, non-controlled drugs, prescription pads, DEA Form 222, patient personal medications, or fraudulently prescribed medications to appropriate government oversight agencies and Watsonville community Hospital (WCH) personnel.

II. POLICY:

- All WCH affiliated entities where controlled substances are stocked and/or administered must document and report diversions (including, but not limited to suspected cases of theft) as set forth in this policy. Such affiliated entities include (but are not limited to):
    - Acute Care Facilities
    - Ambulatory Clinics and Physician Practices
    - Retail Pharmacies
- Details of all drug diversion investigations must be reported internally to the appropriate personnel on the "Drug Theft / Loss Report Form"
- Once the Drug Theft / Loss Report Form is completed, whether a preliminary or final report, it must be submitted in a timely manner to the individuals listed on the form, along with copies of supporting documentation, including, but not limited to any drug test reports obtained in the course of the investigation.
- A Medication Variance Report must also be completed for any drug diversions, and the completed Medication Variance Report must be submitted to the appropriate WCH personnel.
- WCH Chief Executive Officer (CEO), or designee, should be advised of any notable (e.g., reportable) drug diversions and should be consulted prior to making any report other than the Drug Theft/Loss Report and a required DEA Form 106 report and prior to taking employee disciplinary action (other than suspension with pay).

III. PROCEDURE:

A. Diversion of Controlled Substances:

1. **Reporting to U.S. Drug Enforcement Administration (DEA):**

    a. **Standard for Reporting to DEA:** Any theft (even a single dosage unit), any in-transit loss, or significant loss of controlled substances [those listed on Schedules I through V of 21 C.F.R. Section 1308 ("Federally Controlled Substances")] shall be reported within one business day to the U.S. Drug Enforcement Administration using DEA Form 106. [Federal Register, Vol. 70, No. 155, August 12, 2005/Rules and Regulations].

        1) **Federally Controlled Substances Only:** Only thefts or significant losses of Federally Controlled Substances are to be reported to the DEA. Theft or significant loss of other drugs that may be classified as a controlled substance by individual

states should be reported to state authorities in compliance with individual state law or regulations but should not be reported to the DEA using Form 106.

2) **Theft:** The theft of any amount (even a single dose) of one or more Federally Controlled Substance must be reported to the DEA. This includes theft by employees.

3) **In-Transit Loss:** All in-transit losses of Federally Controlled Substances must be reported to the DEA. An in-transit loss is any loss that occurs while Federally Controlled Substances are in route from one DEA registered facility to another (e.g., from a wholesale supplier to a hospital). A facility must report to DEA the in-transit loss of any Federally Controlled Substance if the loss is discovered after the facility has accepted (i.e., signed for) the shipment. If the loss is discovered before the facility has accepted the shipment, then the supplier is responsible for reporting the loss to the DEA.

4) **Significant Loss:** A loss not resulting from theft is only to be reported to the DEA if the loss is significant. Whether a loss of a controlled substance is significant is to be determined by evaluating the criteria below.

   - The actual quantity of controlled substances lost, particularly in relation to the volume of controlled substances handled at the facility;
   - The specific controlled substances lost;
   - Whether the loss of the controlled substances can be associated with access to those drugs by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
   - Whether there is a pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses;
   - Whether the specific controlled substances are likely candidates for diversions;
   - Local trends and other indicators of the diversion potential of the missing controlled substance
   - Example: Based on these criteria, a loss of 5 doses of zolpidem (Ambien®) or 1 dose of morphine sulfate, with are out any suspicious pattern of access, activities, or similar losses, would usually not be considered a significant loss and would not require reporting to the DEA.

5) **Losses that are Not Significant:** If a loss of a Federally Controlled Substance is determined to be not significant, it should not be reported to DEA. But, the loss must be documented using the hospital's incident report forms and these forms should be reviewed regularly to determine if there are any apparent patterns. A pattern of repeated small losses should be investigated because this may indicate an ongoing diversion.

6) **Spillage:** Tablets broken during repackaging or glass ampules that are dropped and broken are not to be reported to the DEA if they are witnessed and explained losses. However, records such as incident reports should be maintained and regularly reviewed by the facility's Pharmacist in Charge, and if a pattern indicative of diversion is discovered, a subsequent report to the DEA may be required.

7) **Example:** An employee is noted to break fentanyl ampules routinely when filling anesthesia kits. Analysis of the spilled solution reveals that it is something other than fentanyl. A complete investigation should be conducted and all fentanyl dosages

previously recorded as spillage that are connected with the employee should be immediately reported to the DEA as set forth in this policy.

8) **Miscounts:** Known miscounts or inventory adjustments resulting from clerical errors (e.g., incorrect transcription of quantity on an inventory form that results in a discrepancy) should not be reported to the DEA.

b. **Process for Reporting of a Suspected Theft or Significant Loss of Controlled Substances to DEA:**

1) **Timing:** When a theft or significant loss of a Federally Controlled Substance is identified (even if the exact amount of theft or loss cannot be determined immediately), it must be reported to the DEA in writing within one business day of discovery. Such situations may include, but are not limited to:

- Identification of documentation discrepancies in narcotic waste by an anesthesia provider;
- Falsification of administration records by a nurse;
- An in-transit loss in which all or part of a shipment does not arrive;
- Unexplained inventory discrepancies within the Pharmacy.

2) **106 Form:** A DEA 106 Form must be submitted to the DEA within one business day if the facts of the situation are known at the time of discovery.

i) The 106 Form should be submitted electronically via the DEA website. The electronic DEA 106 Form submission portal can be found online at: https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp. Print a copy of the electronically submitted DEA 106 Form for recordkeeping purposes

ii) Example: It is discovered that a pharmacy technician stole seven doses of diazepam (Valium®). All of the relevant facts are clear upon discovery. A DEA Form should be submitted to the DEA electronically within one business day. A Drug Theft/Loss Report Form and a Medication Variance Repot must also be completed.

iii) The Drug Theft/Loss Report for all investigations whether reported or not reported to the DEA should be completed A copy should be kept on file at the facility. Make note on the Drug Theft/Loss Report form if a DEA 106 Form has been completed and submitted internally but has not been submitted to the DEA.

3) **Amendment of DEA 106 Form:** If the facts set forth on a DEA 106 Form change after it has been submitted to the DEA as a result of further investigation or newly discovered facts, then the DEA 106 Form must be amended. A DEA106 Form should be amended electronically via the DEA 106 online submission portal at https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp. To amend a previously submitted electronic DEA 106 Form, login and use the amendment key code provided by the DEA electronic submission system when the initial DEA 106 Form was submitted.

4) **Insufficient Information to Complete 106 Form within 1 Day:** If a theft or significant loss is discovered but the circumstances are not clear enough to complete and file a DEA 106 Form within one business day (for example if the exact amount of controlled substance missing cannot be determined), then a written Initial

Notification must be submitted to the local DEA field division office within one business day (via facsimile).

i) The Initial Notification must be written and must inform the DEA of the known facts and that an investigation is being conducted. Addresses and fax numbers for DEA field division offices are available on the DEA website.

ii) The investigation must be completed and a final report must be submitted to the DEA regional field office within thirty (30) days.

iii) If the investigation confirms that a theft or significant loss occurred, a DEA Form 106 must be completed and submitted electronically to the DEA within the 30 day period.

iv) If the investigation reveals that no theft or signification loss occurred, then a DEA 106 Form is not required to be submitted to the DEA, but the results of the investigation finding that no theft or significant loss occurred must be reported to DEA in a letter or conclusion within the 30 day period.

v) Example: Ten doses of zolpidem (Ambien®) cannot be located in the Pharmacy CII Safe during the monthly physical inventory but the circumstances surrounding the loss are unclear. A written Initial Notification must be submitted to the DEA field division office within one business day of the discovery. A Drug Theft/Loss Report form and a Medication Variance Report should also be completed and submitted. A paper copy of a DEA 106 Form should be completed, submitted internally along with the Drug Theft/Loss Report form and kept on file at the facility. Make note on the Drug Theft/Loss Report form that a DEA 106 Form has been completed but not submitted to the DEA. If the investigation determines that no loss actually occurred (e.g., the drugs were later located or a recordkeeping issue is identified and corrected), then a letter of conclusion should be submitted to the DEA.

vi) If the investigation cannot be completed within 30 days after the date of discovery, a letter of continuation must be submitted to DEA, stating that the investigation is ongoing. If a letter of continuation is submitted, a 106 Form or letter of conclusion should be submitted within 30 days after the letter of continuation.

5) **Recordkeeping:** Copies of all reports submitted to DEA (including initial notification, DEA 106 forms, letters of conclusion and/or letters of continuation) must be maintained on file with the facility's controlled substance records in accordance with the facility's record retention policy.

2. **Reporting to State Authorities:**

a. Contact CEO or designee with regard to state controlled substance theft/loss reporting requirements.

b. If a 106 Form is submitted to the DEA, a copy must also be forwarded to the relevant state authority (i.e., the Boar d of Pharmacy).

c. Any loss of controlled substance shall be reported to the California State Board of Pharmacy within thirty (30) days of discovery, including their amounts and strengths.

1) If the cause of the loss is theft, diversion, or self-use, report to the Board of Pharmacy shall be made within 14 days of discovery.

d. Copies of all state theft/loss reports must be maintained on file at the facility in accordance with the facility's record retention policy.

3. **Internal Reporting:**

a. Drug Theft / Loss Report Form

1) When a theft or significant loss of controlled substance is discovered, the Chief Executive Officer or designee must be immediately notified.

2) Immediately following the determination that a diversion of any controlled substance has occurred, the Corporate Drug Theft / Loss Report Form (attached) must be completed within seventy-two (72) hours from the time the facility first became aware of the theft or loss.

3) When completing the Drug Theft/Loss Report Form, indicate on the form in the appropriate check box whether the report is preliminary or final. Any preliminary report must be followed up by a final report at the conclusion of the investigation and not longer than 30 days for the initial preliminary report date.

4) A copy of this form is to be maintained at the facility in accordance with the facility's record retention policy.

b. **Event Report Form/Medication Variance Report:**

1) A Medication Variance Report (Form RM-3302) must be completed immediately by the individual discovering the theft or loss of any controlled substance where the diversion results in an impact to any patient.

2) The completed report should be submitted to the facility's primary administrator, the facility Director of Pharmacy, and the CNO, if applicable.

3) A copy of this form is to be maintained at the facility in accordance with the facility's record retention policy.

B. Non-Controlled Substances:

1. Theft or significant loss of non-controlled substances shall be immediately reported to the CEO or designee to determine a course of action (including whether the incident should be reported to state or federal authorities in compliance with individual state law or federal regulations), or reported to local law enforcement as a theft of Hospital property.

2. All thefts or losses of non-controlled substances must be investigated and such investigations must be completed within ten (10) days of the date that the theft or loss is discovered. .

3. **Pseudoephedrine and Ephedrine products:** Thefts and unusual or excessive losses or disappearances of certain OTC products containing ephedrine or pseudoephedrine must be reported to federal and/or state authorities. Consult CEO or designee in the event of any theft or loss of ephedrine or pseudoephedrine products in order to determine if reporting is required.

C. Theft or Loss of Prescription Pads, DEA Form 222, or Patient Personal Medications:

1. Theft or significant loss of prescription pads, DEA Form 222, or patient personal medications shall be immediately reported to the CEO or designee to determine a course of action (including whether the incident should be reported to state or federal authorities in

compliance with state law or federal regulations), or reported to local law enforcement as a theft of Hospital property.

2. All thefts or losses of prescription pads, DEA Form 222, or patient personal medications must be investigated, and such investigations must be completed within ten (10) days of the date that the theft or loss is discovered. .

D. Fraudulent Prescriptions:

1. Prescriptions physically presented, verbally communicated, or electronically transmitted to pharmacies deemed to be fraudulent with the primary source being a facility employee or individual associated with a WCH affiliated entity shall be immediately reported to the CEO or designee to determine a course of action (including whether the incident should be reported to state or federal authorities in compliance with state law or federal regulations), or reported to local law enforcement.
2. All alleged fraudulent prescriptions must be investigated, and such investigations must be completed within ten (10) days of the date that the incident was discovered.

E. Patient Charge Review:

1. The investigation of theft or loss of drugs shall include a medical record review to verify all doses charged to the patient's financial record are appropriately documented in the patient's medical record and match the prescriber's order. Appropriate charges or credits shall be adjusted as necessary to correct any discrepancies.

F. Licensing Board Notification:

1. If the person believed to have diverted controlled or non-controlled substances is a licensed professional, or otherwise registered with a licensing board, the diverter's professional licensing board must be notified by phone within 24 hours after the facility has completed the preliminary investigation and, as a result, developed a good faith belief that the person has diverted the substances in question, and a written report to such board must follow shortly.
    a. California Board of Pharmacy shall be notified within fourteen (14) days of discovery of licensed employee theft or impairment: [California Law: Business and Professions Code 4104(c)(1-6)]
        1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.
        2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.
        3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
        4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.
        5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
        6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

2. If the pharmacy has reasonable cause to believe a dangerous drug or dangerous device in, or having been in its possession is counterfeit or the subject of fraudulent transaction, the pharmacy will notify the board within 72 hours of obtaining that knowledge. [California Law: Business and Professions Code 4107.5]

G. State and Local Police Notification:

1. In general, thefts of facility property (including controlled or non-controlled substances, prescription pads, DEA Form 222, patient personal medication, and fraudulent prescriptions) should be reported in a timely manner to the appropriate state and/or local law enforcement authorities, by the facility's primary administrator (e.g, CEO).

H. Referral to Human Resources:

1. Disciplinary actions against employees who have diverted drugs, refused drug testing, or have violated other hospital policies shall be coordinated with the hospital and Human Resources, in consultation with the CEO or his/her designee.

References:

- Joint Commission Standards: LD.04.01.03 EP 1 – 3; LD.04.01.07 EP 1 – 2; MM.03.01.01 EP 1 - 6
- Drug Theft/Loss Report Form
- DEA Form 106
- DEA Practitioner's Handbook
- DEA Pharmacist's Manual
- Medication Variance Form (RDM-3302) - Emprint
- Federal Register, Vol. 70, No. 155, August 12, 2005 / Rules and Regulations
- California Board of Pharmacy: CCR 1715.6
- California Board of Pharmacy: BPC 4104(c)(1-6), 4107.5

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By:	Jennifer Gavin				
Revised:	**1st**	**2nd**	**3rd**	**4th**	**5th**
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By:	J. Gavin	J. Gavin	J. Gavin	J.Gavin	J.Gavin
Revised:	**6th**	**7th**	**8th**	**9th**	**10th**
Date:	3/2020	4/2022	5/2023		
By:	J.Gavin	J.Gavin	J. Gavin		

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Controlled Substances: Audits	Manual Location	Provision of Care		
Policy/Procedure #	2003	Effective	4/06	Page	1 of 4
Department Generating Policy	Pharmacy	Revised	~~3/2020~~5/2023		

I. PURPOSE:

To establish a process to audit use of controlled substances and additional selected drugs at Watsonville Community Hospital (WCH).

II. POLICY:

A. Ordering, prescribing, dispensing, administration, and waste of controlled substances and additional selected drugs listed in Policy #2705: *Controlled Substance: Drugs Requiring Inventory Accountability in Acute Care Facilities* will be audited to ensure compliance with federal, state, and local statutes, as well as WCH Controlled Substance Policies.

- In this policy, reference to controlled substances and other medication requiring inventory accountability as listed in Policy #2705 shall be noted as "controlled substances and additional selected drugs"

B. A written plan shall be developed and implemented by the Director of Pharmacy detailing the criteria and selection methodology for monitoring all aspects of controlled substance use within the facility.

C. The Chief Executive Officer (CEO) or designee shall be responsible to ensure the completion of all audits within the selected timeframes of this policy.

D. Audit processes within this policy may be enhanced with more stringent procedures at the discretion of the CEO.

III. PROCEDURE

A. **Audit Plan:**

1. Watsonville Community Hospital will implement a comprehensive program to audit accountability of controlled substances ~~and additional selected drugs~~ used within the facility.
   a. The intent is to ensure that every department within the facility that dispenses or administers controlled substances ~~and additional selected drugs~~ is audited, at a minimum, every 12 months.
   b. The plan should include Standardized Audit Reports, Drug-Specific Audits, Surgical Care Area Audits, Suggested Pharmacy Department Areas of Audit, Random Patient Care Providers Audits, and Waste Audits, as specified by this policy.
2. The audit plan will be reviewed on an annual basis by an appropriate quality or medical staff committee.
3. Audits must verify that:
   - Orders (electronic, written and verbal) for controlled substances ~~and additional selected drugs~~ are authentic and prescribed by an authorized practitioner
   - Dose prescribed is documented in the patient's medication administration record (MAR)
   - Validation of pain assessment and reassessment is included in nursing documentation and is consistent with the patient's need
   - Any waste is correctly witnessed / documented
4. **Standardized Audit Reports:**
   a. Standardized reports from Pyxis shall be the primary reports used for review.

b. Reports selected for review should include, at a minimum, the "Proactive Diversion Report" for Pyxis.

~~5. Drug-Specific Audits:~~

~~a. Drugs shall primarily be selected for audit based on high risk and/or high volume use.~~

~~b. Low use items should be audited based on unusual inventory patterns or suspected inappropriate use.~~

~~c. In addition to controlled substances, audits should include one other high cost drug (e.g., Procrit®, Retavase®)~~

~~d. Drug specific audits shall be conducted in both the pharmacy and patient care areas.~~

~~e. Drug specific audits should be performed a minimum of once quarterly.~~

6.5. **Surgical Care Area Audits:**

a. Controlled substances and additional selected drugs used within the OR shall be audited by reconciling the following:
   - Patient anesthesia records
   - Controlled substance "proof of use" records (e.g., Pyxis MedStation receipt)
   - Returned waste
   - Patient charges

b. Controlled substance waste from surgical services areas shall be analyzed on a random basis, and ~~shall~~ should include large volume infusions and an analysis of waste by every anesthesia provider at least once each quarter.

7. **Suggested Pharmacy Department Areas of Audit** (minimum):
   a. Purchase records and invoices will be validated against current inventory records
   b. CSOS (Controlled Substance Ordering System) and DEA 222 purchase and distribution documents will be reconciled
   c. Distribution from Pharmacy to patient care areas shall be reconciled
   d. Purchases to patient charges will be reconciled
   e. Waste records will be reconciled against appropriate documentation
   f. Validation technology shall be re-calibrated at least every 6 months, or as recommended by instrument manufacturer

8. **Waste Audits:**
   a. All PCA / large volume (e.g., epidurals) controlled substance waste is to be returned to the Pharmacy for validation.
   b. Controlled substance waste from nursing units and the OR / ED shall be analyzed on a random basis to include large volume infusions and should include every anesthesia provider at least once on a quarterly basis.
   c. Partial dose waste from any other patient care area may be analyzed on a random basis when justified.

9. **Random Patient Care Provider Audits:**
   a. Potential diversion by patient care providers should be assessed by random or stratified sampling using the following:
      - All patient care areas will be assessed using standard Pyxis reports generated at least once monthly.

- All anesthesia providers ~~will~~ should be audited at least once per quarter using the standard Pyxis reports, Anesthesia Records, and the Anesthesia Proof-of-use Records.

B. **Analysis, Trending, and Reporting of Audit Results:**

1. Audit results showing potential diversion, misuse, or mishandling should be reported to the CEO or designee immediately upon discovery consistent with the Human Resources Policy B.4: *Substance Abuse Testing* and related Human Resources Form 28: *Fitness For Duty/ Reasonable Suspicion Testing Checklist* and investigation consistent with Section C of this policy.
2. Reporting of any significant discrepancies discovered during the auditing process shall be submitted to CEO following Policy #1904: *Reporting of Drug Diversion (including suspected theft)*.
3. Summary results of audits may be provided to appropriate Medical Staff, Quality Improvement, Safety Committees, and/or Pharmacy and Therapeutics Committee.
4. Pyxis Investigation Activity Thresholds for Reporting:
   a. A review of a licensed nurse or anesthesia provider shall trigger additional research, and/or investigation as described in Section C of this policy, if any of the following thresholds are met or exceeded:
      - "Proactive Diversion Report" reveals:
        - Standard deviation of 2 or more for a consecutive 30-day period or longer for the same patient care areas, or
        - Standard deviation of 2 or more for any period of time for multiple patient care areas, or
        - Greater than 2 standard deviations for any time period less than 30 days.
   b. An investigation will be initiated for any licensed practitioner with standard deviations of 3 or greater for any time period.

C. **Reporting Chain of Command:**

1. Reports showing results that warrant further evaluation or research will be forwarded to the CEO or designee.
2. The CEO is responsible for ensuring that all investigations are initiated and completed in a timely manner.
3. The CEO or designee shall initiate an investigation that shall include (at a minimum) the following:
   a. Validation of prescriber orders for controlled substances and additional selected drugs.
   b. Reconciliation of Controlled Substance Administration Records, patient Medication Administration Records, and nurses' notes with respect to valid prescriber orders.
   c. Patient interviews, where appropriate.
   d. Review of pharmacy distribution records, patient charges, and Pyxis reports.
4. Results of any investigation conducted by the CEO or designee shall be reported back to the Director of Pharmacy for final notification of licensing boards or federal and state regulatory agencies.

REFERENCE:

- Joint Commission Standards: LD.04.01.01 EP 1 – 3 MM.03.01.01 EP 1 – 6

	1st	2nd	3rd	4th	5th
Reviewed Date:	8/08				
By:	JGavin				
	1st	**2nd**	**3rd**	**4th**	**5th**
Revised Date:	02/10	12/12	1/19	3/2020	5/2023
By:	J. Gavin	J. Gavin	J.Gavin	J.Gavin	J. Gavin

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Controlled Substances: Discrepancy Resolution	Manual Location	Provision of Care		
Policy/Procedure #	2024	Effective	3/90	Page	1 of 1
Department Generating Policy	Pharmacy	Revised	3/2020		

I. PURPOSE:

To provide guidelines for the immediate investigation and resolution of all discrepancies of controlled substances, as well as all drugs requiring additional inventory accountability*.

* See policy #2705: *Drugs Requiring Inventory Accountability in Acute Care Facilities*

II. POLICY:

A. Discrepancies involving controlled substances and drugs requiring additional inventory accountability * must be immediately resolved.

B. Any potential loss or theft must be reported in compliance with federal, state, and local statutes, as well as the requirements of Policy *#1904: Reporting Drug Diversion (including suspected theft).*

III. PROCEDURE

A. Any suspected tampering or diversion of controlled substances and drugs requiring additional inventory accountability must be reported immediately to the Pharmacy Director.

B. If a discrepancy in count cannot be resolved, the Director of Pharmacy, Chief Executive Officer (CEO), and Chief Nursing Officer (CNO) must be notified immediately.

1. Each staff member, including contract and agency employees, potentially involved in the discrepancy will submit to drug testing per the facility's Substance Abuse Screening Policy.
2. Medical Staff members are subject to Medical Staff Bylaws.

C. Personnel may not leave the premises until all keys are returned and shift counts are correct / verified.

D. Any unresolved count requiring an adjustment to inventory records may only be made by an authorized pharmacist.

E. Any theft of a controlled substance (including the theft of a single dosage unit) or a significant loss of controlled substances or drug requiring additional inventory accountability * must be reported following Policy *#1904: Reporting Drug Diversion (including suspected theft).*

REFERENCE:

- Joint Commission Standards: LD.04.01.01 EP 1 – 3 MM.03.01.01 EP 1 – 6

		1st	2nd	3rd	4th	5th
Reviewed Date:		12/94	10/97	8/12/09	4/10	5/15
	By:			Jennifer Gavin	J.Gavin	J. Gavin
		6th	7th	8th	9th	10th
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	By:	J.Gavin	J. Gavin			
		1st	2nd	3rd	4th	5th
Revised Date:		1/12	3/2020			
	By:	J. Gavin	J.Gavin			

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Drugs Requiring Inventory Accountability in Acute Care Facilities	Manual Location	Provision of Care		
Policy/Procedure #	2705	Effective	2/10	Page	1 of 3
Department Generating Policy	Pharmacy	Revised	3/2020		

I. PURPOSE:

To establish a process to ensure security and accountability of medication associated with abuse and diversion.

II. POLICY:

A. The drugs listed below have been associated with abuse and diversion; therefore, additional control measures shall be taken to ensure security and accountability (* includes non-formulary medication)

- Butalbital-containing combination drugs (eg, Fioricet®)
- Cyclobenzaprine (Flexeril®)
- Ephedrine (all dosage forms)
- Human Growth Hormone (somatropin, Genotropin®, Saizen®)* and Human Growth Hormone Releasing Factor (sermorelin, Geref®)*
- Ketorolac (Toradol®) oral and injectable preparations
- Nalbuphine (Nubain®) injection
- Propofol (Diprivan®) injection
- Dexmedetomidine (Precedex®) injection
- Sildenafil (Viagra®, Revatio®)*, Tadalafil (Cialis®)*, Vardenafil (Levitra®)*, and Avanavil (Stendra®)*.
- Pseudoephedrine (Sudafed®), including all combination drugs containing pseudoephredrine *
- Gabapentin (Neurontin®)

B. Facility will comply with more stringent standards for control and accountability of these drugs, as required by law.

C. Retail (i.e., outpatient) pharmacy is not subject to this policy, but must comply with its respective policy, procedures, and regulatory statues for the proper security, storage, distribution, and accountability of these drugs.

1. Dexmedetomidine, ephedrine, and propofol shall only be stocked in the acute care facility; these medications shall not be stocked for dispensing in retail pharmacy.

D. Results of investigations revealing theft or loss of significant quantities of drug shall be reported to the CEO and CNO using the Drug Theft / Loss Report Form.

- Reporting loss or theft of the above drugs to the DEA (Drug Enforcement Administration) is not required. Refer to Policy #1904: *Controlled Substances: Reporting of Drug Diversion (including suspected theft)*

III. PROCEDURE

A. Control of Butalbital-containing products, Cyclobenzaprine, Dexmedetomidine, Ephedrine, Human Growth Hormones, Ketorolac, Propofol, Sildenafil, Tadalfil, Vardenafil, , Avanavil, Pseudoephedrine, Pseudoephedrine-containing products, and Gabapentin.

1. The above listed products shall be maintained on perpetual inventory and controlled in the same manner as any DEA Scheduled II-V controlled substance.
2. All current policies regarding controlled substances are applicable to these products.

3. Inventory control of these products must adhere to Policy # 2706: *Controlled Substances: Distribution*
4. Additional drugs may be added to this list by the facility for additional control and accountability.
5. Facility may consider eliminating certain drugs from formulary status based upon the potential for abuse or availability of alternative drug therapies.
6. Perpetual inventory shall be maintained.
   a. Pyxis MedStations and CII Safe shall be utilized.
   b. If Pyxis (automated dispensing cabinet = ADC) is unavailable, Form RX-2403 Controlled Substance Perpetual Inventory Log may be used.
   c. If sufficient space is not available within ADC / CII Safe, remote locked storage cabinet may be used, with the access key controlled using the ADC or CII Safe.
   d. Distribution of Pseudoephedrine and Products Containing Pseudoephedrine:
      - All pseudoephedrine and products containing pseudoephedrine shall be distributed in unit-dose containers
7. Inclusion of these drugs in a DEA biennial controlled substances (house-wide) inventory is not mandatory, unless required by the DEA or state law.

B. Expired Drugs:
   1. Expired medications will be sequestered in similar fashion to controlled substances with the inventory being transferred to the expired drug inventory by documentation in CII Safe, or documentation of Controlled Substance Perpetual Inventory Log Form if Pyxis is unavailable.
   2. See Policy #2706: *Controlled Substances: Distribution*

C. Storage of Dexmedetomidine and Propofol in Patient Care Areas:
   1. Dexmedetomidine and propofol will only be stocked in the acute care facility; neither will be stocked for dispensing in retail (ie, outpatient) pharmacy.
   2. Products will be stored in Pyxis MedStation in patient care areas, or in a secured storage cabinet.
      a. Ampules and small volume vials should be stored in lockable compartments.
      b. Large volume containers should be stored in Pyxis MedStation (ADC), auxiliary cabinet, auxiliary tower or in a separate locked cabinet with the key secured in Pyxis.
      c. Patient care areas without Pyxis (ADC) will secure the inventory in locked cabinets in a secured storage area (eg, Medication Room, Anesthesia workroom). A licensed nurse or practitioner will control the key to the cabinet at all times.
   3. Waste:
      a. In non-surgical, patient care areas, small volume, partial containers of product to be wasted should not be returned to Pharmacy for disposal unless instructed by Department of Pharmacy.
         1) Residual waste amounts shall be disposed into approved waste management streams with proper documentation that meets the DEA's regulations.
         2) Refer to policy # 1879: *Controlled Substances: Accountability of Waste*
      b. All large volume waste (eg, PCA, epidural, and propofol infusion) from all surgical and non-surgical patient care areas shall be returned to the Pharmacy for analysis and destruction.
      c. For surgical services areas, all partial containers and product to be wasted, if vended and/or administered by an anesthesiologist, shall be returned to Pharmacy for accountability and proper disposal.
         1) Refer to policy # 0227 : *Controlled Substances: OR / Anesthesia*
      d. Facility may implement more stringent policies and procedures for waste return to the Pharmacy, if necessary to ensure accountability.

D. Audit and Reconciliation of Use:
   1. The Director of Pharmacy or designee shall perform periodic audits to ensure the inventory of drugs listed in this policy in the Pharmacy and in patient care areas are secure and that products are used appropriately.
   2. Refer to Policy # 2003: *Controlled Substances: Audits*

E. Discrepancies:
   1. Any discrepancies discovered shall be immediately reported to the Director of Pharmacy or a pharmacist designee in the absence of the Director of Pharmacy.
   2. Results of investigations revealing theft or loss of significant quantities of drugs listed in this policy shall be reported to the CEO and CNO using the Drug Theft / Loss Report Form.

REFERENCES:

- Joint Commission Standards: LD.04.01.01 EP 1 – 3 MM.03.01.01 EP 1 – 6, 8, 18
- Drug Theft/Loss Report Form
- Medication Variance Form (Emprint RDM-3302)

	1st	2nd	3rd	4th	5th
Reviewed Date:	4/13	5/2023			
By:	J. Gavin	J. Gavin			
	1st	**2nd**	**3rd**	**4th**	**5th**
Revised Date:	2/10	4/14	5/15	5/17	1/19
By:	J. Gavin	J. Gavin	J. Gavin	J. Gavin	J.Gavin
	6th	**7th**	**8th**	**9th**	**10th**
Revised Date:	3/2020				
By:	J.Gavin				

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Controlled Substances: Distribution	Manual Location	Provision of Care		
Policy/Procedure #	2706	Effective	3/10	Page	1 of 2
Department Generating Policy	Pharmacy	Revised	3/2020		

I. PURPOSE:

To ensure controlled substances are maintained, distributed, and administered to patients according to federal and state laws.

II. POLICY:

Controlled substances will be maintained, distributed, and administered to patients in compliance with all federal and state laws.

III. PROCEDURE

A. CII Safe (i.e., narcotic vault) Inventory:

1. All controlled substances and selected drugs requiring additional control measures* will be maintained at all times in an approved electronic storage device (i.e., CII Safe) within the Pharmacy, or secured appropriately to prevent diversion (e.g., in a secured tote in the Pharmacy with counts reconciled).
   a. *Refer to Policy#2705: *Drugs Requiring Inventory Accountability in Acute Care Facilities*
2. There shall be no after-hours access to the Pharmacy vault (CII Safe) by anyone other than an approved, licensed pharmacist.
3. A product count (inventory) will be conducted each time an individual product is received into or dispensed (removed) from the CII Safe's inventory.
   a. Refer to Policy#2708: *Controlled Substance: Records* for purchase and receipt records procedures.
4. A separate and secure inventory of expired controlled substances will be maintained to prevent distribution until disposed of by an approved returns vendor (e.g., "inmar/EXP") registered with the DEA following federal and state regulations.
5. Expired medications will be transferred to the expired drug inventory by documentation in CII Safe or on the "Controlled Substance Perpetual Inventory Log" form.

B. Dispensing:

1. Pharmacist-in-Charge may delegate distribution of controlled substances from the CII Safe to an authorized pharmacist or technician; however, all transactions performed by a pharmacy technician must be verified by an authorized licensed pharmacist.
2. The integrity of the drug packaging must be assured prior to distribution from the CII Safe.
3. All oral controlled substances will be issued in the manufacturer's unit dose package or will be repackaged into unit dose containers by the Pharmacy prior to issue to a patient care area.
4. Distribution to Patient Care Areas:
   a. All drugs distributed from or received into the CII Safe inventory from a patient care area will be tracked by "Delivery Signature Receipt" form generated from CII Safe, which include all necessary data elements (e.g., control / transaction number and signatures of all persons handling the product).
      i. CII Safe is not available, documentation shall be via a "Controlled Substance Transfer / Requisition Form" [Emprint #: 100-QHC-AMB-2403HMS]. The control number of this form will be entered into the "Controlled Substances Perpetual Inventory Log" form for tracking purposes.

b. All controlled substances will be delivered discreetly to patient care areas and under constant supervision of a pharmacist, pharmacy technician, or licensed professional / practitioner (e.g., nurse, anesthesia provider).

c. The pharmacist dispensing, the individual delivering, and the licensed professional / practitioner receiving controlled substances must sign the "Delivery Signature Receipt" form (or the "Controlled Substance Transfer / Requisition Form" if Pyxis unavailable).

   i. If Pyxis unavailable, the completed "Transfer / Requisition Form" is returned to Pharmacy for reconciliation with CSAR, and then filed.

d. Only a licensed nurse or an appropriately licensed practitioner (e.g, anesthesia provider) may receive controlled substances.

e. Upon receipt, a licensed professional / practitioner must verify the integrity of the product packaging and inventory amount for each drug received as indicated on the "Delivery Signature Receipt" form.

   i. The licensed professional / practitioner's signature on "Delivery Signature Receipt" form verifies above.

f. If a "Controlled Substance Perpetual Inventory Log" / "Controlled Substance Accountability Record" (CSAR) is utilized (i.e., Pyxis unavailable), drugs must remain with the "Controlled Substance Transfer / Requisition Form" until all drugs are signed into the inventory and securely locked by the receiving licensed professional / practitioner.

g. A licensed pharmacist or licensed professional / practitioner must witness and verify technician filling of controlled substance into Pyxis MedStations (i.e., automated dispensing cabinets).

5. Completed "Delivery Signature Receipt" forms are to be returned to the Pharmacy and then filed.
6. For patient care areas using an automated dispensing cabinet (e.g., Pyxis), a Pyxis Compare Report (or similar report) will be used to verify the receipt and addition of drugs to a specific patient care area automated dispensing cabinet.
7. All documentation forms must be securely stored for a minimum of 3 years.

REFERENCE:
Joint Commission Standards: LD.04.01.03 EP 1 – 3 MM.03.01.01 EP 1 - 6

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Reviewed Date:	5/2023				
By:	J.Gavin				
	1st	2nd	3rd	4th	5th
Revised Date:	12/13	5/15	1/19	3/2020	
By:	J. Gavin	J.Gavin	J.Gavin	J.Gavin	

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Controlled Substances: Pharmacy Licenses and Registrations	Manual Location	Provision of Care		
Policy/Procedure #	2707	Effective	3/10	Page	1 of 1
Department Generating Policy	Pharmacy	Revised	~~3/2020~~5/2023		

I. PURPOSE:

To ensure licenses, permits, and registrations are maintained, according to federal, state, and local regulations, as appropriate.

II. POLICY:

Watsonville Community Hospital Pharmacy must maintain the following licenses, permits, and registrations:

- Current Pharmacy License~~, including state controlled substances permit (where required)~~
- Current DEA Registration
- Power-of-Attorney for anyone authorized to order additional DEA-222 forms
- Power-of-Attorney for anyone authorized to use the DEA Diversion Control Controlled Substance Ordering System (CSOS)
- ~~Alcohol permit or Liquor license, if required by state or local authorities~~
- ~~Fire Marshall's Permit, if required by state or local authorities~~

III. PROCEDURE

A. It shall be the responsibility of the Director of Pharmacy to ~~insure~~ ensure that the above licenses, permits, Power-of-Attorney authorization documents, and registrations are obtained and remain current.

B. The above permits should be displayed (or filed) in accordance with federal, state, and local regulations.

REFERENCE:

- Joint Commission Standards: LD.04.01.01 EP 1 - 3
- Power of Attorney www.dea.gov

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Reviewed Date:	04/13	1/19			
By:	J. Gavin	J.Gavin			
	1st	2nd	3rd	4th	5th
Revised Date:	3/2020	5/2023			
By:	J.Gavin	J. Gavin			

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Controlled Substance: Records	Manual Location	Provision of Care		
Policy/Procedure #	2708	Effective	3/10	Page	1 of 3
Department Generating Policy	Pharmacy	Revised	~~7/2021~~5/2023		

I. PURPOSE:

To ensure the purchase, storage, distribution, and accounting of controlled substances are conducted in accordance with federal, state, and local regulations, as appropriate.

II. POLICY:

- The purchase, storage, distribution, and accounting of controlled substances will be conducted in accordance with all federal and state laws and standards of professional practice.
- The Director of Pharmacy and/or the Pharmacist-in-Charge is responsible for compliance with this policy.
- Theft or loss of controlled substance ordering records or forms (e.g., DEA Form 222, CSOS documentation) shall be reported to Chief Executive Officer (CEO) or designee and other agencies as required in Policy #1904: *Controlled Substance: Reporting Drug Diversion (including suspected theft).*

III. PROCEDURE

A. Controlled substance records are legal documents and entries may not be altered. Only approved abbreviations may be used, and Roman numerals should not be used on any controlled substance record.

B. Registration: Refer to Policy#2707: *Controlled Substance: Pharmacy Licenses and Registrations*

C. Purchase / Receipt:

1. All Schedule II (CII) controlled substances must be ordered on the official DEA Schedule II order form (DEA Form 222) or electronically via the Drug Enforcement Administration's Controlled Substance Ordering System (CSOS) under the registration for this facility by the Director of Pharmacy or designee to whom Power-of-Attorney has appropriately been granted.
2. DEA-222 forms may only be ordered from the Drug Enforcement Administration (DEA) by individuals appropriately granted DEA Power-of-Attorney by the individual named on the facility DEA registration.
3. All DEA-222 form numbers will be recorded onto the "DEA 222 Form Receipt & Use Log" immediately upon receipt from the DEA.
    a. All unused forms will be maintained in locked storage (i.e., CII Safe in Inpatient Pharmacy, locked cabinet in Outpatient Pharmacy).
4. When using CSOS, each DEA Form e222 order number shall be reconciled at least once monthly by the Director of Pharmacy or designee as described in Policy #2709: *Controlled Substance: DEA Controlled Substance Ordering System (CSOS).*
5. All CII drugs obtained by using CSOS will adhere to Policy #2709: *Controlled Substance: DEA Controlled Substance Ordering System (CSOS).*
6. Only those pharmacists granted permission by the individual named on the facility DEA Registration may order CII controlled substances / sign DEA 222 forms.
7. Once CII controlled substances are received from the supplier, the supplier invoice must be reconciled with a copy of the DEA 222 form.

8. Completed DEA 222 forms, supplier invoices, and CSOS documents shall be filed in locked storage under the control of the Director of Pharmacy as required by federal and state law for a period of no less than three years.
9. All controlled substances shall be delivered directly to and received by the Pharmacy Department.
    a. Upon receipt, the contents of the shipment must be inspected to detect any visible tampering or damage; if tampering or damage is present, the Director of Pharmacy must be immediately notified.
    b. The contents of the shipment must immediately be reconciled with the shipping invoice.
    c. These medications, if not immediately entered into the inventory, must be place into locked storage within the Pharmacy until added to the inventory.

D. Inventory
1. All controlled substances and selected drugs requiring additional control measures* must be maintained on a perpetual inventory and maintained in locked storage within the Pharmacy and under double-locks (or within a secure automated dispensing cabinet - i.e., Pyxis) after being dispensed to floor stock.
    a. *Refer to Policy#2705: *Controlled Substance: Drugs Requiring Inventory Accountability in Acute Care Facilities*
2. The inventory must be entered electronically into the approved automated system (i.e., CII Safe, Pyxis MedStation) or onto "Controlled Substance Perpetual Inventory Log" forms.
3. Purchase Review:
    a. Documentation of all received controlled substances and additional drugs requiring inventory accountability listed in Policy#: 2705: *Controlled Substance: Drugs Requiring Inventory Accountability in Acute Care Facilities*, should be reviewed by two licensed professionals comparing wholesaler invoices, the CSOS records and/or DEA 222 forms, and the ADS (Pyxis) inventory increase report.
    b. Purchases from non-wholesale providers (e.g., outsourced pharmacy) shall be reviewed monthly by review of the purchase order, the DEA Form 222 or CSOS documentation, invoice and the ADS (Pyxis) inventory increase report.
    c. All documents shall be signed by individuals conducting the review and shall be securely stored in the Pharmacy for a minimum of 3 years.
    d. Any discrepancies shall be immediately reported to the Director of Pharmacy and Chief Executive Officer or designee following the procedures outlined in Policy# 1904: *Controlled Substance: Reporting Drug Diversion (including suspected theft).*
4. A biennial controlled substance (house-wide) inventory must be conducted every other year as per California state law requirement.
    a. This inventory must be documented and signed by the Pharmacist-in-Charge.
    b. Inventory must also be dated and include time – indicating either opening or closing inventory.
    c. The record of this inventory must be maintained in locked storage for a minimum of three years.
5. A vault inventory of all controlled substances should be conducted monthly using a blinded count method and verified by two licensed professionals This inventory must be documented in an approved electronic system (i.e., CII Safe) or on "Controlled Substance Perpetual Inventory Log."
6. Inventory reconciliation of all federal Schedule II controlled substances will be completed at least every three months, including [CCR 1715.65]:
    a. A physical count, not an estimate, of all quantities of federal Schedule II controlled substances
    b. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation

c. A comparison of the two above mentioned items to determine if there are any variances

d. All records used to compile each inventory reconciliation report shall be maintained in the pharmacy for at least three years in a readily retrievable form

e. Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report

~~e.~~f. The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report.

E. Prescriber DEA Registration

1. Only authorized prescribers with current DEA registration numbers may prescribe controlled substances.
2. The Pharmacy shall maintain a current file of approved prescribers' signature and DEA registration numbers (including a copy each prescriber's current registration) to enable enforcement of any restrictions.

F. Records

1. All controlled substance proof-of-use forms (e.g., CSARs), transfer / requisitions forms, inventory records, DEA 222 forms / logs, CSOS drug procurement records, administration records, invoices, and any related records must be readily retrievable and maintained under the direct control of the Pharmacy for a minimum of three years.
   a. The term "readily retrievable" is defined as a record kept or maintained in such a manner that it can be separated out from all other records in a reasonable time or that it is identified by an asterisk, redline, or some other identifiable manner such that it is easily distinguishable from all other records.
2. Electronic records must meet the same requirements for retrieval, security, and duration.
3. Each supplier's invoice for Schedule II controlled substance medication will be attached to the corresponding DEA Form 222 or CSOS record on which a pharmacist (or nurse) has recorded the required information for each item received.

REFERENCE:

- Joint Commission Standards: LD.04.01.03 EP 1 – 3; LD.04.01.07 EP 1 - 2; MM.03.01.01 EP 1 – 6
- Drug Enforcement Administration: http://www.deadiversion.usdoj.gov/faq/general.htm
- DEA Form 222 Receipt and Use Log (Emprint 100-RX-2402)
- Controlled Substances Perpetual Inventory Log (Emprint RX2403)
- Anesthesia Proof-of-Use Record
- California Board of Pharmacy: CCR 1715.65

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Reviewed Date:	04/13	5/15	1/19		
By:	J. Gavin	J. Gavin	J.Gavin		

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Revised Date:	1/12	7/15	3/2020	7/2021	5/2023
By:	J.Gavin	J. Gavin	J.Gavin	J.Gavin	J. Gavin

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Controlled Substance: DEA Controlled Substance Ordering System (CSOS)	Manual Location	Provision of Care		
Policy/Procedure #	2709	Effective	2/10	Page	1 of 4
Department Generating Policy	Pharmacy	Revised	3/2020		

I. PURPOSE:

To establish standards for controlled drug ordering and receiving services utilizing the Drug Enforcement Administration's Controlled Substance Ordering System (CSOS) program that allow for secure electronic controlled substance orders without the supporting paper DEA Form 222.

II. POLICY:

Controlled substances will be ordered by Pharmacy using CSOS program as defined by this policy.

III. PROCEDURE:

A. The Drug Enforcement Administration's Controlled Substance Ordering System (CSOS) requires that each individual purchaser enroll with the DEA to acquire a CSOS digital certificate.

B. Use of the paper DEA Form 222 will continue to be allowed for certain processes, including the return of C-II controlled substances to the wholesaler, alternative vendor, manufacturer, or a reverse distributor.

C. CSOS shall be implemented to potentially provide more accurate and efficient advantages over the use of traditional DEA 222 forms.

D. Establishing CSOS to Purchase Controlled Substances, Schedule II.

1. The CSOS regulations require the following persons to be identified:
    a. DEA Registrant – the person who last signed / renewed a DEA Form 224, Application for Registration
        1) The DEA specifies that the DEA Registrant must be the Chief Executive Officer (CEO) of the facility
        2) Further duties associated with the controlled substance ordering / management may be delegated by the CEO using a Power of Attorney (POA)
            i. The DEA recommends that the Director of Pharmacy be delegated this duty with a POA
    b. CSOS Coordinator – each DEA Registrant identifies a person to hold the DEA number, monitor license renewal, designate those employees eligible to order controlled substances electronically, retain all digital certificates, and to manage these activities
        1) The DEA recommends that the Director of Pharmacy be the CSOS Coordinator for the facility. The DEA Registrant shall convey this responsibility through a POA
    c. Power of Attorney (POA) Designees – the DEA recommends that a named individual be identified as the primary person to order C-II controlled substances for the facility (primary designee)
        1) The DEA Registrant or the CSOS Coordinator may assume this duty of ordering C-II controlled substances
        2) Alternatively, the CSOS Coordinator may identify another pharmacist as the primary designee. A pharmacy technician may be selected as an alternate if the facility only employs one full-time pharmacist as the Director of Pharmacy
        3) The primary designee must have a POA submitted to the DEA for final authorization to order C-II controlled substances

4) Additional pharmacists may also be identified to order C-II controlled substances in the absence of the primary designee. Such "secondary designees" must also have a POA submitted to the DEA to be fully authorized to submit orders

2. The CSOS Coordinator must submit all required documents to the DEA for issuance of digital signatures to the individuals granted POA's and maintain a copy of each document submitted in a secure area in the Pharmacy.
   a. Each individual granted a POA will be e-mailed his or her access code and password delivered by U.S. mail
   b. POA access codes and passwords must not be shared with any other persons
   c. With the digital signatures, the CSOS Coordinator must download the Digital Certificates from the DEA website to the hospital-based computer
   d. The CSOS Coordinator is responsible for notifying the facility's pharmacy wholesale vendor or alternative drug supplies that the facility wishes to place orders electronically for C-II controlled substances
      1) This includes account setup of CSOS ordering at the wholesale vendor or alternative drug supplier website. It includes the creation of access to the respective vendor websites for all staff with POA privileges.
3. Multiple computers may have the CSOS software available for use. Only computers approved by the Director of Pharmacy should be used for placing and receiving all CSOS orders.
4. Ordering / Receiving Functions
   a. Ordering and receiving of C-II controlled substances must be performed by different individuals unless mitigating circumstances prevent this from occurring. In such instances, compensating controls should be implemented (e.g., additional independent reviews, outside audits)
   b. The facility should consider limiting the ordering and receiving authority of any Controlled Substance product to designated staff members, not all Pharmacy Department Staff members.
   c. As part of CSOS use, both ordering and receiving must be performed in the vendor's website program
      1) The receiving process must include a reconciliation of drugs received against the packing slip or invoice
      2) The printed invoice must be signed and dated by the receiver indicating completion of this phase of receipt of product
      3) With the invoice signed and dated, the receiver or another staff member with POA access must receive the C-II controlled substance in the vendor's website system. Completion of this activity may allow downloading of the receipt record into the hospital personal computer for permanent storage
         i. NOTE: the receiver's signature and dating of the invoice and receipt into the vendor's software system must be a separate action from the signing of the invoice by the Director or authorized person approving payment for Accounts Payable
5. Record Keeping
   a. Records must be kept for a minimum of 3 years
   b. Purchase records should be electronically confirmed on the vendor's website (e.g., Cardinal Wholesale) and/or downloaded from the respective vendor websites to the

hospital-based computer that will include the order placed for the CII controlled substances and the receipt acknowledgment of the order.

c. Electronic file storage is required for both the DEA electronic order and the vendor's CSOS file to prove receipt; these files must be retained for 3 years

d. The Coordinator should validate the accessibility of the records on a yearly basis.

e. A minimal amount of DEA 222 forms should be maintained in the Pharmacy for use if the CSOS system experiences an interruption in service

6. Security
   a. Security of the system is the responsibility of the Coordinator
   b. Passwords assigned to each registrant are to remain confidential and are not be shared with anyone
   c. Certificate Revocation – revocation is the process of invalidating a CSOS Certificate before its expiration date. The CSOS places invalidated certificates on a Certificate Revocation List (CRL) that is checked by all suppliers before a CSOS transaction is completed
      1) Reasons for Revocation include the following:
         i. Termination of subscribers' employment
         ii. Change in legal name
         iii. Change in e-mail address
         iv. Policy violations
         v. Password compromised
      2) Revocation may be requested by the certificate's owner or a Coordinator for the certificate's associated DEA Registration
      3) Certificates may be revoked by digitally signed E-mail (preferable) or phone call. All requests will be thoroughly authenticated by the CSOS.
   d. Certificate renewal – a CSOS Signing Certificate, used for electronic orders of controlled substances, is associated with a DEA Registration. The certificate is set to expire when the current DEA Registration expires and must be renewed at the same time. Notice is sent to the registered e-mail at least 45 days prior to the expiration with procedures for renewal.
7. Auditing Processes
   a. The facility will implement a comprehensive audit of CSOS ordering and receiving processes that will be congruent with Policy# 2003: *Controlled Substances: Audits.*
   b. Orders placed using CSOS and DEA Form 222s shall be reviewed and reconciled at least once monthly by the Director of Pharmacy or a designated pharmacist.
      1) Reconciliation shall include validation of the receipt of controlled substances comparing the e222 record, invoice, history ordering reports from the vendor, and automated dispensing system reports.
      2) All order receipt audit records shall remain in one readily retrievable location and be signed and dated by the Director of Pharmacy or a designated pharmacist.

References:

- Joint Commission Standards: EC.02.01.01 EP 3 MM.03.01.01 EP 1 - 6
- Drug Enforcement Administration, Office of Diversion Control, E-Commerce Program, http://www.deadiversion.usdoj.gov.
- Form: Power of Attorney (POA) www.dea.gov

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Reviewed:					
Date:	5/2023				
By:	J. Gavin				
Revised:	1st	2nd	3rd	4th	5th
Date:	7/15	2/16	1/19	3/2020	
By:	J. Gavin	J.Gavin	J.Gavin	J.Gavin	

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Controlled Substances: Floor Stock Accountability	Manual Location	Provision of Care		
Policy/Procedure #	2710	Effective	3/10	Page	1 of 2
Department Generating Policy	Pharmacy	Revised	3/2020		

I. PURPOSE:

To ensure documentation of storage, inventory, administration, and wastage of controlled substances and selected drugs requiring additional inventory accountability* are in accordance with federal and state laws.

- *Refer to Policy#2705: *Drugs Requiring Inventory Accountability in Acute Care Facilities*

II. POLICY:

- All controlled substances and drugs requiring additional inventory accountability* must be securely stored, inventoried, and properly wasted with administration and wastage accurately documented in compliance with federal and state laws as well as professional practice standards.
- Floor stock drugs shall be defined as limited inventories of drugs stored in patient care areas compliant with approved security measures.

III. PROCEDURE

A. Only licensed professionals / practitioners in the course of their job functions (e.g., nurses, pharmacists, physicians) may receive controlled substances and drugs requiring additional inventory accountability* for placement into the secured floor stock inventory.
   1. Licensed professionals / practitioners must supervise controlled substances and drugs requiring additional inventory accountability* added to Pyxis MedStations (i.e., automated dispensing cabinets) or a Controlled Substance Accountability Record (CSAR).
   2. Only licensed personnel, or a pharmacy technician, may remove controlled substances and drugs requiring additional inventory accountability* from inventory, either for administration to a patient or for return to the Pharmacy.

B. When using Pyxis (i.e., automated dispensing system), an inventory may be conducted daily (versus end of each shift, if Pyxis is unavailable), preferably between change of shift and by two licensed personnel.
   1. The on-coming and off-going inventory should be conducted by different personnel when possible.
   2. Inventory may be limited to only those pockets accessed (if the system provides this capability) on days Tuesday through Sunday, and attention must be placed on insuring the integrity of the drug packaging.
      a. A complete inventory of controlled substances must be conducted each Monday at the change of shift.
   3. If Pyxis MedStation (i.e., automated dispensing system) is configured to dispense only single doses of all controlled substances (e.g., Pyxis Minidrawers filled with only a single dose in each section), then daily inventories may not be required if approved by Pharmacy and Nursing.
      a. This system configuration and process shall be double checked and validated by Pharmacy department in collaboration with Nursing, if appropriate.
      b. Director of Pharmacy shall coordinate this review with appropriate department Director.
   4. A complete inventory of controlled substances must also be completed at the time a patient care area "closes" and again upon reopening of that patient care area.
      a. "Closing" a MedStation requires physical inactivation by Pharmacy; i.e., Pyxis MedStation would be inaccessible until "re-opened" for use by Pharmacy staff.

5. The Pharmacy will be responsible for verifying the accuracy of inventory

C. If Pyxis is unavailable, inventory will be conducted at end of each shift:
   1. All inventory removals or additions, totals, and documentation of waste must be verified by the licensed personnel performing the inventory.
   2. Documentation may be on Controlled Substance Accountability Record (CSAR).
   3. CSAR may only be used for a 24 hour period. A new form will be initiated for subsequent 24 hour periods.
   4. All CSAR's must be returned to the Pharmacy each day.
   5. Pharmacy will be responsible for verifying the accuracy of the CSAR within one business day.

D. Administration and waste of partial doses must be documented in Pyxis (or on CSAR, if Pyxis unavailable).
   1. Administration of each dose must also be recorded on the patient's Medication Administration Record (MAR).
   2. Effectiveness of PRN and pain medication must also be documented in the nurse's notes or other approved flow sheets.

E. Waste of controlled substances and drugs requiring additional inventory accountability* requires a witness by a licensed nurse (or practitioner approved by individual state law to administer medications) or physician and documentation by both – either in Pyxis, or on the CSAR, that pertains to the patient care area from which the drugs were removed.

F. Accountability of keys to controlled substance storage cabinets must be documented on the CSAR, if used.
   1. All keys must be returned and accounted for before any personnel are allowed to leave the facility at the end of each shift.

REFERENCE:

- Joint Commission Standards: LD.04.01.01 EP 1 – 3 MM.03.01.01 EP 1 – 6, 8, 18
-

	1st	2nd	3rd	4th	5th
Reviewed Date:	04/13	5/2023			
By:	J. Gavin	J. Gavin			
	1st	**2nd**	**3rd**	**4th**	**5th**
Revised Date:	5/15	1/19	3/2020		
By:	J. Gavin	J.Gavin	J.Gavin		

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Controlled Substance: Prescription Forms (Pads and Paper)	Manual Location	Provision of Care		
Policy/Procedure #	2711	Effective	4/10	Page	1 of 2
Department Generating Policy	Pharmacy	Revised	3/2020		

I. PURPOSE:

To provide guidelines for appropriate storage and accountability of prescription pads and paper.

II. POLICY:

- Prescription forms (pads) shall be printed to comply with individual state and federal law and provide optimum security to prevent prescription fraud.
- Facility shall not print "generic" prescription forms with the name of the facility, using the hospital's DEA registration number.
- Physicians may not prescribe controlled substances using the hospital's DEA registration.
- Pre-printed labels with patient-specific information should not be affixed to a written or printed prescription. Patient information should be hand-written or printed on the prescription using a prescription writing program (e.g., MedHost).
- Electronic prescription forms (e.g., paper used in printers) used for printing prescriptions shall be secured in lockable printer paper storage receptacles and in other storage locations at all times.
- The Director of Pharmacy shall oversee the ordering and security of prescription forms and paper.
- Theft or significant loss of prescription forms (pads) shall be reported to the Chief Executive Officer (CEO) or designee in compliance with Policy #1904: *Controlled Substance: Reporting Drug Diversion (including suspected theft).*

III. PROCEDURE

A. The Director of Pharmacy shall approve the ordering of all prescription pads and paper. All stock shall be received, secured, stored, and distributed by Pharmacy.

B. Prescription forms (pads) for Emergency Department physicians may be provided by the contracted ED physician practice group.

C. Any preprinted prescription forms (pads) should be printed by an approved vendor, including security paper and include all federally (or state, whichever is more stringent) required elements for prescription form security.

1. Controlled substance security prescription forms will have a unique serialized number in a format approved by the Department of Justice. (Health & Safety Code, § 1162.1, subdivision (a)(15))

D. Prescription forms (pads) and electronic prescription paper shall be maintained in secure, locked storage to prevent theft.

E. Physicians are encouraged to maintain and use their own personalized prescription forms (pads). These forms may be printed by a contracted vendor.

F. Prescription Paper:

1. Pharmacy shall distribute prescription paper to patient care areas and place in a secure location (e.g., Pyxis) for restocking of printers. The key for the printer tray or receptacle may be placed in an automated dispensing cabinet (e.g., Pyxis) or other secured location for access by approved licensed personnel.
2. Printer paper that meets federal and state regulations for prescriptions shall be kept secure at all times.

3. The receptacles holding printer paper shall remain secured in a locked area only accessible by designated personnel.
4. Back stock of prescription paper shall be secured in a locked area only accessible by designated personnel.
5. Keys or other access to the prescription paper shall be restricted to specific licensed / registered personnel (e.g., physician, nurse, pharmacist, pharmacy technician).

REFERENCE:

- Joint Commission Standards: LD.04.01.01 EP 1 – 2
- California Board of Pharmacy: Health and Safety Code section 11162.1

	1st	2nd	3rd	4th	5th
Reviewed Date:	04/13	5/2023			
By:	J. Gavin	J.Gavin			
	1st	**2nd**	**3rd**	**4th**	**5th**
Revised Date:	12/13	7/15	1/19	3/2020	
By:	J. Gavin	J.Gavin	J.Gavin	J.Gavin	

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Controlled Substances: Emergency Department Administration Reconciliation	Manual Location	Provision of Care		
Policy/Procedure #	2781	Effective	4/11	Page	1 of 3
Department Generating Policy	Pharmacy	Revised	3/2020		

I. PURPOSE

To ensure verification and reconciliation of all controlled substances administered in the ED.

II. POLICY:

- Ordering, prescribing, dispensing, administration, and waste of controlled substances and additional selected drugs procured for patient use in the Emergency Department (ED) will be verified and reconciled to ensure compliance with federal, state, and local statutes.
- Reports from Pyxis (Automated Dispensing System = ADS) and the MedHost EDIS clinical system or patient medical records shall be used to reconcile controlled substance administration.
- Verification of use shall be included in the facility's written audit plan detailing the criteria and selection methodology for monitoring all aspects of controlled substance use within the ED.
- Reconciliation process shall be performed daily.

III. PROCEDURE:

A. Reconciliation of controlled substances and additional selected drugs prescribed and administered in the ED will provide verification that use of all controlled substances is legally ordered and properly documented.

B. Pyxis Controlled Substance Usage Report shall be developed and implemented for review using the following procedure:

1. Reports Menu > Choose "Batch Reports"
2. Click "ADD" on the bottom left of the screen
3. Choose Activity Reports > All Station Events
4. Sort by Stn/PT
5. For Stations, Choose "Select" and then Choose "ED"
6. For Med Classes, Choose "Select" and then highlight all of the Controlled Substances categories
7. Select "Save"
8. Add Report to the "Auto Run" schedule

C. MedHost EDIS Report shall be developed and implemented for review using the following procedure:

1. Log in to MedHost EDIS
2. Select "Reports"
3. Select "ED Audit" (report built for ED reconciliation)
4. Choose Relative Date: "Yesterday"
5. Select "Run"
6. During downtime (i.e., MedHost EDIS is not available), ED will provide copies of all written orders to the Pharmacy.

D. Pharmacy technicians or pharmacists will perform the following duties:
   1. Use the above reports as reference for all controlled substances and additional selected drugs removed for the previous day.
   2. Verify that all controlled substances listed on the Pyxis Report have been properly ordered and documented as administered in MedHost EDIS
   3. Document any discrepancy discovered, using available system (e.g., ERS [Event Reporting System] or if ERS unavailable, attached *Discrepancy Notification Form*)
   4. If a technician has created the report, all discrepancy reports must be reviewed by a pharmacist

E. Pharmacists will perform the following duties:
   1. Review any technician documented discrepancy report to verify accuracy.
   2. Complete ERS, or if ERS unavailable, complete *Discrepancy Notification Form.*
      a. If ERS systems used, an email with discrepancy will be forwarded automatically to ED Director for review and proper action.
      b. If *Discrepancy Notification Form* is used, send the completed *Discrepancy Notification Form* to the ED Director for review and proper action.
         1) A copy may be provided to the Chief Nursing Officer (CNO) or designee.

F. ED Director or designee will review the discrepancy within one business day and document the results of any investigation.
   1. If *Discrepancy Notification Form* is used, documentation of the outcome will be returned to the Director of Pharmacy or designee within three (3) business days.

G. Director of Pharmacy or designee will review all reports, documentation, and corrective actions.

H. Statistics of variances will be reported by the Director of Pharmacy to the CEO, CNO, and appropriate Quality and Medical Staff Committees.

I. Upon evidence of a medication error, a report will be completed for the medication variance in the Event Reporting System.

J. Potential diversions and unresolved discrepancies should be reported per Policy# 1904: *Reporting of Drug Diversion* and Policy# 2024: *Controlled Substances: Discrepancy Resolution.*

REFERENCE:

- Joint Commission Standard: LD.04.01.01 EP 1 – 3 MM.03.01.01 EP 1 - 6

Revised:	**1st**	**2nd**	**3rd**	**4th**	**5th**
Date:	1/15	1/19	3/2020	_____	_____
By:	J. Gavin	J.Gavin	J.Gavin	_____	_____

Attachment A: *Discrepancy Notification Form*

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

Discrepancy Notification Form

Date of Discrepancy: _____

Patient Name: _____

Account Number: _____

Description of Discrepancy:

_____

_____

_____

_____

_____

Discrepancy Notification Prepared by _____ (Pharmacist)

Date Delivered to ED Director _____

Nursing Response:

_____

_____

_____

_____

Date Returned to Pharmacy _____ Reviewed by DOP _____

If an addendum must be made in the chart, attach a copy of the addendum to this form. Send the original addendum to medical records. When making an addendum in the chart, DO NOT add an order under the orders tab. There must be an addendum made into the body of the nurse's notes. Please make sure to document the correct date and time that the medication was actually given.

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Prescription Drug Disposal Program	Manual Location	Provision of Care		
Policy/Procedure #		Effective	5/15	Page	1 of 1
Department Generating Policy	Pharmacy	Revised	5/2023		

I. PURPOSE:

To provide guidance for facility non-participation in controlled substance disposal programs.

[NOTE: Watsonville Community Hospital (WCH) Outpatient Pharmacy participates in mail back envelope service, separately from WCH Inpatient Pharmacy.]

II. POLICY:

A. Watsonville Community Hospital (WCH) shall not participate in controlled substance (DEA Schedule II – V) disposal programs, including take-back events, mail-back programs, and collection receptacles.

B. All controlled substance waste shall be destroyed in accordance with Policy #1879: *Controlled Substances: Accountability of Waste.*

III. PROCEDURE

A. Patient owned personal (ultimate user) prescription-controlled substance medications will not be accepted for destruction.

B. Inpatients with personal controlled substance prescription drugs shall follow Policy #1577: *Patient Own Medication / Drugs*.

C. Patients should make arrangements to have their personal controlled substance prescription medications disposed of by available methods, which include the following:

1. Place in a community-controlled substance disposal collection receptacle unaffiliated with WCH;
2. Deliver to a take-back event sponsored by a federal, state, or local law enforcement agency;
3. Send drugs to an authorized collection vendor as part of a mail-back program, using official mail-back packaging; or
4. Destroying the controlled substance themselves. When doing this, patient should always follow any specific disposal instructions included on the medication label or packaging. EPA and FDA offer guidance on how patients may safely dispose of medications.

REFERENCE:

- Joint Commission Standards: MM.03.01.05 EP 1 – 3
- www.federalregister.gov/Vol. 79, No. 174/Tuesday, September 9, 2014/Rules and Regulations. (accessed 10/22/2014)
- www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf. (accessed 10/22/2014)

	1st	2nd	3rd	4th	5th
Reviewed Date:	12/2020				
By:	J.Gavin				
Revised Date:	1st	2nd	3rd	4th	5th
By:	5/2023 J. Gavin				

WATSONVILLE
COMMUNITY HOSPITAL

To: Committees: P&T, MEC, BoT **Date:** 3 May 2023
From: Jennifer Ura Gavin, Director of Pharmacy
Re: P#384: Epidural Pain Management

Re-institution of previously archived policy.

Collaboration between Nursing and Pharmacy to ensure clear process outlined for Nursing in management of patient on epidural.

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Epidural Pain Management, Adult	Manual Location	Volume II – Assessment & Care of the Patients		
Policy/Procedure #	0384	Effective	3/98	Page	1 of 5
Department Generating Policy	Pharmacy/Nursing	Revised	~~7/07~~5/2023		

I. PURPOSE:

A. To provide specific guidelines for Nursing staff in the care of post operative patients with epidural pain therapy.

B. To clarify the role of the anesthesia provider and the nurse in management of the epidural in adult patients.

II. POLICY:

Initiation and management of epidural analgesia is restricted to anesthesia providers and physicians who are certified in the treatment of pain. Anesthesia providers shall make all setting and dose changes on the pump.

III. PROCEDURE

A. General Guidelines:

1. Anesthesia provider will order medication: Specific rates and dosage including setting requirements and four hour lockout and bolus as appropriate.
   (a) Standard concentration~~s~~: Fentanyl ~~5mcg~~2mcg/ml + Bupivacaine ~~0.0625~~0.125% in 0.9% Sodium Chloride
   (b) Nonstard concentration may be ordered but will take up to 2 hours so advanced timely planning is recommended

   ~~b. Hydromorphone 20mcg/ml + Bupivacaine 0.06% in 0.9% Sodium Chloride~~
2. No additional narcotics, sedatives, or antiemetics are to be given by any route of administration without consulting the managing anesthesiologist.
3. No fibrinolytic and/or thrombolytic therapy while epidural is in place without consulting the managing physician (eg, anesthesiologist).
4. After epidural catheter is discontinued: 24 hour delay before (re)starting anticoagulation therapy.
   a. Prescribing physician will provide his/her emergency telephone number on orders.
5. Equipment:
   a. Infuser - CADD PRIZM PCS II pump
   b. Patent IV line
   c. CADD infusion tubing
   d. Bag of prescribed medication
   e. CADD pump key
6. CADD set-up procedure:

   ~~(Pump Operation: Copy of Quick Reference Card for Clinicians attached to this policy, see attachment A)~~
   a. Epidural infusion shall be started in PACU or Labor and Delivery
   b. Prior to transfer to nursing unit, epidural shall be infused in PACU or Labor and Delivery until all of the following parameters are met:

1) Pain controlled
2) Vital signs stable
3) Assessment stable

c. Place 9V battery in pump, and listen for "beep"
d. Attach tubing, that has been spiked into epidural bag, to pump using side of CADD key
e. Lock CADD pump by inserting side of CADD key into "large lock"
f. Observe infuser system, self-test complete
g. Load analgesia bag into CADD infuser pump
h. Program CADD infuser pump with the correct settings as written on MD orders
i. Prime infusion tubing with analgesia (NOTE: prime after programming pump, so reservoir volume is accurate)
j. Close infuser pump door & lock "small lock" with CADD key & open clamp
k. Verify CADD pump settings with second RN
l. Connect CADD tubing to epidural tubing at shoulder
m. Secure CADD tubing on a tongue blade, and tape to patient's back
n. Tubing and solutions are a set and shall be changed together at least every 72 hours

7. Documentation
   a. Anesthesia will manage the pump infusion. Nursing will document medication, dose, route, modifications, clinician boluses, and pain assessment are recorded on the (PCA/epidural) Pain Management Flowsheet.
   b. Document start time, start date, setting, volume if needed to prime pump tubing and verify with two RN signatures on Pain Management Flowsheet.
   c. At the end of each eight (12) hour shift, 2 RN's will document (2 signatures required):
      1) total ml/mg or ml/mcg infused
      2) PCA (patient controlled analgesia) doses given/attempted
      3) reservoir volume, actual and calculated
   d. Additional information to document, as appropriate:
      1) Record all relevant physician communication in Nurses Notes
      1) Patient and family education provided
      2) Any adverse effects
      3) Catheter/equipment not intact q shift
      4) Any evidence of catheter dislodgment
      5) Verification of catheter placement (indicators that the catheter is not in the correct space, i.e., blood return or clear, colorless fluid return)
      6) Respiratory depression
      7) Allergic reactions
      8) Spinal headache
   e. Document pain score on **Pain Management Flowsheet** after medication initiation and after dose increase, then every 30 minutes x 2, then every 4 hours.
   f. Document sedation using sedation scale on **Pain Management Flowsheet** at the same time as documentation of pain score

g. Any changes in settings by anesthesia provider will be documented and verified by two RNs on the **Pain Management Flowsheet**

h. Shift change report shall include catheter placement, verification of medication, infusion volume remaining, infusion dose administered for the shift, PCA doses per shift, and current infusion rate.

B. **NURSING CARE:**

1. **General:**

a. Place on a continuous oximeter

b. Label head of bed "**EPIDURAL PROTOCOL**"

c. Label end of the catheter "**EPIDURAL**"

d. Patient must have patent saline lock or IV line

e. Upon initiation of epidural, monitor respiratory rate, BP, pulse, oxygen saturation, and pain score, every 5 minutes x 6, then every hour x 1, then every 4 hours

f. Complete set of vital signs, oxygen saturation, and pain score when patient arrives in unit and after any change in rate or bolus dose

g. Monitor respiratory rate, BP, pulse, oxygen saturation, level of consciousness, and pain score after initial set up, and every 30 minutes x 2 after any dose increase, then every 4 hours and as needed

h. Notify physician for oxygen saturation less than 94% for orders.

i. Encourage cough and deep breaths every 2 hours.

j. If respiratory rate is below 8/minute, oxygen saturation is dropping and decreased level of consciousness, call rapid response and notify provider to consider order for naloxone (Narcan®) 0.4mg IV push; may repeat 0.4mg IV every 2 minutes. Support respiratory status as necessary with an ambu bag until oxygen saturation and level of consciousness improve; ie, O_2 sat greater than 94% .

1) If respiratory arrest occurs, call CODE BLUE and notify physician

k. Document pain score on 0-10 scale, location and quality at initial set up, 30 minutes after any setting change x 2, then every 4 hours and as needed

j. Observe for hypotension, urinary retention, pruritus, nausea and vomiting, severe back pain or weakness, and postural headache.

k. Every four hours assess for lower extremity numbness, tingling, muscle weakness, decreased motor function, decreasing mental status, dermatome level increasing above T-4, or epidural catheter tubing disconnect. Notify physician immediately for any of the above findings. (pinpoint pupils may be normally expected)

l. Emergency medication/supplies are available in areas as indicated:

1) Narcan and Ephedrine available in the Pyxis MedStation.

2) Ambu bag available on crash carts

3) O_2 flow meter, O_2 NC delivery system and suction available in patient rooms

m. If physician has written an order allowing patient to ambulate, nurse will assess muscle strength prior to ambulation

1) Nurse will be in attendance if patient is to ambulate (stand, walk or sit) with epidural still in place

2) Medication used and placement of catheter usually allows for pain relief without muscle weakness or decreased motor function

2. Catheter and dressing:

a. Physician shall do all dressing and position changes of the catheter

b. Nurse may reinforce the dressing, but shall NOT change or remove the dressing

c. Careful handling and maintenance of sterility for the catheter is essential

d. Check catheter site each shift for infection, leakage, and possible dislodging

1) Continuous leakage of clear or bloody drainage, reflux of blood in the visible portion of the catheter and notable irritation or extreme patient discomfort at the catheter site indicates loss of catheter integrity

e. Secure the end of the catheter to the patient's shoulder and back with tape or transparent dressing

f. Document the integrity of the catheter site each shift and as needed

g. Notify managing anesthesiologist on his/her next round of assessments, unless the situation requires immediate attention; i.e., bleeding or fluid seepage

h. Ensure infusion tubing is secured to catheter adapter, tape connection site to tongue blade

i. Observe that the dressing remains occlusive and that there are not obvious breaks or knots in the tubing.

j. If the dressing has become loose or if the catheter got displaced, reinforce the existing dressing and notify the managing physician (eg, anesthesiologist) immediately.

k. If the catheter is completely dislodged from the patient, observe the catheter for the presence of a black or blue mark near the tip of the catheter (ie, validation that the catheter is still intact and has not sheared within the patient's epidural space)

1) Save catheter for the anesthesiologist.

2) Cover the insertion site with a small dressing or bandage

3) Notify managing physician (eg, anesthesiologist) of assessment regarding catheter integrity

4) Document assessment

3. Removal of EPIDURAL Catheter:

a. Removal is performed by the anesthesiologist.

b. Nursing responsibilities include:

1) Apply small, sterile dressing after removal

2) Observe site for leakage or infection

3) Document time of removal

4) Notify Pharmacy once infusion is discontinued

~~4~~5) Document waste/remainder in (infusion) bag in Pyxis. Return epidural bag and copy of flowsheet to Pharmacy via external return bin for Pyxis for reconciliation. Please clamp off epidural bag to ensure it does not leak.

4. Patient and Family Education:

a. Nurse will instruct patient on epidural and pump, and how to use PCA (ie, give self demand doses)

b. Nurse will explain to family NOT to push PCA button for patient due to risk of over sedation.

c. Pain booklet will be provided to patient

5. Examples of change of condition to report to the anesthesia provider
   a. Pain NOT controlled
   b. Unrelieved nausea, vomiting, pruritis or somnolence
   c. Respiratory rate less than 8/minutes with dropping oxygen saturation
   d. Allergic reaction
   e. Hypotension

C. PHARMACY:

1. Premixed solutions will be used when possible
2. Supplemental label indicating **"EPIDURAL"** shall be affixed to bag, if Pharmacy prepares.
3. Epidural solutions shall be preservative free solutions
   a. Ingredients containing preservatives or bacteriostatic agents shall NOT be used in preparation of epidural infusion bags
4. ~~Upon initiation of therapy, Pharmacy will provide a second copy of the label for the nurse to affix to the initial Medication Administration Record (MAR).~~

	1st	2nd	3rd	4th	5th
Reviewed Date:	1/01	11/01	7/07		
By:			J.Gavin, PharmD		

	1st	2nd	3rd	4th	5th
Revised Date:	12/2020	5/2023			
By:	J.Gavin, M.Straley	Nursing / Pharmacy			

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Compounded Sterile Products: End Product (Final) Examination	Manual Location	Provision of Care		
Policy/Procedure #	2726	Effective	6/10	Page	1 of 1
Department Generating Policy	Pharmacy	Revised	10/2022		

I. PURPOSE:

To provide guidelines to ensure all compounded sterile products (CSPs) undergo a final examination by a pharmacist.

II. POLICY

- Sterile products shall be quarantined after compounding.
- A pharmacist shall perform an end product (final) examination of all compounded sterile products prior to their release from the Pharmacy.

III. PROCEDURE

A. Examination Procedure
   1. The examination procedure must ensure:
      a. Accuracy of profiles or other records (comparison with original order).
      b. Accuracy of calculations.
      c. Use of proper solutions, additives and equipment.
      d. Labels contain at least the product name and volume, additive name and amount, patient's name and other information when applicable.
      e. Proper assignment of beyond-use-date (BUD).
      f. Integrity of the container.
      g. Qualitative integrity:
         1) Absence of particulate matter, precipitates, turbidity, discoloration, or other signs that the product should not be used.
      h. Quantitative integrity:
         1) Potency at 90 to 110% of expected

B. Disposition of Products Not Passing Final Examination
   1. The pharmacist shall reject and destroy all products that do not pass the final examination.

C. Documentation of Final Product Examination
   1. Pharmacists shall document final product examinations prior to releasing them from the pharmacy.

D. Quality Assurance:
   1. At a minimum, an annual potency test to evaluate quantitative integrity will be completed.
      a. End product test should not be performed using an antibiotic.
   2. Also, at a minimum, annual media fill and glove tip finger sampling to evaluate qualitative integrity will be completed.
   3. In the event a compounded drug product is discovered to be below standard for quality and/or quantity (potency), pharmacist shall reject and destroy all product and personnel shall be immediately re-instructed, their sterile compounding technique re-evaluated by a pharmacist, and successfully complete written exams, competencies, and/or media-fills as required.

REFERENCES:
Joint Commission Standards: MM.05.01.07 EP 2 – 4
California State Board of Pharmacy: CCR 1735.8

Reviews:	1st	2nd	3rd	4th	5th
Date:	6/2009	3/15	11/17	12/2020	
By:	CHS Corporate Pharmacy Services	J.Gavin	J.Gavin	J.Gavin	

Revise:	1st	2nd	3rd	4th	5th
Date:	10/2022				
By:	J.Gavin				

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Observers-Shadowers in Clinical Settings	Manual Location	Medical Staff, Quality Management		
Policy/Procedure #		Effective	7/16	Page	1 of 6
Department Generating Policy	Medical Staff , Quality Management	Revised			

I. PURPOSE

A. To provide guidelines for the presence of non-vendor observers or shadowers in Clinical Departments.

B. To protect the confidentiality of patients and maintain HIPAA compliance.

C. To assure that patients' rights are respected.

~~C.~~**D. To comply with certain health requirements for non-vendor observers or Shadowers in contact with patients.**

Covered Persons: Individuals over 18 years of age who have some interest and/or connection to the healthcare field.

II. POLICY

A. Observers or "shadowers" of health professionals who will be in contact with patients must comply with certain prerequisites. Licensed independent practitioners, including mid-levels, with a compelling reason to observe physicians in a clinical care setting are included in this policy.

B. At no time will the observer be allowed to provide patient care.

C. A signed Patient Consent for Presence of Observer (Attachment C) will be required before an observer may be present, when the focus of the observation or shadowing is solely for the purpose of the patient's clinical diagnosis and subsequent care.

If a group of patients is included in the observation experience such as patient rounding on an inpatient unit, consent may be a verbal response from patients. In all circumstances, however, the patient(s) are to be made aware of the observer's status and the option to not allow the observer's presence. If verbal consent is obtained, that must be documented in the patient's medical record.

Sponsor is responsible for introducing observer to the patient(s) involved and obtaining patient's written consent (as described above). The consent will become part of the patient's medical record.

D. Clinical Department Chair (or designee) or the Chief Executive Officer (or designee) may exclude any observer at any time without cause.

E. Observers will be under the direct supervision of the sponsoring person.

F. Observers are bound by the same code of professional conduct as employees.

G. The Clinical Department Chair (or designee), Medical Staff Services Department, sponsor, and observer must assure that the prerequisites are met prior to the observation experience. All documentation will be held on file in the Medical Staff Services Department.

III. PROCEDURE

A. The sponsor of the observer must contact the Clinical Department Chair (or designee) for approval of the observation experience.

B. Observer Application Form (Attachment A) must be completed, including the attestation of the Sponsor's responsibility.

C. Medical Staff Department Clinical Observer Checklist must be completed by the Medical Staff Office prior to the experience (Attachment B). This document is to be retained for the period calendar year plus 3 years.

D. Observer must complete the Confidentiality Agreement with *Watsonville Community Hospital* (Attachment D).

~~D.~~ **E. Observer must obtain clearance, including health clearance, with Employee Health, (Attachment E).**

	1st	2nd	3rd	4th	5th
Revised Date:	_____	_____	_____	_____	_____
By:	_____	_____	_____	_____	_____
	1st	**2nd**	**3rd**	**4th**	**5th**
Reviewed Date:	_____	_____	_____	_____	_____
By:	_____	_____	_____	_____	_____

ATTACHMENT A

Observer Application

OBSERVER IDENTIFICATION DATA

Name (printed):_____

Address:_____

Telephone number: _____

City State, Zip: _____

Email address:_____

Date of birth: _____

Name of school, if applicable: _____

AREA AND DATES OF OBSERVATION REQUESTED – PLEASE BE SPECIFIC

Date(s) Requested	Observation/Areas Requested

I certify I have no known physical or mental illness or condition, including any contagious disease, which could be detrimental to the welfare or interfere with the care of any hospital patient or staff.

Observer signature: _____

Sponsor Contact Information:

Department/Clinic name: _____	Phone_____
Sponsor Contact Person: _____	
Contact information: _____	Phone_____

I hereby request the above-named individual for observation privileges. I acknowledge that she/he will be under my direct supervision at all times and will be allowed only observation of such activities as described. I further attest that violations of *Watsonville Community Hospital* policies or procedures will result in termination of this agreement.

Sponsor signature: _____ Date_____

REQUIRED APPROVALS

Clinical Department Chair (or designee) Signature:

_____ Date_____

Chief Executive Officer (or designee) Signature:

_____ Date_____

Attachment B

Medical Staff Department Clinical Observer Checklist

To be used by the Medical Staff Services Department. All documentation will be held on file for a minimum period of calendar year plus 3 years.

- ☐ Copy of government issued photo ID
- ☐ Observer Application form, assure that Sponsor has signed Attestation (Attachment A)
- ☐ Confidentiality statement (Attachment D)
- ☐ Patient Consent for Observation (Attachment C)

Medical Staff Department Approval: _____

Date: _____

Attachment C

PATIENT CONSENT FOR OBSERVATION

THE HOSPITAL IS REQUESTING YOUR CONSENT TO PERMIT THE OBSERVER, IDENTIFIED BELOW, TO OBSERVE PROVIDERS INVOLVED IN THE DELIVERY OF YOUR CARE.

The individual identified below has signed a statement stating that they are to maintain in strict confidence all information and data relating to the hospital's patients, and that the observer is not to disclose such information to any other person under any circumstances. The consent applies only for the dates set forth below.

I understand that the individual who is assigned to me is:

Name: _____

Dates individual will be observing: _____

I understand that I have the right to refuse a participant in the Observation Program by circling "no" below. Not signing this Consent is the same as a refusal and the hospital will honor my wishes. I also understand I can withdraw my consent to have an observer at any time. I understand that having an observer, or not having an observer, will not affect my care in any way at this hospital.

I CONSENT TO HAVING AN OBSERVER: (Circle One) YES NO

Signed: _____ Date: _____ Time: _____

Print Patient Name: _____ Relationship to Patient: _____

Witness: _____ Date: _____ Time: _____

Attachment D

Shadow/Observation Confidentiality Agreement

I, _____, acknowledge that during my shadow/observation experience at *Watsonville Community Hospital,* I agree to keep all information in strict confidence and will not disclose or disseminate any confidential information that I may be exposed to. I understand that I am obligated to maintain patient confidentiality at all times, both at the facility and when elsewhere.

I understand that all the medical information/records regarding a patient are confidential. This information will not be given to other individuals, unless proper authorization is obtained. I understand that it is not appropriate to discuss any patient's care and treatment in public places or with people that have not been involved in the case nor have reason to know details of the patient's health care. I also agree that I will not share conversations I hold with any healthcare provider during the course of the observation experience. I further agree that I will not take pictures or share information on any social network web site or in emails.

I understand that all patient, associate and/or organizational information, (clinical and/or financial), retrieved from any and all computer system(s) is strictly confidential. It should not be reproduced, transmitted, transcribed, or removed from the premises in any form.

I understand that any deviation from the above could result in legal action against Watsonville Community Hospital and me. I further understand that any breach of confidentiality, intentional or unintentional, may result in immediate termination of my shadow/observation experience and the denial of any future opportunities for observation.

My signature below certifies that all of the above confidentiality considerations have been explained to me and I was afforded the opportunity to ask questions.

Signature of Observer _____ Date_____

Policy/Procedure Title	Observers-Shadowers in Clinical Settings	Manual Location	Medical Staff, Quality Management		
Policy/Procedure #		Effective	7/16	Page	7 of 6
Department Generating Policy	Medical Staff , Quality Management	Revised			

Name:
DOB:

WATSONVILLE COMMUNITY HOSPITAL

Date: _____

APPENDIX E

EMPLOYEE HEALTH /STUDENT / OBSERVERS-SHADOWERS IN THE CLINICAL SETTING CHECKLIST

_____ Pre-Placement Health Evaluation form.

_____QuantiFERON Gold, Tuberculin Screening or TST (within last 12 mos. OR blood assay test for TB permissible if performed). If history of positive PPD, copy of positive results (TST or QFT) and chest x-ray report performed within last 12 mos. All individuals must complete a current TB signs and symptoms assessment.

_____ Drug Screen verification of negative 10 panel drug screen. (1 YEAR for students who are precepted in the clinical environment.) **Observers-Shadowers in the Clinical Setting will attest to negative current drug use as opposed to a drug screen verification

_____ MMR – Measles, Mumps and Rubella: provide proof of immunity (preferred) OR documentation of 2 vaccines and completed declination form.

_____ Varicella (Chicken Pox): provide proof of immunity (preferred) OR documentation of 2 vaccines and completed declination form.

_____ Hepatitis-B vaccine Series: provide proof of immunity (preferred) OR documentation of vaccination series and completed declination form.)

_____ Flu vaccination: provide documentation of receipt of current season's flu vaccine OR declination form (declination requires masking in patient care areas per order of local Public Health Officer) – Required October-March only.

_____ TdaP vaccination: provide proof of vaccination in previous 10 years OR declination form.

_____ Covid Vaccines + Booster

_____ N95 Mask Fitting (1860 and BYD models) **Does not apply to Observers-Shadowers in the Clinical Setting

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Medical Staff Policy Regarding Peer Review, Ongoing Professional Practice Evaluation (OPPE) & (FPPE)	**Policy #**	MS2842
Responsible	Medical Staff , Quality Management Director	**Revised/Reviewed**	01/17/2023

I. SCOPE

Applies to all credentialed members of the Medical Staff and Allied Health Practitioners.

EXCEPTION:
No volume providers with medical staff membership and without clinical privileges per Joint Commission clarification are exempt from the Ongoing Professional Performance Evaluation and Focused Professional Practice Evaluation requirements contained within this document.

II. PURPOSE:

To assure that the Board of Trustees, through the activities of its medical staff, assesses the ongoing professional practice and competence of its medical staff, conducts professional practice evaluations, and uses the results of such assessments and evaluations to improve professional competence, practice, and the quality of patient care;

To define those circumstances in which an external review or focused review may be necessary.

To address identified issues in an effective and consistent manner.

"Professional Practice Evaluation" is considered an element of the peer review process and the records and proceedings relating to this policy are confidential and privileged to the fullest extent permitted by applicable law.

III. DEFINITIONS

Peer:
For purposes of this policy, the term "Peer" refers to any practitioner who possesses the same or similar knowledge and training as the practitioner whose care is the subject of review.

Individual Case Review:
The process outlined for peer review of a particular case identified with a potential quality of care issue.

Ongoing Professional Practice Evaluation:
The ongoing process of data collection for the purpose of assessing a practitioner's clinical competence and professional behavior. Information gathered during this process is factored into decisions to maintain, revise, or revoke an existing privilege(s) prior to or at the time of the two-year membership and privilege renewal cycle.

Focused Professional Practice Evaluation:

The time-limited evaluation of practitioner competence in performing a specific privilege. The process is consistently implemented as a means to verify clinical competence for all initially requested privileges, for a newly requested privilege, and whenever a question arises regarding a practitioner's ability to provide safe, high- quality patient care. FPPE is not considered an investigation or corrective action as defined in the Medical Staff Bylaws and is not subject to the Bylaws provisions related to the corrective action process.

FPPE affects only the privileges for which a relevant concern has been raised and related privileges for which the same concern would apply. Other existing privileges in good standing should not be affected by the decision to initiate FPPE.

Peer Review

Peer Review is the process by which a practitioner, or committee of practitioners, examines the work of a peer and determines whether the practitioner under review has met accepted standards of care in rendering medical services. The professional or personal conduct of a physician or other healthcare professional may also be investigated. Individual Case Review, Ongoing Professional Practice Evaluation, and Focused Professional Practice Evaluation are components of peer review.

Practitioner Proctoring:

Please Refer to Proctoring Policy (#0158)

Focused Professional Practice Evaluation (FPPE)

A. Initiation of FPPE

FPPE will be initiated in the following instances:

- Upon initial appointment;
- When a new privilege is requested by an existing practitioner;
- When a question arises through the OPPE process, individual case review, or other peer review process regarding a currently privileged practitioner's ability to provide safe, high-quality patient care. For example, when a trigger is exceeded and preliminary review indicates a need for further evaluation.

A recommendation of FPPE may be made by:

- The Credentials Committee;
- A Department of the Medical Staff;
- The Chief of the Department;
- A special committee of the medical staff;
- The MEC

The FPPE monitoring plan for a new practitioner, or newly requested privilege(s) will be specific to the requested privileges or group of privileges as defined in the Medical Staff Proctoring policy.

FPPE is not considered an investigation as defined in the Medical Staff Bylaws and is not subject to the bylaws provisions related to investigations. If FPPE results in an action plan to perform an investigation, the process identified in the Medical Staff Bylaws would be followed.

B. Timeframe for Collection and Reporting

The period of FPPE must be time-limited. Time-limited may be defined by;
A specific period of time;
A specific volume (number of procedures/admissions)

The medical staff may take into account the practitioner's previous experience in determining the approach, extent, and time frame of FPPE needed to confirm current competence. The practitioner's experience may be individualized based upon one of the following experience/training examples:

1. Recent graduate from a training program at another facility, where the requested privileges were part of the training program (competence data is not available)
2. A practitioner with regular experience exercising the requested privilege of fewer than two to five years on another medical staff

FPPE shall begin with the applicant's first admission(s) or performance of the newly requested privilege. FPPE should optimally be completed within three months, or a suitable period based upon volume. The period of FPPE may be extended as necessary at the discretion of the medical staff but may not extend beyond the first biennial reappointment.

C. Methods for Conducting FPPE/Communication to the Practitioner

FPPE may be accomplished by:

1. Chart reviews, both concurrent and/or retrospective
2. Simulation
3. Discussion with the involved practitioner and/or other individuals involved in the care of the practitioner's patients
4. "Non-Mandatory" Direct observation/proctoring, i.e., observation/proctoring of a nature that does not restrict the physician's privileges or right to practice in the hospital, including the right to proceed with procedures or surgeries. Non-Mandatory observation/proctoring preserves the physician's right to proceed with a procedure or surgery regardless of the presence of an observer/proctor. Any requirement to the contrary is reserved solely for decision of the Medical Executive Committee, may implicate reports to the Board and Data Bank, and may require the grant of hearing rights under the Medical Staff Bylaws.
5. For dependent AHP's, FPPE methods may include review or proctoring by the sponsoring physician.
6. Internal or external peer review.

The terms of all FPPE shall be communicated in writing to the affected practitioner, including the following:

- The cause for the focused monitoring
- The anticipated duration
- The specific mechanism by which monitoring will occur (i.e., chart reviews, proctoring, peer observation, etc.)

D. Performance Monitoring Criteria and Triggers

Monitoring criteria, including specific performance elements to be monitored, as well as thresholds or triggers, are developed and approved by the medical staff or medical staff department/committee. The triggers are defined as potentially unacceptable levels of performance. Triggers to consider include, but are not limited to:

- A single egregious case or evidence of a practice trend
- Exceeding the predetermined thresholds established for OPPE
- Patient/staff complaints
- Non-compliance with Medical Staff Bylaws, Rules and Regulations
- Elevated infection, mortality and/or complication rates
- Failure to follow approved clinical practice guidelines
- Unprofessional behavior or disruptive conduct

If the results for a practitioner exceed thresholds established by the Medical Staff, outliers may be forwarded for peer review after initial screening by the Quality Management Department.

Attachment B Performance Measures & Triggers

E. Conclusion of FPPE

At the conclusion of the initial FPPE, findings will be reviewed by the Medical Executive Committee or responsible Department, for decision and recommendation. Decisions may include moving forward with OPPE, extending the period of FPPE, development of a performance improvement plan, or recommending to limit or suspend the privilege. Such recommendations are reported to and approved by the Medical Executive Committee and Board of Trustees. For recommendations resulting in restriction, suspension, revocation of specific privileges or other limitation on privileges, the processes pursuant to the Medical Staff Bylaws Appendix A (Fair Hearing Plan) will apply.

Each practitioner will be notified of their performance and outcome(s) following FPPE. A letter is forwarded to the Medical Staff member including, but not limited to, the following:

- Findings and outcome of FPPE
- Specific actions, if any, that need to be taken by the Practitioner to address any quality concerns and the method for follow-up to ensure that the concerns have been addressed; and
- If the focused review is complete or will continue (duration will be specific if the focused review will continue)
- The period of initial FPPE is completed and the practitioner will move into OPPE
- The period of FPPE for a specific privilege is completed and the practitioner will continue with OPPE

At the end of the period of focused evaluation, in the event that the practitioner's activity/volume has not been sufficient to meet the requirements of FPPE:

- The practitioner may voluntarily resign the relevant privilege(s), or
- The practitioner may submit a written request for an extension of the period of focused evaluation, or

- If the practitioner has sufficient volume of the privileges in question at another local facility, external peer references specific to the privilege/procedure will be obtained.
- FPPE may be extended at the discretion of the responsible medical staff department or committee.

The practitioner is not entitled to a hearing or other procedural rights for any privilege that is voluntarily relinquished.

Results of FPPE are maintained in the Practitioner's Confidential Quality File.

F. Performance Improvement Plan

If FPPE outcomes identify the need for an improvement plan, the plan will be drafted by the responsible medical staff department, committee or chair. The written improvement plan and supporting FPPE outcomes should be presented to the Medical Executive Committee for approval. The involved Practitioner should also be offered the opportunity to address the Committee and respond to the findings before the improvement plan is finalized and implemented.

Methods identified to resolve performance issues shall be clearly defined. Examples of improvement methods may include:

- Necessary education
- Proctoring (but only as described under Section C.) and/or mentoring
- Counseling
- Practitioner Assistance Program
- Suspension or revocation of privilege, subject to the provisions of the Bylaws.

Following approval by the Medical Executive Committee (MEC), the Department or Committee Chair, or Chief of Staff will meet with the Practitioner to communicate the improvement plan. If the Practitioner agrees with the plan, the written document should be signed by the Practitioner and forwarded to the Quality Department. If the Practitioner does not agree with the plan and/or refuses to implement the improvement plan, the outcome will be reported to the responsible department chief and/or Medical Executive Committee for resolution.

ONGOING PROFESSIONAL PRACTICE EVALUATION

A. Timeframe for Collection and Reporting

OPPE will be initiated and reported on all providers with clinical privileges. Results of OPPE will be reported for review and/or action six months if possible, and in no event less frequently than every nine months.

B. Indicators for Review

1. The type of data to be collected and related thresholds, or triggers, is determined by individual medical staff committees/departments and approved by the Medical Staff. Indicators may change as deemed appropriate by the department and/or medical staff and should be reviewed and approved on an annual basis. Data collected should not be

limited to negative/outlier trending data. Good performance data should also be considered.

a. Each Medical Staff department will select three to five specialty-specific indicators based upon their clinical service. These indicators may be evidence-based, such as post-op infection rate, etc.
b. The Medical Staff will select general indicators that apply to all credentialed practitioners.
c. The Medical Staff may consider using the six areas of "General Competencies" developed by the
d. Accreditation Council for Graduate Medical Education (ACGME). These include:
    i. Patient care
    ii. Medical/clinical knowledge
    iii. Practice-based learning and improvement iv. Interpersonal and communication skills
    iv. Professionalism
    v. Systems-based practice

2. Thresholds/triggers for performance must be defined for the selected indicators. Triggers are defined as unacceptable levels of performance within the established defined criteria and are used to identify those performance outcomes that could trigger FPPE. Triggers to consider include, but are not limited to:
    - Defined number of events occurring
    - Defined number of individual peer reviews with adverse determinations
    - Elevated infection, mortality, and/or complication rates
    - Sentinel events
    - Small number of admissions/procedures over an extended period of time
    - Increasing lengths of stay in comparison to peers
    - Increasing number of returns to surgery
    - Frequent unanticipated readmission for the same issue
    - Patterns of unnecessary diagnostic testing/treatments
    - Failure to follow approved clinical practice guideline
3. Two level 4 judgments within a rolling 24 month period
4. Any combination of four level 3 and 4 judgments within a rolling 24 month period
5. 3 incidents of significant disruptive behavior incidents (as judged by MEC) within a rolling 12 month period

C. Oversight and Reporting

The organized Medical Staff delegates the collection of the selected performance indicators to the appropriate hospital department. The overall process, data compilation and reporting is coordinated by the Quality Management Department.

The review of performance data and any recommendation(s) for action, if necessary, may be the responsibility of one of the following:

- The Medical Executive Committee;
- The specific Medical Staff Department;

- The Chief of the Department;
- The Medical and Surgical Quality Review Committees

D. Results and Reporting of Data Analysis

Data are analyzed and reported to determine whether to continue, limit, or revoke any existing privilege(s). The results of the individualized practitioner report are referenced in the MEC meeting minutes, maintained in the quality file and incorporated into the two-year reappointment process.

The outcome of the evaluation must be documented and maintained in the practitioner quality file.

During the course of OPPE, FPPE may be triggered by the following special circumstances:

- A single egregious case or evidence of a practice trend
- Exceeding the predetermined thresholds established for OPPE
- Patient/staff complaints
- Non-compliance with Medical Staff Bylaws, Rules and Regulations
- Elevated infection, mortality and/or complication rates
- Failure to follow approved clinical practice guidelines
- Unprofessional behavior or disruptive conduct

If unprofessional behavior or disruptive conduct is identified as a possible concern, the Disruptive Practitioner Policy will be initiated as a component of the OPPE.

At the completion of the review period, the results of OPPE (the practitioner profile report) will be communicated to the individual practitioner. The original report will be maintained in the practitioner quality file.

RESPONSIBILITIES OF THE QUALITY MANAGEMENT DEPARTMENT:

1. The Quality Management Department will be responsible for compiling and reporting results of FPPE and OPPE to the Medical Staff Committee(s) every six months in no event less frequently than every nine months. A practitioner-specific profile will be utilized.

2. In order to facilitate FPPE for Allied Health Professionals, and/or those practitioners requesting a new privilege, the practitioner must notify the Quality Management Department of the first scheduled procedure or encounter. The practitioner must also provide the Quality Management Department with a patient listing or log until the specified patient volume or FPPE requirement is met.

3. The OPPE practitioner-specific profile that illustrates performance over the two-year reappointment cycle will be utilized at the time of reappointment.

4. The Quality Management Department will be responsible for working with each Medical Staff Committee on an annual basis to review the continued relevance of the selected indicators and triggers.

Individual Case Review Process

Cases identified with potential quality of care issues are referred to either the Medical Quality Review Committee or Surgical Quality Review Committee for review. The Quality Management Department is responsible for coordinating the Peer Review Process.

Cases may be identified through OPPE, FPPE, case management, risk management, audits, sentinel events, clinician referrals, allegations of suspected substance abuse or disruptive behavior and other sources. All cases should be initially screened by the Quality Management department utilizing medical staff approved screening criteria, prior to forwarding for physician review. If there are no potential quality of care issues identified following the quality management screening, the case is closed, the findings are documented and trending is performed in the Quality Department.

If potential quality of care issues are identified through Quality Management screening, the following process for peer review shall be implemented:

A. Reviewer Selection & Duties

Reviews are completed by the designated Medical Staff Quality Review Committee.

The Committee Chair shall determine the individual physician(s) to perform the initial review and shall designate a deadline within which the individual physician reviewers shall complete the review which shall not be greater than 60-days and at least 2 weeks prior to the next committee meeting. This will allow time for the involved Practitioner to respond prior to the meeting (see below Communication to Involved Practitioner).

The individual physician reviewer(s) shall perform the initial review, complete the Peer Review Form, including initial grade (see Review Form Summary below). The reviewer will report written findings and recommendations to the Committee at its next regularly scheduled meeting following the completion of the review period.

The designated reviewer may not review a case where he/she participated in the care.

B. Reviewer Disqualification & Replacement

If a reviewer does not feel he/she can adequately review a medical record due to a conflict of interest or believes he/she is not qualified to address a certain issue, the reviewer may discuss the issue with the Chairperson of the Committee, Department Chief or Chief of Staff. If the Chair concurs, the Chair shall reassign the record(s) to another reviewer. If a member has reviewed a record that needs to be presented but is unable to attend the meeting, the member shall report to the Chair so that the presentation may be reassigned to another Committee member or presented by the Chairperson. If the chairperson is the practitioner subject to review, the record review will be assigned to another Active Staff member by the Chief of Staff. Should the hospital have only one practitioner in a particular specialty, or the pool of eligible reviewers is otherwise conflicted or unable to serve, the MEC or the Board of Trustees may request external peer review by a practitioner who is Board certified within the same specialty.

C. Communication to Involved Practitioner

Any Practitioner who is the subject of a review receiving an assigned peer review score of 3 or greater, shall be notified in writing at least two weeks prior to the medical staff meeting where the outcome of review is reported. Communication shall include the case medical record number, admission/discharge date, reason and ~~outcome~~ **summary** of the review. ~~Comments and/or opinions made by the reviewer may be included; however, the~~ **The** identity of the reviewer should be redacted.

The involved Practitioner is provided the opportunity to respond to the results of the review in writing in advance of the meeting where the outcome is reported. At the request of the Department Chief, or Chief of Staff, the Practitioner **will** be invited to attend the meeting to discuss the case.

D. Circumstances Requiring External Peer Review

If no practitioner on staff is qualified to conduct a review, the MEC, Chief of Staff, Department Chair or the Board of Trustees may request external peer review by a practitioner who is Board certified within the same specialty. External Peer Review may be necessary, but not limited to, the following circumstances:

- The pool of eligible reviewers is unable to serve
- There is no qualified practitioner on staff to conduct the review
- Litigation risk
- The facility has only a single practitioner in a particular specialty and no other practitioner has similar background, training or experience.

No practitioner may require the Hospital to obtain external peer review if it is not deemed necessary by the Chief of Staff, Executive Committee or Board of Trustees. ~~**The Practitioner will be given a copy of their external peer review findings.**~~

Where the body conducting the peer review seeks external or outside peer review by a qualified practitioner within the same specialty or discipline as the practitioner under review, it shall appoint such external or outside reviewer to be a member of the peer review committee, without vote. Any report generated by such external or outside reviewer shall be considered to be a report of the peer review committee and shall be utilized for the committee's purposes. Likewise, where the peer review committee in its discretion affords the practitioner under review the opportunity to respond to the report of an external or outside reviewer, the practitioner shall attend a peer review committee meeting to discuss such response, and any information submitted by the practitioner under review in response to such report shall be considered to have been acquired in connection with or in the course of the peer review committee proceeding. An external or outside reviewer who is appointed to the peer review committee shall attend peer review committee meetings personally or telephonically, as is appropriate under the circumstances, for the purpose of deliberations related to any report by such external or outside reviewer. All information pertaining to any external or outside review by a qualified practitioner who is appointed to the peer review committee shall be protected to the fullest extent permitted by state law. For purposes of this paragraph, "peer review committee" shall include, without limitation, any medical review committee, departmental peer review committee, and the Medical Executive Committee.1

E. Review Form Summary

Reviewing practitioners must complete the Peer Review Form, Attachment One, clearly and concisely. The reviewing practitioner must sign his/her name on the review form which shall grade the care and outcome based on the following schedule:

1 = Treatment appropriate, outcome good, and any patient impact was minimal
2 = Treatment appropriate but patient sustained significant adverse outcome
3 = Treatment inappropriate but adverse impact on patient was minimal
4 = Treatment inappropriate and patient sustained a significant adverse outcome

DOCUMENTATION OF PEER REVIEW ACTIVITIES:

Reports of OPPE and FPPE and individual case review findings and recommendations shall be presented to the MEC. The MEC may adopt the recommendations of the Medical Staff Quality Review Committees and/or make further recommendations, including recommendation for further investigation and/or Corrective Action in accord with the Medical Staff Bylaw.

Results of OPPE, FPPE and Peer Review outcomes shall be documented and maintained in the practitioner's quality file and referenced at reappointment.

CONFIDENTIALITY OF REVIEW

All proceedings conducted as the result of this policy are subject to the California Evidence Code Section 1157 and The Health Care Quality Improvement Act of 1986 (HCQIA), 42 USC §11101.

I. REFERENCES

N/A

II. STAKEHOLDERS

MEC

WATSONVILLE COMMUNITY HOSPITAL

PEER REVIEW WORKSHEET

☐ MQRC ☐ SQRC ☐ B&T

MEDICAL STAFF BUSINESS NOT TO BE INCLUDED IN PATIENT CHART

Physician #	Account #	Medical Record #	*INPATIENT*		Outpt./ER Date	Review Date
	3050562		Admission Date	Discharge Date		

Referral Source:

□ QRC-specific process audits or clinical practice guideline audits. □ QRC-specific clinical indicators or outcome measurements.
□ Referrals from external agencies related to practitioner-specific issues. □ Sentinel events dealing with practitioner-specific issues.
□ Specific patient complaints dealing with clinical and/or practitioner specific issues. □ Hospital-wide generic indicators.
□ New legal cases identified by the organization, which may relate to physician performance. □ Staff concerns.
□ Referrals from other medical staff or organizational committees or team related to practitioner specific issues. □ Event reports.

Case Summary:

Key Questions for Reviewer:

Reviewer Findings/Conclusions:

Case Review Scoring	
RN	□ Case reviewed by a RN outside of committee with no identified opportunity for improvement. □ Case referred to physician for review. RN Signature: _____
Care by the Physician	□ Treatment was appropriate and medically necessary. □ Treatment was not appropriate, either all or in part. *(See Practitioner Care Issues)* □ Treatment was not medically necessary. *(See Practitioner Care Issues)* □ Treatment was controversial, unproven, experimental or investigational. □ Treatment was not timely or not performed in the proper sequence. *(See Practitioner Care Issues)* □ Response time and/or ongoing assessment were not adequate. *(See Practitioner Care Issues)*

ADDITIONAL COMMENTS MAY BE WRITTEN ON THE BACK OF THIS FORM.

Case Review Scoring		
Practitioner care Issues: (*Check all that apply*)	□ Clinical Judgment/Decision-Making □ Diagnosis □ Knowledge □ Policy Compliance □ Technique/Skills	□ Communication/Responsiveness □ Follow-up/Follow-through □ Planning □ Supervision (House Physician or AHP) □ Other: _____
Contributing Causes	□ Judgment of the physician. □ Hospital systems/process issues. □ Failure by physician to comply with hospital/Medical Staff bylaws, Rules and Regulations. □ Issues identified with providers of care other than the physician under review. □ Inadequate documentation/not timely and/or poor interdisciplinary communication.	□ Contributing cause not identified
	□ Case reviewed by a physician outside of committee with no identified opportunity for improvement. □ Refer to QRC for Physician Concern or □ Refer to QCC for Process Problem	_____ Reviewer Signature

Case Review Scoring		
Committee Review	Is physician/provider response needed? □ Yes □ No (Care Appropriate, no issues or concerns) If yes, letter sent □ Yes □ No Date 1: _____ Date 2: _____	
Practitioner Response	□ Letter received and discussed	□ No letter received
Committee's Final Score	□ 1 – Treatment appropriate, outcome good and any adverse impact on the patient was minimal. □ 2 – Treatment appropriate, but in spite of that the patient sustained a significant adverse outcome. □ 3 – Treatment inappropriate, but the adverse impact on the patient was minimal. □ 4 – Treatment inappropriate and the patient sustained a significant adverse outcome.	
Additional Committee Recommendations:		

DISPOSITION

QRC Action: □ Score Upheld □ Score Modified _____

□ Refer to _____ Department / SQRC / MQRC / MEC / QCC/CNO □ External Peer Review

□ Informational Letter to _____ □ Track and Trend □ Case Closed

Chairperson Signature _____ Date _____

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: May 31, 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: May 31,2023
Report Type: Discussion

Title: Update by Chief Financial Officer (CFO)

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.

Attachment A: Financial Performance Report (To be Delivered)

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

	Jan-23	Feb-23	Mar-23	Apr-23
Assets				
Cash	$ 5,982	$ 6,078	$ 1,916	$ 3,958
A/R	43,166	43,452	42,474	39,084
Less: Allowance for BD	(8,134)	(7,325)	(6,587)	(6,365)
Prior yr Cost Report Settlement				
Supplies	2,079	2,073	2,118	2,069
Prepaid Expenses	1,185	1,209	1,104	1,096
Other Current Assets	722	1,195	2,551	2,271
Total Current Assets	$ 45,000	$ 46,682	$ 43,576	$ 42,113
Net PP&E	35,245	35,168	35,150	35,074
Operating Lease ROU, Net	1,676	1,634	1,491	1,449
Notes Receivable				
Deposits	5	5	5	5
Unamortized Loan Costs	50	50	50	50
Physician Recruitment Costs	-	-	-	-
Deferred MIS Charges	698	631	562	496
Goodwill (Placeholder)	(20,666)	(20,551)	(20,963)	(20,963)
Total Other Assets	$ (18,237)	$ (18,231)	$ (18,855)	$ (18,963)
Total Assets	$ 62,008	$ 63,619	$ 59,871	$ 58,224
Liabilities and Equity				
Current maturities of LTD	$ (47)	$ (57)	$ (68)	$ (79)
Accounts Payable	6,622	7,194	7,009	7,361
Accrued Emp. Comp.	9,401	10,052	7,793	8,535
Operating Lease - Current	30	20	319	324
Other Accrued Liabilities	5,844	7,716	7,006	5,955
Total Current Liabilities	$ 21,850	$ 24,925	$ 22,059	$ 22,096
Deferred Credits	6,935	6,880	6,405	6,318
Operating Lease Liabilities	1,693	1,655	1,194	1,159
Long Term Debt	39,836	39,847	40,358	40,369
Total Liabilities	$ 70,314	$ 73,307	$ 70,016	$ 69,942
Stockholders' Equity	(8,306)	(9,688)	(10,145)	(11,718)
Total Liabilities and Equity	$ 62,008	$ 63,619	$ 59,871	$ 58,224

Watsonville Community Hospital
Consolidated Income Statement
For The Month of April, 30, 2023

CURRENT PERIOD					YTD			
Apr-23	BUDGET	VARIANCE	% VARIANCE		ACTUAL	BUDGET	VARIANCE	% VARIANCE
				Operating Revenues				
28,404,857	35,224,309	(6,819,452)	-19.4%	Inpatient Revenue	119,831,376	139,448,472	(19,617,096)	-14.1%
51,347,100	46,648,297	4,698,803	10.1%	Outpatient Revenue	202,226,532	185,903,768	16,322,764	8.8%
79,751,957	**81,872,606**	**(2,120,649)**	**-2.6%**	**Total gross patient revenue**	**322,057,908**	**325,352,240**	**(3,294,332)**	**-1.0%**
				Deductions From Revenue:				
70,729,558	71,403,794	(674,236)	-0.9%	Contractual Allowances	285,248,310	282,752,641	2,495,669	0.9%
(1,599,179)	(1,599,179)		0.0%	QAF	(6,396,717)	(6,396,717)		0.0%
(128,059)	(128,059)		0.0%	Disproportionate Share DSH	(512,234)	(512,234)		0.0%
69,002,320	**69,676,556**	**(674,236)**	**-1.0%**	**Total Deductions From Rev**	**278,339,359**	**275,843,690**	**2,495,669**	**0.9%**
10,749,637	**12,196,049**	**(1,446,412)**	**-11.9%**	**Net Revenue**	**43,718,549**	**49,508,549**	**(5,790,000)**	**-11.7%**
(169,683)	104,035	(273,718)	-263.1%	Provision for Bad Dbt	(1,500,610)	422,217	(1,922,827)	-455.4%
10,919,320	**12,092,014**	**(1,172,694)**	**-9.7%**	**Collectible Patient Revenue**	**45,219,159**	**49,086,332**	**(3,867,173)**	**-7.9%**
88,840	132,138	(43,298)	-32.8%	Other Revenue	2,893,269	528,551	2,364,718	447.4%
11,008,160	**12,224,152**	**(1,215,992)**	**-9.9%**	**Total Net Operational Revenue**	**48,112,428**	**49,614,884**	**(1,502,456)**	**-3.0%**
				Operating Expenses				
5,759,299	5,365,548	393,751	7.3%	Salaries & Wages	23,394,647	22,437,835	956,812	4.3%
1,723,342	2,030,084	(306,742)	-15.1%	Benefits	6,374,235	8,148,953	(1,774,718)	-21.8%
503,147	550,000	(46,853)	-8.5%	Contract Labor	2,274,623	2,315,000	(40,377)	-1.7%
7,985,788	**7,945,632**	**40,156**	**0.5%**	**Subtotal Salaries Wages & Benefits**	**32,043,505**	**32,901,788**	**(858,283)**	**-2.6%**
710,036	831,725	(121,689)	-14.6%	Medical Spec Fees	2,678,291	3,343,843	(665,552)	-19.9%
911,733	841,079	70,654	8.4%	Supplies	3,876,625	3,517,775	358,850	10.2%
135,260	100,945	34,315	34.0%	Repairs & Maintenance	412,848	403,781	9,067	2.2%
168,525	161,240	7,285	4.5%	Utilities	1,052,584	646,307	406,277	62.9%
1,033,045	1,349,658	(316,613)	-23.5%	Purchased Services	5,135,836	6,237,238	(1,101,402)	-17.7%
309,328	208,886	100,442	48.1%	Lease Cost and Rent	634,094	830,796	(196,702)	-23.7%
189,401	270,698	(81,297)	-30.0%	Prop Taxes & Ins	723,541	1,085,409	(361,868)	-33.3%
750	4,167			Marketing	1,694	16,667		
662,252	942,611	(280,359)	-29.7%	Other Operating Exp	2,620,593	3,999,457	(1,378,864)	-34.5%
12,106,118	**12,656,642**	**(550,524)**	**-4.3%**	**Total Operating Exp**	**49,179,611**	**52,983,061**	**(3,803,450)**	**-7.2%**
(1,097,958)	**(432,491)**	**(665,467)**	**153.9%**	**EBITDA**	**(1,067,183)**	**(3,368,177)**	**2,300,994**	**-68.3%**
82,606	96,850	(14,244)	-14.7%	Depreciation and Amortization	369,657	384,878	(15,221)	-4.0%
390,722	402,210	(11,488)	-2.9%	Interest	1,554,012	1,603,289	(49,277)	-3.1%
473,328	**499,060**	**(25,732)**	-5.2%	**Total Other Expenses**	**1,923,669**	**1,988,167**	**(64,498)**	-3.2%
(1,571,286)	**(931,551)**	**(639,735)**	68.7%	**Net Income/Loss from Operations**	**(2,990,852)**	**(5,356,345)**	**2,365,493**	-44.2%
147,488				Total Normalizing Adjustments	(1,775,603)			
(950,471)				**Normalized EBITDA**	**(2,842,786)**			

Watsonville Community Hospital
Income Statement
For The Month of April, 30, 2023

CURRENT PERIOD					YTD			
Apr-23	BUDGET	VARIANCE	% VARIANCE		ACTUAL	BUDGET	VARIANCE	% VARIANCE
				Operating Revenues				
28,404,857	35,224,309	(6,819,452)	-19.4%	Inpatient Revenue	119,831,376	139,448,472	(19,617,096)	-14.1%
50,844,755	46,181,607	4,663,148	10.1%	Outpatient Revenue	200,192,479	184,025,507	16,166,972	8.8%
79,249,612	**81,405,916**	**(2,156,304)**	**-2.6%**	**Total gross patient revenue**	**320,023,855**	**323,473,979**	**(3,450,124)**	**-1.1%**
				Deductions From Revenue:				
70,422,404	71,150,773	(728,369)	-1.0%	Contractual Allowances	283,997,107	281,705,324	2,291,783	0.8%
(1,599,179)	(1,599,179)		0.0%	QAF	(6,396,717)	(6,396,717)		0.0%
(128,059)	(128,059)		0.0%	Disproportionate Share DSH	(512,234)	(512,234)		0.0%
68,695,166	**69,423,535**	**(728,369)**	**-1.0%**	**Total Deductions From Rev**	**277,088,156**	**274,796,373**	**2,291,783**	**0.8%**
10,554,446	**11,982,381**	**(1,427,935)**	**-11.9%**	**Net Revenue**	**42,935,699**	**48,677,606**	**(5,741,907)**	**-11.8%**
(172,908)	101,619	(274,527)	-270.2%	Provision for Bad Dbt	(1,491,922)	412,819	(1,904,741)	-461.4%
10,727,354	**11,880,762**	**(1,153,408)**	**-9.7%**	**Collectible Patient Revenue**	**44,427,621**	**48,264,787**	**(3,837,166)**	**-8.0%**
13,973	113,024	(99,051)	-87.6%	Other Revenue	2,615,606	452,096	2,163,510	478.6%
10,741,327	**11,993,786**	**(1,252,459)**	**-10.4%**	**Total Net Operational Revenue**	**47,043,227**	**48,716,883**	**(1,673,656)**	**-3.4%**
				Operating Expenses				
5,505,911	5,106,772	399,139	7.8%	Salaries & Wages	22,395,774	21,357,756	1,038,018	4.9%
1,674,770	1,971,538	(296,768)	-15.1%	Benefits	6,183,774	7,886,151	(1,702,377)	-21.6%
503,147	550,000	(46,853)	-8.5%	Contract Labor	2,274,623	2,315,000	(40,377)	-1.7%
7,683,828	**7,628,310**	**55,518**	**0.7%**	**Subtotal Salaries Wages & Benefits**	**30,854,171**	**31,558,907**	**(704,736)**	**-2.2%**
691,808	816,758	(124,950)	-15.3%	Medical Spec Fees	2,657,124	3,267,031	(609,907)	-18.7%
901,345	835,280	66,065	7.9%	Supplies	3,852,190	3,493,341	358,849	10.3%
135,226	100,828	34,398	34.1%	Repairs & Maintenance	412,737	403,314	9,423	2.3%
167,419	160,394	7,025	4.4%	Utilities	1,046,772	641,578	405,194	63.2%
967,713	1,316,108	(348,395)	-26.5%	Purchased Services	4,923,559	6,103,037	(1,179,478)	-19.3%
285,139	189,964	95,175	50.1%	Lease Cost and Rent	536,817	759,855	(223,038)	-29.4%
181,171	263,544	(82,373)	-31.3%	Prop Taxes & Ins	695,938	1,054,177	(358,239)	-34.0%
750	-	750		Marketing	1,694	-	1,694	
-	-			Management Fees	-	150,000	(150,000)	-100.0%
660,313	940,664	(280,351)	-29.8%	Other Operating Exp	2,608,131	3,835,453	(1,227,322)	-32.0%
11,674,712	**12,251,850**	**(577,138)**	**-4.7%**	**Total Operating Exp**	**47,589,133**	**51,266,693**	**(3,677,560)**	**-7.2%**
(933,385)	**(258,064)**	**(675,321)**	**261.7%**	**EBITDA**	**(545,906)**	**(2,549,810)**	**2,003,904**	**-78.6%**
-	-			Depreciation and Amortization	-	-		
9,409	15,752	(6,343)	-40.3%	Interest	25,925	57,455	(31,530)	-54.9%
9,409	**15,752**	**(6,343)**	-40.3%	**Total Other Expenses**	**25,925**	**57,455**	**(31,530)**	-54.9%
(942,794)	**(273,816)**	**(668,978)**	244.3%	**Net Income/Loss from Operations**	**(571,831)**	**(2,607,265)**	**2,035,434**	-78.1%
147,488				Total Normalizing Adjustments	(1,775,603)			
(785,898)				**Normalized EBITDA**	**(2,321,509)**			

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: May 31, 2023
Report Type: Discussion

Title: Line of Credit

Recommendation: Receive information regarding $5,000,000 Commercial Revolving Line of Credit, secured by external agency(s) funding presenting the opportunity for the Pajaro Valley Health Care District Hospital Corporation Board of Directors to provide the Hospital with short term working capital.

Contact: Julie Peterson, Chief Financial Officer

Executive Summary
The Pajaro Valley Health Care District Hospital Corporation desires a $5,000,000 Commercial Revolving Line of Credit from Santa Cruz County Bank to provide short term working capital while the Hospital implements its various turnaround plan initiatives. Multiple external entities have expressed a willingness to secure the line of credit on behalf of the Hospital Corporation.

The Line of Credit is expected to mature one year from the initiation date. Interest only payments will be due monthly at a variable rate of US Prime + 1.0% margin. The origination fee will be $1,000.00 plus all 3rd party fees (legal fees, reports, etc.). A deposit account relationship will be established at Santa Cruz County Bank to facilitate easy access and repayment for the Line of Credit.

Quarterly reporting to Santa Cruz County Bank will include balance sheet and income statements compared to budget.

A formal resolution and loan documents will be presented to the Hospital Corporation and District Boards to approve the Line of Credit in a future meeting.

Background

The Hospital negotiated new payer contracts with all of it's major insurance companies. The contracts are being implemented in a staggered timeline to reduce the disruption of cashflow needed to cover daily operations. There were some delays by some payers in loading contract rates and/or other information into their claims payment systems which resulted in delays in payment to Watsonville Community Hospital.

The Hospital sought and received short term cash advances against claims from Kaiser Permanente ($2.5 million) and Central California Alliance for Health ($1.0 million) earlier in 2023. Both of the cash advances have been fully repaid to the respective payers.

The timing of the turnaround initiatives and full implementation of their benefits necessitates the larger dollar line of credit and longer one year term. The Hospital Corporation leadership has met with Santa Cruz County Bank and the external parties to present current progress on the turnaround plans and current YTD financial performance.

Given the limited asset base available to the Hospital Corporation to secure its own Line of Credit, it is believed that this is the best option to secure a commercial revolving line of credit with reasonable terms and fees.

Analysis

A review of weekly Accounts Payable disbursements and bi-weekly payroll disbursements were compared to weekly cash collections. Given the timing to implement initiatives in the Turnaround Plan, Watsonville Community Hospital believes this revolving line of credit will provide a financial cushion for unforeseen circumstances or any further delays in reimbursements due to the Hospital Corporation.

Financial Impact

The Hospital will have access to a $5,000,000 commercial revolving line of credit. There is a $1,000 loan origination fee plus 3rd party fees for legal and reporting services. The interest rate is variable at US Prime + 1% margin. Monthly payments are based on the amount of credit line in use. The current variable May US Prime rate of 8.25% plus 1%.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: May 31, 2023
Report Type: Discussion

Title: Medical Committees Reports May 2023

Recommendation: Pass a **Motion** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of May 2023.

Contact: Clay Angel, M.D., Vice 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:

A-Medical Executive Committee Reports