PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Members

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

Closed Meeting Agenda

Wednesday, July 26, 2023-5:00 pm

Kathleen King Community Room - 85 Nielson Street, Watsonville

https://zoom.us/j/93443061917

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

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

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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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.

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Spanish language translation is available on an as needed basis. Please make advance arrangements at least three business days before the meeting at by calling at (831) 763.6040 or by emailing at info@pvhcd.org.
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Pajaro Valley Health Care District Hospital Corporation
Closed Meeting Agenda- Wednesday, July 26, 2023

Call to Order

Roll Call

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.

Public Comment on Matters on the Agenda

Adjourn to Closed Session

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

2. **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

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 Members

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

Regular Meeting Agenda

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

Call to Order

Roll Call

Closed Session Report

Agenda Modification Consideration

Public Comment on Matters Not on the Agenda

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

2. **Medical Executive Committees Report June 2023**
   Recommendation: Pass a **Motion** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of July 2023; 2) OPPE template for Pediatric Physicians; 3) Reappointment Application Attestation Questions; and 4) 2023 Surgical Quality Review Indicators.

   Contact: Executive Sponsor-Dr. Angel, Chief of Staff, Medical Executive Committee

Discussion

3. **Chief Executive Officer Matko Vranjes Oral Report on Operational Hospital Activities**
   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. **California Department of Health Care Access and Information (HCAI) Hospital Distressed Loan Program**
   Recommendation: Pass a **Resolution** authorizing the execution and delivery of a promissory note, Loan and Security Agreement, and certain actions in connection therewith for a loan in an aggregate amount not to exceed $6,500,000 from the California Health Facilities Financing Authority under the Distressed Hospital Loan Program.
   Contact: Julie Peterson, Chief Financial Officer

6. **Line of Credit-Santa Cruz County Bank**
   Recommendation: Pass a **Motion** 1) authorizing staff to negotiate a $5.0 million Line of Credit agreement between the Pajaro Valley Health Care District Hospital Corporation (PVHCDHC) (the "Hospital") and Santa Cruz County Bank and 2) directing staff to place a Resolution approving the final agreement on a future PVHCDHC agenda.
   Contact: Julie Peterson, Chief Financial Officer

7. **Watsonville Community Hospital Strategic Plan Approval**
   Recommendation: 1) Provide Chartis with input on: a) mission, vision, and values statements, and b) strategic priorities and tactics, and c) strategic plan roadmap and accountable leaders and 2) pass a **Motion** approving the mission, vision and values statements and Strategic Plan.
   Contact: Matko Vranjes, Interim Chief Executive Officer

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: July 26, 2023
Report Type: Consent

Title: Policy/Summaries July 2023

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

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

Analysis

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

Financial Impact: None.

Attachment A:
Reports

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOD			
Reporting Period: July 26, 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
Rehabilitation (REHAB)				
Assessment-Reassessment OT	REHAB0001	No Changes	Regulary Scheduled Review	Author: REHAB Director 05/2023 Medicine Comm.: 06/21/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO: 07/14/2023 MEC: 07/18/2023 BOD:
Assessment-Reassessment PT	REHAB0002	No Changes	Regulary Scheduled Review	Author: REHAB Director 05/2023 Medicine Comm: 06/21/2023 CNO: 07/13/2023 VP/Sr.Leader/CEO: 07/14/2023 MEC: 07/18/2023 BOD:
Assessment-Reassessment Rehab,	REHAB0003	No Changes	Regulary Scheduled Review	Author: REHAB Director 05/2023 Medicine Comm: 06/21/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO:07/14/2023 MEC: 07/18/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOD			
Reporting Period: July 26, 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
Patient Charges	REHAB0467	No Changes	Regulary Scheduled Review	Author: REHAB Director 05/2023 Medicine Comm: 06/21/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO:07/2023 MEC: N/A BOD:
Communication with Patients/Family	REHAB1730	No Changes	Regulary Scheduled Review	Author: REHAB Director 05/2023 Medicine Comm: 06/21/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO:07/14/2023 MEC: 07/18/2023 BOD:
Therapeutic Exercises and Other Interventions	REHAB1753	No Changes	Regulary Scheduled Review	Author: REHAB Director 05/2023 Medicine Comm: 06/21/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO:07/2023 MEC: 07/18/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOD			
Reporting Period: July 26, 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
Referral Guidelines	REHAB1918	No Changes	Regulary Scheduled Review	Author: REHAB Director 05/2023 Medicine Comm: 06/21/2023 CNO: 07/13/2023 VP Sr. Leaser/CEO: 07/14/2023 MEC: 07/18/2023 BOD:
(Massage Lotion) Use of Massage Cream or Other Lotions in Rehab Department	REHAB1739	No Changes	Regulary Scheduled Review	Author: REHAB Director 05/2023 Medicine Comm: 06/21/2023 CNO: 07/13/2023 VP/Sr Leader/CEO:07/2023 MEC: 07/18/2023 BOD:
Myofascial-Soft Tissue	REHAB2043	No Changes	Regulary Scheduled Review	Author: REHAB Director 05/2023 Medicine Comm: 06/21/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO:07/14/2023 MEC:07/18/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOD			
Reporting Period: July 26, 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
Biofeedback in Rehab	REHAB2652	No Changes	Regulary Scheduled Review	Author: REHAB Director 05/2023 Medicine Comm: 06/21/2023 CNO:07/13/2023 Vp/Sr. Leader/CEO:07/2023 MEC: 07/18/2023 BOD:
PHARMACY (PHARM)				
Designated Person for Sterile Compounding	PHARM0797	New Policy,	New Policy	Author: Pharmacy Director 07/03/2023(2022) PTIC: 07/05/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO: MEC: 07/18/2023 BOD:
Controlled Substance Audit Plan		Change D and E to reflect current process at Watsonville Community Hospital	Yearly Review	Author: Pharmacy Director 07/03/2023(2022) PTIC: 07/05/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO: MEC: 07/18/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOD			
Reporting Period: July 26, 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
Metered Dose Inhaler Protocol	PHARM1418	Un-Retire		Author: Pharmacy Director 07/03/2023 PTIC: 07/05/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO: MEC: 07/18/2023 BOD:
Obtaining Non-Formulary Medication	PHARM1568	ADD A.2. Patient may use own medication after validation by pharmacist. See policy #1577: Patient Own Medication/Drugs	Regulary Scheduled Review	Author: Pharmacy Director 07/03/2023 PTIC: 07/05/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO: MEC: 07/18/2023 BOD:
Approved Drugs for Non-Approved Uses	PHARM2088	No Changes	Regulary Scheduled Review	Author: Pharmacy Director 07/03/2023 PTIC: 07/05/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO: MEC: 07/18/2023 BOD:
Standards(Specifications): Medications, Chemicals, and Biologicals	PHARM2090	Change C3 and 4 - from shall to should	Regulary Scheduled Review	Author: Pharmacy Director 07/03/2023 PTIC: 07/05/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO: MEC: BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOD			
Reporting Period: July 26, 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
Supplying Medications to Other Healthcare Organozations	PHARM2095	No Changes	Regulary Scheduled Review	Author: Pharmacy Director 07/03/2023 PTIC: 07/05/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO: MEC: 07/18/2023 BOD:
Discharge Prescriptions	PHARM1578	Change to electronic transmission of prescriptions as primary	Regulary Scheduled Review	Author: Pharmacy Director 07/03/2023 PTIC: 07/05/2023 CNO:07/13/2023 VP/Sr. Leader/CEO: MEC: 07/18/2023 BOD:
Adverse Drug Reaction	PHARM1429	New Template. Change to current facility reporting system; remove B.1.b – report no longer available	Regulary Scheduled Review	Author: Pharmacy Director 07/03/2023 PTIC: 07/05/2023 CNO: 07/13/2023 Vp/Sr. Leader/CEO: MEC: 07/18/2023 BOD:
Investigational Drug Studies	PHARM1565	Remove IRB (not available at WCH; run thru P&T or "equivalent Medical Staff Committee")	Regulary Scheduled Review	Author: Pharmacy Director 07/03/2023 PTIC: 07/05/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO MEC: 07/18/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOD			
Reporting Period: July 26, 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
Warfariin(Coumadin) Protocol-Administration Monitoring	PHARM0274	New Template: (No changes)NOTE:NOTE: the following policy were approved thru P&T last year (7/2022) but missed going to MEC and Board – so are being re-run thru system now. (No changes)	Regulary Scheduled Review	Authir: Pharmacy Director 07/03/2023(07/2022) PTIC: 07/05/2023 CNO: 07/13/2023 VP/Sr. Leader/CEO: MEC: 07/18/2023 BOD:
Antiocoagulant Management	PHARM004	NOTE:NOTE: the following policy were approved thru P&T last year (7/2022) but missed going to MEC and Board – so are being re-run thru system now.(No Changes)	Regulary Scheduled Review	Author: Pharmacy Director 07/03/2023(07/2022) PTIC: 07/05/2023 CNO: 07/13/2023 VP/Sr. Leade/CEO: MEC: 07/18/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Assessment/Reassessment, Occupational Therapy	Policy #	REHAB0001
Responsible	Director of Rehab Services	Revised/Reviewed	~~09/03/2020~~05/24/2023

I. PURPOSE

To define patient assessment and reassessment parameters, a process to prioritize patient care, and criteria that are utilized during the assessment process by Occupational Therapists. The assessment process is vital for establishing proper plans of care for the individual patient receiving Occupational Therapy services.

II. POLICY

1. All patients receiving inpatient or outpatient Occupational Therapy services at WCH will receive an initial assessment that takes into account their immediate and emerging needs. The data gathered will be analyzed to create information needed for care decisions concerning any need for further assessments, treatment, interventions, and reassessments.
2. Each admitted patient's initial assessment is conducted within a time frame identified by the service and/or patient care needs. Reassessment occurs throughout the care process and includes the reason for reassessment, key reassessment points and/or time intervals are defined.
3. Assessments are performed within the Occupational Therapy scope of practice, state licensure laws, applicable federal/state regulations and laws, or certification.
4. Plans of care will be based upon the patient and upon data and information gathered in assessments and reassessments. This data will be utilized in prioritizing patient care needs and selecting appropriate interventions.
5. Prioritizing patient care will occur as follows:
   a. Emergent needs
   b. Actual needs
   c. Education needs
   d. Potential needs

III. DEFINITIONS

1. Assessment – The systemic collection and analysis of patient specific data necessary to determine patient care needs and treatment interventions, the scope of which is determined by the patient's diagnosis, the care setting, the patient's desire for care, and the patient's response to any previous care.
2. Reassessment - Further data collection and analysis, the scope of which is determined by the patient's diagnosis, the care setting, patient's status and care needs, the patient's desire for treatment, and the patient's response to care, treatment or services. Reassessment is ongoing and occurs when there are significant changes in the patient's status, condition, or diagnosis. Reassessment determines treatment progress and if changes in treatment are indicated.

IV. PROCEDURE

1. Occupational Therapy Initial Assessment
   a. Patients will be assessed by an Occupational Therapist (OTR) withing 48 hours of receipt of physician order (inpatient) and scheduled withing 4 days of receipt of physician referral/authorization (outpatient). The scope of the assessment and tests administered will vary based on the diagnosis or problem and the patient's age and developmental level, and may include the following:
      i. Patient Interview
      ii. Chart Review
      iii. Evaluation of:

Activities of Daily Living
Functional Range of Motion
Functional strength
Coordination
Sensation
Perceptual motor planning
Edema
Pain
Feeding (NICU/infants)
Ergonomics and body mechanics
Hand function
Functional ADL equipment or splinting needs

2. Occupational Therapy Reassessment
   a. Reassessments are performed whenever there is a change in the patient's status or diagnosis and to review the effectiveness of the treatment plan.
   b. Information for reassessment will be gathered from patients, families, other healthcare professionals, and physician input. Reassessment documentation will be located in the therapy progress notes.
   c. Reassessments are performed by a registered Occupational Therapist.
   d. Scope of reassessments include at a minimum:
      i. Current functional level.
      ii. Progress toward rehabilitation goals.
      iii. Effectiveness of treatment interventions and revisions/additions needed in the patient care plan to address the patient's rehabilitation goals.
      iv. All problems identified in the assessment.
      v. New problems or goals.

V. REFERENCES

American Occupational Therapy Association Practice Guidelines

VI. STAKEHOLDERS

Occupational Therapists

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Assessment/Reassessment, Physical Therapy	Policy #	REHAB0002
Responsible	Director of Rehab Services	Revised/Reviewed	~~09/3/2020~~05/24/2023

I. PURPOSE

To define patient assessment and reassessment parameters, a process to prioritize patient care, and criteria that are utilized during the assessment process by Physical Therapists. The assessment process is vital for establishing proper plans of care for the individual patient receiving Physical Therapy services.

II. POLICY

1. All patients receiving inpatient or outpatient Physical Therapy services at WCH will receive an initial assessment that takes into account their immediate and emerging needs. The data gathered will be analyzed to create information needed for care decisions concerning any need for further assessments, treatment, interventions, and reassessments.
2. Each admitted patient's initial assessment is conducted within a time frame identified by the service and/or patient care needs. Reassessment occurs throughout the care process and includes the reason for reassessment, key reassessment points and/or time intervals are defined.
3. Assessments are performed within the Physical Therapy scope of practice, state licensure laws, applicable federal/state regulations and laws, or certification.
4. Plans of care will be based upon the patient and upon data and information gathered in assessments and reassessments. This data will be utilized in prioritizing patient care needs and selecting appropriate interventions.
5. Prioritizing patient care will occur as follows:
   a. Emergent needs
   b. Actual needs
   c. Education needs
   d. Potential needs

III. DEFINITIONS

1. Assessment – The systemic collection and analysis of patient specific data necessary to determine patient care needs and treatment interventions, the scope of which is determined by the patient's diagnosis, the care setting, the patient's desire for care, and the patient's response to any previous care.
2. Reassessment - Further data collection and analysis, the scope of which is determined by the patient's diagnosis, the care setting, patient's status and care needs, the patient's desire for treatment, and the patient's response to care, treatment or services. Reassessment is ongoing and occurs when there are significant changes in the patient's status, condition, or diagnosis. Reassessment determines treatment progress and if changes in treatment are indicated.

IV. PROCEDURE

1. Physical Therapy Initial Assessment
   a. Patients will be assessed by a Physical Therapist (PT) withing 24 hours of receipt of physician order (inpatient) and scheduled withing 4 days of receipt of physician referral/authorization (outpatient). The scope of the assessment and tests administered will vary based on the diagnosis or problem and the patient's age and developmental level, and may include the following:
      i. Patient Interview
      ii. Chart Review

iii. Evaluation of:

Range of motion
Strength
Coordination
Sensation
Edema
Pain
Ergonomics and body mechanics
Developmental age
Functional mobility
Gait
Posture
Motor control
Reflexes
Balance Endurance
Wound/Skin condition
Mobility equipment and other equipment needs

2. Physical Therapy Reassessment
   a. Reassessments are performed whenever there is a change in the patient's status or diagnosis and to review the effectiveness of the treatment plan.
   b. Information for reassessment will be gathered from patients, families, other healthcare professionals, and physician input. Reassessment documentation will be located in the therapy progress notes.
   c. Reassessments are performed by a licensed Physical Therapist. Physical Therapy Assistants (PTA) may record current functional level, vital signs, range of motion, objective data on standardized tests, subjective pain scale rating, and progress toward established rehabilitation goals. The PTA reports to the licensed therapist any patient not making progress toward their rehabilitation goals for the therapist to reassess the treatment plan.
   d. Scope of reassessments include at a minimum:
      i. Current functional level.
      ii. Progress toward rehabilitation goals.
      iii. Effectiveness of treatment interventions and revisions/additions needed in the patient care plan to address the patient's rehabilitation goals.
      iv. All problems identified in the assessment.
      v. New problems or goals.

V. REFERENCES

American Physical Therapy Association Practice Guidelines

VI. STAKEHOLDERS

Physical Therapists

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Assessment/Reassessment, Rehab	Policy #	REHAB0003
Responsible	Director of Rehab Services	Revised/Reviewed	~~09/3/2020~~05/24/2023

I. PURPOSE

To define patient assessment and reassessment parameters, a process to prioritize patient care, and criteria that are utilized during the assessment process by Occupational, Physical or Speech Therapists. The assessment process is vital for establishing proper plans of care for the individual patient receiving Occupational Therapy services.

II. POLICY

1. All patients receiving inpatient or outpatient Rehab services at WCH will receive an initial assessment that takes into account their immediate and emerging needs. The data gathered will be analyzed to create information needed for care decisions concerning any need for further assessments, treatment, interventions, and reassessments.
2. Each admitted patient's initial assessment is conducted within a time frame identified by the service and/or patient care needs. Reassessment occurs throughout the care process and includes the reason for reassessment, key reassessment points and/or time intervals are defined.
3. Assessments are performed within the Therapist's scope of practice, state licensure laws, applicable federal/state regulations and laws, or certification.
4. Plans of care will be based upon the patient and upon data and information gathered in assessments and reassessments. This data will be utilized in prioritizing patient care needs and selecting appropriate interventions.
5. Prioritizing patient care will occur as follows:
   a. Emergent needs
   b. Actual needs
   c. Education needs
   d. Potential needs

III. DEFINITIONS

1. Assessment – The systemic collection and analysis of patient specific data necessary to determine patient care needs and treatment interventions, the scope of which is determined by the patient's diagnosis, the care setting, the patient's desire for care, and the patient's response to any previous care.
2. Reassessment - Further data collection and analysis, the scope of which is determined by the patient's diagnosis, the care setting, patient's status and care needs, the patient's desire for treatment, and the patient's response to care, treatment or services. Reassessment is ongoing and occurs when there are significant changes in the patient's status, condition, or diagnosis. Reassessment determines treatment progress and if changes in treatment are indicated.

IV. PROCEDURE

1. General
   a. Regardless of the point of entry into the hospital for treatment (inpatient or outpatient), an initial assessment will be done. The initial assessment will include at a minimum the following:
      i. Verification of the patient using 2 identifiers
      ii. Presence of an advanced directive
      iii. Screening for potential abuse or neglect
      iv. Nutritional/Hydration Screen
      v. Smoking status of all patients 13 years and older will be evaluated

vi. Functional Screen
vii. Pain Assessment
viii. Educational Needs and Readiness/Ability to learn
ix. TB Screen
x. Allergies
xi. Medications
xii. Pertinent Medical History
xiii. Psychosocial Screen
xiv. Discharge Needs

b. In outpatient settings, patients will complete a health history form to provide the information, which is then reviewed with the patient by the therapist.
c. The scope and intensity of further assessment will be determined by:
   i. Patient diagnosis/care needs and condition
   ii. Care setting
   iii. Patient's past/present response to treatments, procedures, and interventions
   iv. Scope of assessment identified by the service being received
d. Age specific assessment will include the appropriate data collection based on the patient's age and development, physical and psychosocial needs and desires, and the specialty completing the assessment.
e. Neonates/Infants/Toddlers:
   i. Emotional, cognitive, communication, social and daily activity needs
   ii. Family's expectation for, and involvement in, the care and treatment of the neonate/infant/toddler.
   iii. Gestational/Developmental age, length, weight, and head circumference (under 2 years of age and older toddler with head trauma or an appropriate diagnosis i.e. meningitis)
   iv. Effect of the family or guardian on the neonate/infant/toddler's condition and the effect of the neonate/infant/toddler's condition on the family or guardian.
   v. Educational needs of the family or guardian.
f. Pre-School/School Age Child
   i. Emotional, cognitive, communication, social, education (school) and daily activity needs.
   ii. Family's expectation for involvement in the care and treatment of the child.
   iii. Developmental age, length or height, weight, and head circumference (children with head trauma or an appropriate diagnosis i.e. meningitis).
   iv. Effect of the family or guardian on the child's condition and the effect of the child's condition on the family or guardian.
   v. Educational needs of the child and family or guardian.
g. Adolescent
   i. Emotional, cognitive, communication, social, educational (school) and daily needs.
   ii. Family's expectations for and involvement in the care and treatment of the adolescent.
   iii. Developmental age, height, and weight.
   iv. Effect of the family or guardian on the adolescent's condition and the effect of the adolescent's condition on the family or guardian.
   v. Educational needs of the adolescent and the family or guardian.
   vi. High risk behaviors – sexual activity, substance abuse.
h. Older Adult/Elderly Adult
   i. Emotional, cognitive, communication, social, and daily needs.
   ii. Family's expectations for and involvement in the care and treatment of the older/elderly adult.
   iii. Educational needs of the patient and the family or caregiver.
   iv. All patients 65 years and older will be asked about Advanced Directive status and documentation.

2. Assessment of Functional Status
   a. Each patient who is referred to Rehab in the inpatient or the outpatient will be assessed for his/her functional status at the time of the initial evaluation.
      i. Difficulty with independently getting out of bed and walking and difficulty independently getting out of chairs, toilet, car or difficulty with age-appropriate mobility skills.

ii. Difficulty with independently performing self-care (dressing, grooming, bathing, toileting) or difficulty with age-appropriate ADL's.
iii. Difficulty with swallowing (Dysphagia).
iv. Communication difficulties such as aphasia or apraxia (not language barrier, intubation, or dementia).
v. Also asked are the Level of Assist needed, whether it is a new or worsening problem or related to the reason for admission or unaddressed prior to admission. NICU patients with needs are identified during daily rounds, and weekly multidisciplinary rounds. Affirmative answers to these criteria will trigger a rehab therapist evaluation.

b. A Physical Therapist, Occupational Therapist, or Speech Language Pathologist will further evaluate all patients identified by nursing or ancillary departments as having potential functional needs. The inpatient evaluation by PT and Dysphagia will be initiated within 1 day of the patient being identified and the inpatient evaluation by OT and Speech will be initiated within 2 days of the patient being identified. NICU patients are assessed within 2 days of being identified. The outpatient assessment will be performed as part of the initial evaluation following receipt of a physician order. Evaluation consists of a review of the electronic Medical Record (H&P, nurse assessment and notes). As necessary, the therapist may communicate with the nurse and/or the patient/family in order to determine recommendations.
c. Referral to Rehabilitation Services (Physical Therapy, Occupational Therapy, or Speech Language Pathology) for an assessment is appropriate at any time during an admission when a new onset of a neuromuscular, cardiovascular, musculoskeletal, or integumentary disorder appears to have limited the person's ability to function. This would be accomplished by entering a request for evaluation on MedHost. Functional impairments may evidence themselves as:
    i. Difficulty/inability to swallow or drink safely (cough, choking, drooling of liquid or solid, food/liquid in mouth after swallow initiated).
    ii. Difficulty/loss of mobility (bed mobility/sitting up, transfers in/out of bed, sitting/standing, balance, walking, and wheelchair mobility).
    iii. Difficulty/loss of self-care skills (eating, bathing, grooming/oral hygiene, dressing, household skills).
    iv. Decreased cognitive functioning (long term/short term memory, judgment, thinking skills, unsafe or inappropriate behavior).
    v. Impaired communication (formation of sounds/words, phrases, accurately responds to simple questions, commands or concepts, attention, receptive/expressive responses, ability to speak and understand clearly).
    vi. Developmental delay in newborns or infants or children.
d. The therapist(s) will document in the medical record that the functional evaluation was completed and the findings/recommendations.

V. REFERENCES

American Occupational Therapy Association Practice Guidelines; American Physical Therapy Association Practice Guidelines; Association of Speech Language Pathology Practice Guidelines

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Physical Therapy Assistants, Speech Therapists

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Patient Charges	Policy #	REHAB0467
Responsible	Director of Rehab Services	Revised/Reviewed	~~03/30/2022~~05/24/2023

I. PURPOSE

To establish guidelines for the charging of services for the Rehabilitation Department at WCH.

II. POLICY

Each patient will be charged for treatment rendered on a daily basis by the Rehabilitation Department at WCH. All procedures performed during a patient's visit will be documented properly in the patient's medical record as per regulatory guidelines. If any employee is found to have charged for improper or unreasonable treatment, medically unnecessary treatment or for treatment procedures that were not provided, the employee is subject to progressive disciplinary actions as per hospital policy.

III. DEFINITIONS

NA

IV. PROCEDURE

1. It is the ultimate responsibility of each employee to ensure the accuracy and correctness of the charge for each patient at the end of the day. The Director of Rehabilitation is responsible for the overall accuracy of all charges submitted by the rehabilitation department.
2. Each day's charges will be reviewed by the responsible clinician and the Director of Rehabilitation or his/her designee as part of the internal auditing process. Only hospital approved standard uniform codes and abbreviations will be used in the billing process. Any discrepancies found will be corrected, if possible, prior to the charges being submitted. Charges submitted must be supported by documentation for those services rendered.
3. Questions from patients regarding the cost of procedures will be directed to the Director of Rehabilitation and to the business office for explanation, if necessary. Questions regarding the accuracy of billing will be referred to the Director of Rehabilitation for resolution. If necessary, an investigation will be conducted, and the findings submitted in writing to the Director of Rehabilitation and/or hospital business office manager. Any missed charges, additions or deletions will be submitted promptly either to IS on batch control log forms or through batch charge entry if within 3 days of service date.

V. REFERENCES

WCH Business Office policies

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Physical Therapy Assistants, Speech Therapists, Schedulers

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Communication with Patient / Family	Policy #	REHAB1730
Responsible	Director of Rehabilitation Services	Revised/Reviewed	03/27/2023

I. PURPOSE

To establish guidelines and protocol for the rehabilitation department at WCH in communicating with patients and/or their families.

II. POLICY

The rehabilitation department staff will maintain communication with the patient regarding the rehabilitation process and will obtain patient input in setting goals and the development of the treatment plan. If the patient is unable to participate in this process, the therapist will communicate with the appropriate family members, case management or appropriate significant others/caregivers.

III. DEFINITIONS

NA

IV. PROCEDURE

1. Evaluation Process:
    - **a.** The therapist will inform the patient of the evaluation procedures and tests needed to address the problem and obtain expected outcomes for their therapy.
    - **b.** During the evaluation process the patient will be involved in the development of goals and the expected plan of care to achieve these goals.
    - **c.** The outpatient department will require a consent for treatment and will inform patients that the results of the evaluation will be sent to their physician for approval.
    - **d.** The treatment plan may also be provided to the referral and/or funding source for approval prior to the initiation of treatment.
2. Treatment Process:
    - a. Once treatment is initiated, the patient is educated about their condition, the expected treatment outcome, their responsibility for active participation in the rehabilitation process, and the probable duration of treatment.
    - b. Throughout the treatment process, the patient will be advised of any possible side effects of the treatment and/or any changes in the plan of care.
3. Discharge Planning:
    - a. The patient is involved in the discharge planning process including post discharge referral(s) to other services and the obtaining of necessary equipment.
    - b. Prior to discharge, when appropriate, the therapist may discuss the following with the patient:
        - i. The patient's condition prior to discharge and any functional limitations.
        - ii. Individualized home instructions that may be given in writing to the patient and family.
        - iii. The type and provider of follow-up care.
        - iv. Equipment, if applicable, with instructions given for proper use.

V. REFERENCES

APTA and AOTA Practice Acts

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Physical Therapy Assistants, Speech Therapists

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Therapeutic Exercises and Other Interventions	Policy #	REHAB1753
Responsible	Director of Rehabilitation Services	Revised/Reviewed	~~03/30/2022~~05/24/2023

I. PURPOSE

To provide a set of guidelines that will be followed during the application of various treatment interventions with physical and occupational therapy patients by WCH Rehabilitation Department.

II. POLICY

Standard guidelines will be followed for the application of therapeutic intervention techniques with patients receiving care from WCH's Rehabilitation Department.

III. DEFINITIONS

Therapeutic exercise is the scientific application of activities to maintain or restore function for persons who have some type of illness or injury that has impaired function.

IV. PROCEDURE

1. Therapeutic exercises will vary and be dependent upon the condition of the patient, the diagnosis, and the specific need. Careful considerations will be given to the types of exercises ordered depending on the established goals.
    a. Therapeutic exercises may include, but are not limited to, the following:
        i. Active, passive, isometric, and resistive range of motion exercise to increase strength, range of motion and overall tolerance to activity.
        ii. Active assistive exercises allow the patient to move through a range of motion that would be unattainable with active exercises.
        iii. Passive exercises with the therapist performing the movement while the patient remains relaxed.
        iv. Isometric exercise is a form of active exercise where the muscle or muscle group is actively contracted and relaxed without production of movement.
        v. Active resistive exercise is utilized when the patient can perform full active range of motion without assist.
        vi. Progressive resistive exercise assists the individual in gaining strength and overall tolerance to activity.
        vii. Neuromuscular re-education involves the inhibition of abnormal movements and the facilitation of normal sensory-motor movement utilizing postural and sensory integration with motor activity.

2. Gait training and functional mobility activities will be utilized to assist the individual with increasing their ability to safely perform mobility activities in a variety of settings. These activities may include, but are not limited to, the following:
    i. Ambulation: Home, community and recreational.
    ii. Transfer training.
    iii. Bed Mobility.
    iv. Balance: Standing and sitting both dynamic and static.
    v. Work, sport and/or ADL simulation as appropriate.

V. REFERENCES

American Physical and Occupational Therapy Practice Act Guidelines

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Physical Therapy Assistants

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Referral Guidelines	Policy #	REHAB1918
Responsible	Director of Rehabilitation Services	Revised/Reviewed	03/27/2023

I. PURPOSE

To provide guidelines for handling patient referrals to Rehabilitation Services.

II. POLICY

Rehabilitation Services are initiated only upon the receipt of an order from a physician, dentist, podiatrist, or chiropractor unless direct access is allowed by state law. Inpatients are assessed per policy within 24 hours if possible, for physical, speech and occupational therapies. Outpatients are scheduled, if possible, within 72 hours of the referral and completion of all required authorizations.

III. DEFINITIONS

NA

IV. PROCEDURE

1. Inpatient orders should contain:
    a. Date
    b. Time
    c. Patient's Name
    d. Rehabilitation Diagnosis/Admitting Diagnosis
    e. Any Precautions/Contraindications
    f. Referring/Admitting Physician
    g. Discipline
2. Outpatient prescription/orders must contain:
    a. Date
    b. Patient's Name
    c. Diagnosis/Treatment Diagnosis
    d. Desired Intervention, i.e. Evaluation, Evaluate and Treat, and/or Specific Treatment
    e. Discipline
    f. Physician Signature
3. The therapist will evaluate the patient and consult with the referring physician to develop an appropriate treatment plan and goals as indicated. If the physician has ordered a specific protocol, it will be followed. If changes are sought by the treating therapist following evaluation of the patient, the physician will be contacted to approve desired changes in treatment plan/interventions.
4. Request For Inpatient Services: Physician's orders for Physical Therapy, Occupational Therapy, and Speech/ Language Pathology services are written in the patient's medical record, then entered into the hospital computer by Nursing services. If computer capability is unavailable, Nursing services may verbally notify department of an existing order or may complete a written request and send or Fax the order information to the Rehabilitation Department.
5. Request for Outpatient Services: Written Outpatient orders are acceptable on therapy order forms, prescription forms or other forms signed by the referring physician. Therapy order forms are usually available at physician's offices, or the physician's prescription form may be used. Electronic signatures are also accepted on orders that are sent electronically to the outpatient rehab department for those physicians who are on the hospital electronic signature allowance list.

6. Verbal Orders: Verbal orders for inpatients are recorded as such in the medical record on the physician order sheet in accordance with hospital policy for the handling of verbal orders. Verbal orders are accepted from physicians or his designee only. Verbal orders for physical, occupational therapy and/or speech language pathology may be taken by a registered nurse or licensed therapist. The order will be signed by the physician in accordance with hospital policy.

V. REFERENCES

APTA and AOTA Practice Acts

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Speech Therapists, Clinical Support Staff

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Use of Massage Cream or Other Lotions in Rehab Department	Policy #	REHAB1739
Responsible	Director of Rehabilitation Services	Revised/Reviewed	03/27/2023

I. PURPOSE

To ensure that guidelines are established for patient safety and infection control in the application of creams, lotions, or gels during treatment at WCH's Rehabilitation Department.

II. POLICY

Creams or lotions applied to patients from multiple use containers will be dispensed using a new tongue depressor for each application or may be extracted from the container by the therapist wearing gloves.

III. DEFINITIONS

Massage Creams, Lotions: Massage cream acts as a lubricant, aiding the therapist's hand to glide with less effort and friction over the patient's skin.

IV. PROCEDURE

1. The therapist applying cream or lotion to a patient from a multiple use container will extract lotion or cream using newly donned gloves or with a newly opened tongue depressor. Bare hands will never be used secondary to infection control risks.
2. This will not apply to substances used from a multiple use container such as ultrasound gel as the container does not come in contact with the patient and the substance is dispensed from a squeezed container.

3. REFERENCES

Infection Control Guidelines

4. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Physical Therapy Assistants, Rehab Technicians

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Myofascial Release/Soft Tissue Mobilization	Policy #	REHAB2043
Responsible	Director of Rehabilitation Services	Revised/Reviewed	03/21/2023

I. PURPOSE

To ensure standardized quality care that is safe and appropriate and reflects the needs and interests of the individuals served.

II. POLICY

Myofascial Release and Soft Tissue Mobilization (MFR/STM) are terms used interchangeably to describe the same basic procedure. The procedure employs techniques that improve or restore the natural integrity of soft tissues that have been damaged by acute or chronic injury. These injuries may have resulted in scarring, fibrosis, adhesions, and other inflammatory effects that limit mobility and/or cause pain, all of which potentially benefit from MFR/STM.

1. Indications:
   a. Soft tissue injuries causing acute or chronic pain.
   b. Injuries causing functional loss to support structures such as muscle, tendon, ligament, nervous tissue, and fascia.

✷ ***Caution should be used when considering myofascial release for patients having the following conditions: clotting disorders, connective tissue disorders, advanced age or debility, and chronic steroid therapy.***

2. Goals of treatment: To restore function and reduce pain.

III. DEFINITIONS

Myofascial Release and Soft Tissue Mobilization (MFR/STM): manual therapy techniques that improve or restore the natural integrity of soft tissues (muscle, tendon, ligament) that have been damaged by acute or chronic injury. A type of gentle, constant massage that releases tightness and pain throughout myofascial tissues.

IV. PROCEDURE

1. Preparation of patient:
   a. Inform patient and obtain consent for procedure. Information provided to the patient should include a clear description of the technique that will be used, along with the expected benefits and possible adverse effects.
   b. Patient is placed in position of comfort and in the optimal situation for application of procedure.
2. Select the appropriate technique(s), including but not limited to:
   a. Trans-friction massage
   b. Kneading
   c. Stretching (Passive ROM)
   d. Strain/Counterstrain
   e. Trigger point pressure application
   f. Connective tissue massage
   g. Manual lymphatic drainage
   h. Percussion
3. Apply the appropriate topical agent if needed. Massage cream should be dispensed from the container with a tongue depressor, not with the fingers, to avoid contamination.

4. Reexamination and reevaluation:
    a. The therapist reexamines and reevaluates the patient's response to the procedure continually and modifies or discontinues the procedure accordingly.
    b. Both subjective and objective responses should be assessed.
    c. The patient may be educated on the possible residual discomfort which may follow MFR/STM and which is a normal expectation after such a procedure. This may include latent soreness, possible mild bruising, local redness, and skin reactions to topical agents used.
    d. Instruction provided may also cover use of the procedure at home.
5. Documentation:
    a. Manual Therapy/MFR/STM will be documented under treatment procedures and will be included in the Plan of Care.
    b. The type, body area and duration of treatment will be documented in the daily note.

V. REFERENCES

APTA Orthopaedic Clinical Practice Guidelines

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Physical Therapy Assistants

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Biofeedback in Rehab Services	Policy #	REHAB2652
Responsible	Director of Rehabilitation Services	Revised/Reviewed	~~09/20/2022~~05/24/2023

I. PURPOSE

To establish guidelines for the safe and effective use of Biofeedback in Rehab Services.

II. POLICY

The portable EMG Biofeedback machine (such as MyoTrac) will be used in accordance with the manufacturers' instructions for the machine, when indicated, to provide neuromuscular re-education to patients.

III. DEFINITIONS

Electromyography (EMG) is a diagnostic procedure to assess the health of muscles and the nerve cells that control them (motor neurons).

Biofeedback is a technique you can use to learn to control some of your body's functions, such as your heart rate. During biofeedback, you're connected to electrical sensors that help you receive information about your body.

IV. PROCEDURE

Procedure details

1. Following the instructions for use in the instruction manual, apply the electrodes attached to the unit to the specific treatment area of the patient in order to facilitate biofeedback, muscle relaxation or muscle re-education.
2. Adjust the sound volume, threshold level, gain setting and power level as appropriate to obtain the required response.
3. After use, clean all surfaces that come into contact with the patient's skin by wiping with a damp cloth.
4. The treatment will be documented as neuromuscular re-education (CPT code 97112), and the patient's response to treatment will be documented as indicated in the medical record.

V. REFERENCES

MyoTrac instruction manual

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Physical Therapy Assistants

{{Watsonville Community Hospital	**Designated Person for Sterile Compounding**
Policy Number/ Version:	797- 2022 version
Policy Start Date:	Initial policy version/implementation

HOW TO USE THIS DOCUMENT (remove this tool tip after adapting to your facility)

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

1. Overview and Scope

1.1 This policy describes the primary roles and responsibilities for the Designated Person(s) (DP) responsible for the oversite of sterile compounding processes and compliance where Compounded Sterile Preparations (CSP) are prepared within Watsonville Community Hospital.

2. Policy

2.1. [USP 797] Watsonville Community Hospital will designate one or more individuals (i.e., the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and all other functions pertaining to CSPs.

2.2. The DP for CSPs will have the following qualifications:

- Completion of CE hours in the area of compounding
- Recommended 3 years of experience preparing CSPs}}

3. Roles & Responsibilities

3.1 [USP 797] The Designated Person(s) for sterile compounding is the Director of Pharmacy.

3.2. [USP 797] The DP(s) is responsible for:

- Overall compliance with USP <797>, applicable federal and state laws and regulations and accreditation standards.
- Oversight of personnel training and competency for those involved in sterile compounding and handling and preparing CSPs
- Selection of components
- Monitoring and observing sterile compounding activities and taking immediate corrective action if deficient practices are observed.
- Ensuring standard operating procedures (SOPs) and/or policies are fully implemented, and that follow-up is carried out if problems, deviations, or errors are identified.

- Establishing, monitoring, and documenting procedures for the handling and storage of CSPs and/or components of CSPs.

3.3. Pharmacy Management is responsible for:

- Ensuring adequate personnel resources for training and adherence to Watsonville Community Hospital's Sterile Compounding procedures,
- Ensuring adequate equipment and facilities to comply with USP <797> standards,
- Coordinating with the Designated Person for Sterile Compounding for local site implementation, monitoring, or concerns.

4. Procedures

4.1 Training and Evaluation:

- [USP 797] The DP creates, implements, and oversees training of all compounders, personnel who have direct oversight of compounders, and personnel who perform restocking or cleaning and disinfection duties. The DP ensures that all persons who enter the sterile compounding area and/or handles CSPs complete training and demonstrate competency in maintaining the quality of the sterile compounding environment.
- [USP 797] The DP performs all training and observation associated with CSPs and/or designates an assigned trainer to complete these functions.

4.2 Personal Hygiene and Garbing:

- [USP 797] The DP evaluates if individuals with certain conditions should be excluded from the sterile compounding environment. Conditions that have a higher risk of contaminating the CSP and the environment are personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.
- [USP 797] The DP may permit individual personnel accommodations to hand hygiene and garbing as long as the quality of the CSP and the environment will not be affected; and will document accommodations as defined in the **Hand Hygiene and Garbing policy.**

4.3 Facility Design and Environmental Control:

- [USP 797] The DP ensures that each area where CSPs are prepared meets the classified air quality standard appropriate for the activities conducted in that area.
- [USP 797] The DP ensures that International Organization for Standardization (ISO) Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality.
- [USP 797] The DP determines the dynamic operating conditions for the sterile compounding environment. The dynamic operating conditions are reproduced during dynamic room certification testing.
    - Dynamic operating conditions are the conditions in the sterile compounding area in which personnel are present and simulating or performing sterile compounding. These conditions will reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the DP.

- [USP 797] The DP identifies and addresses other areas of risk related to placement and movement of materials within the compounding area to ensure the quality of the CSP and the environment will not be affected.

4.4 Certification and Recertification:

- [USP 797] The DP reviews all certification and recertification records to ensure that the classified environments meet the minimum requirements outlined in USP <797>.

4.5 Components:

- [USP 797] The DP assesses and selects acceptable and reliable sources if a component used in the compounding of CSPs cannot be obtained from a Food and Drug Administration (FDA)-registered facility.

4.6 Standard Operating Procedures (SOP)s:

- [USP 797] The DP ensures that SOPs are appropriate and are implemented, which includes ensuring that personnel demonstrate competency in performing every procedure that relates to their job function.
- [USP 797] The DP ensures that corrective actions are taken if problems, deviations, failures, or errors are identified, and documents corrective actions as necessary.
- [USP 797] The DP reviews SOPs at least every 12 months to ensure that they reflect current practices. The review is documented by DP.
- [USP 797] Any changes or alterations to an SOP are made only by a DP and must be documented.

4.7 Quality Assurance and Quality Control:

- [USP 797] The DP ensures that Watsonville Community Hospital has a formal, written Quality Assurance (QA) and Quality Control (QC) program.
- [USP 797] The written QA and QC program establishes a system of:
  - Adherence to procedures
  - Prevention and detection of errors and other quality problems
  - Evaluation of complaints and adverse events
  - Appropriate investigations and corrective action
- [USP 797] The DP reviews the overall QA and QC program once every 12 months and the results of the review are documented and appropriate action taken if necessary.

4.8 Complaint Handling:

- [USP 797] The DP reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.

4.9 Handling and storing CSPs:

- [USP 797] If there is a known excursion to temperatures either below or above the storage temperature limits for the CSP, the DP determines (e.g., by consulting literature or analytical testing) whether the CSP is expected to retain its integrity or quality. If this cannot be determined, the CSP is discarded.

4.10 Allergen Extracts:

- [USP 797] The DP (with training and expertise in allergen immunotherapy) ensures that the personnel who prepare allergenic extract prescription sets are trained, evaluated, and supervised.

5. Definitions

5.1 **Designated Person (DP)**: One or more individuals assigned to be responsible and accountable for the performance and operation of the compounding facility and personnel in the preparation of CSPs.

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

6. Related Policies, Documents, References

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

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Designated Person for Sterile Compounding	Policy #	PHARM797
Responsible	Pharmacy Director	Revised/Reviewed	06/2023

I. PURPOSE

This policy describes the primary roles and responsibilities for the Designated Person(s) (DP) responsible for the oversite of sterile compounding processes and compliance where Compounded Sterile Preparations (CSP) are prepared within Watsonville Community Hospital.

II. POLICY

1. Watsonville Community Hospital will designate one or more individuals (i.e., the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and all other functions pertaining to CSPs.
2. The DP for CSPs will have the following qualifications:
   - Completion of CE hours in the area of compounding
   - Recommended 3 years of experience preparing CSPs

III. DEFINITIONS

1. **Designated Person (DP):** One or more individuals assigned to be responsible and accountable for the performance and operation of the compounding facility and personnel in the preparation of CSPs.

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

IV. ROLES & RESPONSIBILITIES

1. The Designated Person(s) for sterile compounding is the Director of Pharmacy.
2. The DP(s) is responsible for:
   - Overall compliance with USP <797>, applicable federal and state laws and regulations and accreditation standards.
   - Oversight of personnel training and competency for those involved in sterile compounding and handling and preparing CSPs
   - Selection of components
   - Monitoring and observing sterile compounding activities and taking immediate corrective action if deficient practices are observed.
   - Ensuring standard operating procedures (SOPs) and/or policies are fully implemented, and that follow-up is carried out if problems, deviations, or errors are identified.
   - Establishing, monitoring, and documenting procedures for the handling and storage of CSPs and/or components of CSPs.

3. Pharmacy Management is responsible for:
    - Ensuring adequate personnel resources for training and adherence to Watsonville Community Hospital's Sterile Compounding procedures,
    - Ensuring adequate equipment and facilities to comply with USP <797> standards,
    - Coordinating with the Designated Person for Sterile Compounding for local site implementation, monitoring, or concerns.

V. PROCEDURE

1. Training and Evaluation:
    - The DP creates, implements, and oversees training of all compounders, personnel who have direct oversight of compounders, and personnel who perform restocking or cleaning and disinfection duties. The DP ensures that all persons who enter the sterile compounding area and/or handles CSPs complete training and demonstrate competency in maintaining the quality of the sterile compounding environment.
    - The DP performs all training and observation associated with CSPs and/or designates an assigned trainer to complete these functions.

2. Personal Hygiene and Garbing:
    - The DP evaluates if individuals with certain conditions should be excluded from the sterile compounding environment. Conditions that have a higher risk of contaminating the CSP and the environment are personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.
    - The DP may permit individual personnel accommodations to hand hygiene and garbing as long as the quality of the CSP and the environment will not be affected; and will document accommodations as defined in the **Hand Hygiene and Garbing policy**.

3. Facility Design and Environmental Control:
    - The DP ensures that each area where CSPs are prepared meets the classified air quality standard appropriate for the activities conducted in that area.
    - The DP ensures that International Organization for Standardization (ISO) Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality.
    - The DP determines the dynamic operating conditions for the sterile compounding environment. The dynamic operating conditions are reproduced during dynamic room certification testing.
        - Dynamic operating conditions are the conditions in the sterile compounding area in which personnel are present and simulating or performing sterile compounding. These conditions will reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the DP.
    - The DP identifies and addresses other areas of risk related to placement and movement of materials within the compounding area to ensure the quality of the CSP and the environment will not be affected.

4. Certification and Recertification:
    - The DP reviews all certification and recertification records to ensure that the classified environments meet the minimum requirements outlined in USP <797>.

5. Components:

- The DP assesses and selects acceptable and reliable sources if a component used in the compounding of CSPs cannot be obtained from a Food and Drug Administration (FDA)-registered facility.

6. Standard Operating Procedures (SOP)s:
   - The DP ensures that SOPs are appropriate and are implemented, which includes ensuring that personnel demonstrate competency in performing every procedure that relates to their job function.
   - The DP ensures that corrective actions are taken if problems, deviations, failures, or errors are identified, and documents corrective actions as necessary.
   - The DP reviews SOPs at least every 12 months to ensure that they reflect current practices. The review is documented by DP.
   - Any changes or alterations to an SOP are made only by a DP and must be documented.

7. Quality Assurance and Quality Control:
   - The DP ensures that Watsonville Community Hospital has a formal, written Quality Assurance (QA) and Quality Control (QC) program.
   - The written QA and QC program establishes a system of:
     - Adherence to procedures
     - Prevention and detection of errors and other quality problems
     - Evaluation of complaints and adverse events
     - Appropriate investigations and corrective action
   - The DP reviews the overall QA and QC program once every 12 months and the results of the review are documented and appropriate action taken if necessary.

8. Complaint Handling:
   - The DP reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.

9. Handling and storing CSPs:
   - If there is a known excursion to temperatures either below or above the storage temperature limits for the CSP, the DP determines (e.g., by consulting literature or analytical testing) whether the CSP is expected to retain its integrity or quality. If this cannot be determined, the CSP is discarded.

10. Allergen Extracts:
    - The DP (with training and expertise in allergen immunotherapy) ensures that the personnel who prepare allergenic extract prescription sets are trained, evaluated, and supervised.

VI. REFERENCES

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

VII. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Controlled Substance Audit Plan (reviewed 7/5/2023)

Overview:

To comply with Policy #2003: *Controlled Substances: Audits,* a written plan must be developed and implemented by the Director of Pharmacy in cooperation with other departments such as Quality and Nursing that details the criteria and selection methodology for monitoring all aspects of controlled substance use within the facility.

The ordering, prescribing, dispensing, administration, and waste of controlled substances and additional selected drugs listed in Policy #2705, *Controlled Substances: Drugs Requiring Inventory Accountability in Acute Care* Facilities should be audited to ensure compliance with federal, state, and local statutes as well as The Joint Commission Standards.

Every department within the facility that dispenses or administers controlled substances must be audited, at a minimum, every 12 months. Audits should include records from all shifts.

This plan shall be approved by Administration, Pharmacy and Therapeutics Committee, Medical Executive Committee, and Board of Trustees.

Reporting:

Results shall be reported to the Pharmacy and Therapeutics Committee, Medical Executive Committee, and Board of Trustees, as well as the facility CEO for review and follow-up action as necessary.

Plan of Action:

A. Patient Care Areas:

1. Controlled substance audits in patient care areas will be conducted by Pharmacy, Nursing, and/or other designated departments and will cover all areas of controlled substance usage over the course of twelve months.
2. Results will be reviewed by the Director of Pharmacy and reported to the Pharmacy and Therapeutics Committee.
3. Patient care area audits shall include the following:
    1) Validate prescriber orders for controlled substances and additional selected drugs.
    2) Reconciliation of patient Medication Administration Records (MAR) and nurses' notes with respect to valid prescriber orders.
    3) Patient interviews, where appropriate.
    4) Review of pharmacy distribution records, patient charges, and automated dispensing system (i.e., Pyxis) reports.
4. Drugs shall primarily be selected for audit based on high risk and high volume use.
    i. Low use items should be audited based on unusual inventory patterns or suspected inappropriate use.

B. Surgical Care Areas:

1. Controlled substance audits in peri-operative areas will be conducted by pharmacy.
2. Results will be reviewed by the Director of Pharmacy and reported to the Director of Surgery and the Pharmacy and Therapeutics Committee.
3. Controlled substances and additional selected drugs used within the surgical areas will be audited by reconciling the following:
    1) Patient anesthesia records
    2) Controlled Substance Proof-of-Use records
    3) Returned waste
    4) Patient charges

C. Pharmacy Audits:

1. Audits within the Pharmacy will be selected for audit based on high risk and high volume use.
    i. Low use items should be audited based on unusual inventory patterns or suspected inappropriate use.
2. Audits shall be performed a minimum of once quarterly.
3. Suggested audit areas include:
    1) Purchase records and invoices will be validated against current inventory records.
    2) CSOS and DEA 222 purchase and distribution documents will be reconciled.
    3) Reconcile distribution from pharmacy to patient care areas.
    4) Reconcile purchases to patient charges
    5) Waste records are reconciled against the appropriate documentation
    6) Validation technology (e.g., refractometer) is re-calibrated at least every 6 months or as recommended by the instrument manufacturer.

D. Waste:

1. Controlled substance waste from ~~nursing units and the~~ OR~~/ED~~ shall be analyzed on a random basis to include all large volume infusions and should include every anesthesia provider at least once on a quarterly basis.
2. Partial dose waste from any other patient care area may be analyzed on a random basis when justified.

E. Analysis, Trending, and Reporting of Audit Results:

1. Summary results of audits shall be provided to the Pharmacy and Therapeutics Committee.
2. Should any significant discrepancies be discovered during the auditing process at this facility, Administration should be notified immediately and reports filed following the Controlled Substances Policy #1904: *Reporting Drug Diversion including suspected theft*.
3. Loss or theft of non-controlled substances should not be reported to the DEA or other regulatory bodies ~~unless advised by Legal and/or Corporate Pharmacy Services~~until fully reviewed by Pharmacy and Administration. Exception: any controlled substance loss must be reported to California State Board of Pharmacy.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Metered Dose Inhaler Protocol	Policy #	PHARM1418
Responsible	Pharmacy Director	Revised/Reviewed	07/2023

~~Policy/Procedure Title~~	~~Metered Dose Inhaler Protocol~~	~~Manual Location~~	~~Provision of CarePharmacy~~		
~~Policy/Procedure #~~	~~1418~~	~~Effective~~	~~5/04~~	~~Page~~	~~1 of 4~~
~~Department Generating Policy~~	~~Pharmacy~~	~~Revised~~	~~6/137/2023~~		

I. PURPOSE

To provide guidelines for safe administration of medication utilizing a meter dose inhaler (MDI) and one-way valved holding chamber device (spacer).

To deliver medication via MDI in a manner that meets the clinical needs of the patient, minimizes the risk of cross-contamination, and reduces both medication waste and costs to the patient and organization.

II. POLICY

- All patients not in isolation (with the exception of the Emergency Department) and on MDI therapy will be enrolled in this protocol.
- All medication in MDI canister format will be included in this protocol, unless expressly contraindicated by the pharmaceutical manufacturer.
  - Metered dose inhalers (MDIs) will be administered to patients using a one-way valved holding chamber device.
  - Valved holding chambers may also be referred to as a one-way spacer, and will be referred to as a “spacer” in this policy.
  - These devices contain a valve that only allows unidirectional airflow through the device.
- This procedure requires the use of proper hand hygiene before and after the cleaning and disinfecting process and during medication administration.

III. DEFINITIONS

~~III.~~IV. PROCEDURE: (Nursing, Respiratory, Pharmacy)

A. MDI will be provided to the patient unit per Pharmacy via Pyxis.

~~A.~~B. When physician order for MDI therapy is received, Respiratory ~~Therapy~~ Care Practitioner (RCP~~T~~) is notified by phone and/or by computer of order.

~~B.~~C. Each patient who is to receive MDI therapy is dispensed a spacer for use in the hospital and to take home upon discharge.

1. The spacer will be labeled with patient’s information and may be kept at the patient’s bedside.

~~C.~~D. Respiratory ~~Therapist~~ Care Practitioner (RCP~~T~~), or nurse, will use appropriate technique to utilize the one-way valved holding chamber (spacer) to administer the MDI therapy and will provide instructions for use to the patient.

~~D.~~E. MDI will be kept in Pyxis MedStation, "RT Specific Bin", when not in use.

1. Exception: Emergency Department only routinely stocks Albuterol, which will be returned directly to cubie stocking Albuterol.

~~1.~~2. MDIs may not be kept at the patient's bedside.

~~E.~~F. Each patient care area where MDI therapy is provided will be stocked with at least one of each MDI ordered.

~~F.~~G. Each MDI may be used with the patient specific spacer on multiple patients, utilizing the procedures outlined in Section ~~G~~ H below.

~~G.~~H. For administration to a patient:

1. ~~RT~~ RCP or nurse shall remove the MDI from Pyxis ~~under the patient's medication profile~~:.
   a. Albuterol will be removed from Pyxis under the patient's medication profile.
      1) Albuterol will be removed as one puff more than to be administered to patient.
      2) This allows Albuterol to be returned back to cubie pocket in Pyxis.
   ~~a.~~b. All other MDI will be removed from "RT Specific Bin" as patient specific inhaler.
2. ~~RT~~ RCP or nurse will take the MDI to the patient's room.~~,~~
3. Scan the medication and verify the number of puffs to be administered.
4. W~~w~~ipe the actuator tip or MDI mouthpiece with an alcohol prep pad and allow to air dry.~~,~~ See Appendix A, Figure 1.
5. A~~a~~ttach the MDI to the patient's ~~valved holding chamber~~spacer~~, and~~. See Appendix A, Figure 2.
6. A~~a~~dminister the correct number of puffs.
~~3~~7. MDI should then be removed from the spacer.~~,~~
8. Perform hand hygiene and don a pair of clean gloves for cleaning and disinfection.
9. Wipe down the entire MDI (including valve tip and~~the~~ actuator) ~~tip or MDI mouthpiece should be re-wiped~~ with an alcohol prep pad and allow to air dry on a clean, dry surface., ~~and~~
10. Remove gloves and perform hand hygiene before leaving patient care area.
11. MDI should be returned to the appropriate site in Pyxis MedStation.

~~4~~12. The patient may not touch the MDI before, during, or following administration.

~~5~~13. This process should be repeated for subsequent patients.

~~6~~14. Patient shall be instructed to rinse mouth after use of inhaler.

~~H.~~I. MDI treatment will be documented in RT progress notes and patient's MAR.

~~I.~~J. Both RT and nurse will monitor the effectiveness of MDI treatment.

~~J.~~K. This practice allows patients to be charged for what they actually receive from the MDI versus the entire MDI.

1. The spacer may be billed as a separate item.

~~K. Patients under isolation precautions may be excluded from the individualized spacer policy.~~

L. Example~~s~~ of MDI~~'s~~ included in this policy:

1~~Aerobid® (flunisonide)~~.

Proventil HFA® ; Ventolin HFA® (albuterol)~~Atrovent® (ipratropium)~~

~~Combivent® (albuterol/ipratropFlovent® (fluticasone)~~

~~Dulera® (mometasone furoate/formeterol fumarate)~~

M. Exclusions from this policy:

1. Patients in isolation or reverse isolation will be issued dedicated MDI's, except for Emergency Department isolation patients, who will still be eligible for inhaler optimization.

~~1.~~2. Dry powder inhalers (DPI) such as:

a. Serevent Diskus® (Salmeterol)

~~b. Asmanex® (Mometasone)~~

~~c. Foradil® (Formoterol)~~

~~d.~~b. Spiriva® (Tiotropium)

~~e.~~c. Advair Diskus® (Fluticasone/salmeterol) ~~– see below for HFA conversion~~

~~2.~~3. Nasal inhalers

~~3. Asmacort® (Triamcinolone)~~

~~IV.~~V. REFERENCES

1. The Joint Commission Standard: MM.5.10

~~2. CHS Policy #: 13-10-H (10/12)~~

~~3.~~2. Sheils SG, Duncan JL, Wojciechowski WV. The common canister protocol using the Monaghan AeroChamber reveals no cross-contamination and potential cost savings. *Respiratory Care.* 2000;45(8):981.

~~4.~~3. Fluticasone Propionate/Salmeterol Xinafoate in. DRUGDEX® system [internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated Periodically.

~~V.~~VI. STAKEHOLDERS

N/A

~~**Reviewed:**~~	~~**1st**~~	~~**2nd**~~	~~**3rd**~~	~~**4th**~~	~~**5th**~~
~~Date:~~	~~11/17~~				
~~By:~~	~~J. Gavin~~				
~~**Revised:**~~	~~**1st**~~	~~**2nd**~~	~~**3rd**~~	~~**4th**~~	~~**5th**~~
~~Date:~~	~~8/10~~	~~7/2023~~			
~~By:~~	~~J.Gavin~~	~~J.Gavin~~			

APPENDIX A

Figure 1 – Metered dose inhaler

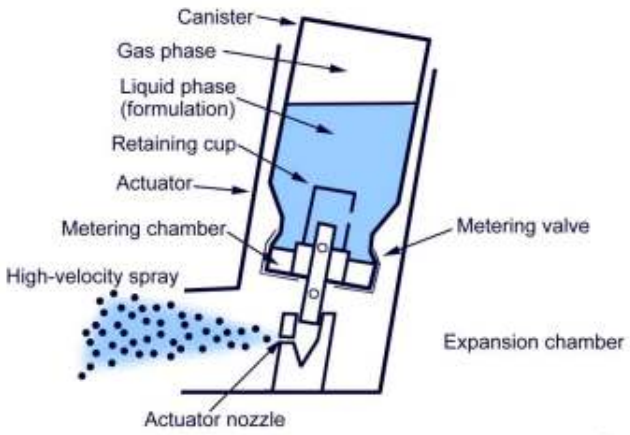
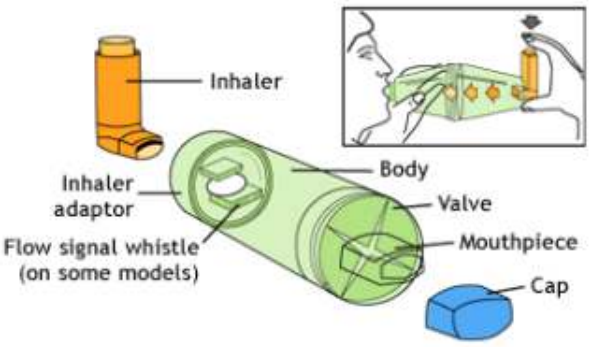


Figure 2 – Metered dose inhaler and valved-holding chamber (spacer)



WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Formulary Obtaining Non-Formulary Medications	**Policy #**	PHARM1568
Responsible	Pharmacy Director	**Revised/Reviewed**	07/2023

~~**Policy/Procedure Title**~~	~~Formulary, Obtaining Non-Formulary Medications~~	~~**Manual Location**~~	~~Provision of CarePharmacy~~		
~~**Policy/Procedure #**~~	~~1568~~	~~**Effective**~~	~~4/92~~	~~**Page**~~	~~1 of 2~~
~~**Department Generating Policy**~~	~~Pharmacy~~	~~**Revised**~~	~~11 147/2023~~		

I. PURPOSE

To provide guidelines for facility's process in managing orders for non-formulary medication.

II. POLICY:

- Non-formulary medications shall be used only after the prescriber has determined that a formulary medication is not appropriate.
- A prescriber shall NOT use medications that the Medical Staff has specifically prohibited from use in this facility.

III. DEFINITIONS

N/A

IV. PROCEDURE:

A. Review by a Pharmacist:

1. A pharmacist shall review requests for non-formulary medications.
   a. Refer to policy #1567: *Formulary System (and Therapeutic Substitutions),* Attachment A: Request for Formulary Review
2. Patient may use own medication after validation by pharmacist. See policy #1577:*Patient Own Medication / Drugs*.

~~3~~2. If the pharmacist believes that there is an appropriate alternative medication on the formulary, the pharmacist shall inform the prescriber.

~~4~~3. A request for a non-formulary medication does not constitute a request for addition of the drug to the formulary.

B. Stocking of Non-Formulary Medications Pending Review and Acceptance:

1. Non-formulary medications (including new medications and medications that have been obtained pursuant to a non-formulary request) may be stocked by the Pharmacy pending their review and acceptance by the Medical Staff.

C. Justification for Procuring Non-Formulary Medication:

1. If an alternative medication is not acceptable to the prescriber, the Pharmacy shall make every reasonable attempt to obtain the non-formulary medication from another hospital, community pharmacy or other approved source within 24 hours.
2. The pharmacist shall notify the prescriber and the patient's nurse of the estimated time that the requested medication will be available.

D. Amount to Obtain:

1. If a non-formulary medication must be obtained, the Pharmacy shall make every reasonable attempt to obtain an amount of the medication sufficient to meet the anticipated needs of the patient for whom it is ordered.

2. If the non-formulary drug cannot be obtained within a reasonable period [e.g., four hours (or less if the need is urgent)], the Pharmacy shall notify the prescriber and Nursing Service.

V. REFERENCE:

- Joint Commission Standard: MM.02.01.01 EP 4 – 5
  MM.02.01.01 EP 7 - 8
- ~~CHS Policy#: 08-03-H (10/12)~~

VI. STAKEHOLDERS

N/A

~~Reviewed:~~	~~1st~~	~~2nd~~	~~3rd~~	~~4th~~	~~5th~~
~~Date:~~	~~12/94~~	~~5/97~~	~~8/99~~	~~05/13~~	
~~By:~~				~~J. Gavin~~	

~~Policy/Procedure Title~~	~~Formulary, Obtaining Non-Formulary Medications~~	~~Manual Location~~	~~Provision of Care~~
~~Policy/Procedure #~~	~~1568~~	~~Page~~	~~3 of 2~~

Policy Title	Formulary Obtaining Non-Formulary Medications	Policy #	PHARM1568

~~Revised:~~	~~1st~~	~~2nd~~	~~3rd~~	~~4th~~	~~5th~~
~~Date:~~	~~12-07~~	~~1/08~~	~~11/14~~	~~7/2023~~	
~~By:~~	~~J. Gavin~~	~~J.Gavin~~	~~J. Gavin~~	~~J.Gavin~~	

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Approved Drugs for Non Approved Uses	Policy #	PHARM2088
Responsible	Pharmacy Director	Revised/Reviewed	07/2023

~~Policy/Procedure Title~~	~~Approved Drugs for Non-Approved Uses~~	~~Manual Location~~	~~Provision of Care~~		
~~Policy/Procedure #~~	~~2088~~	~~Effective~~	~~4/04~~	~~Page~~	~~1 of 2~~
~~Department Generating Policy~~	~~Pharmacy~~	~~Revised~~	~~9/17~~		

I. PURPOSE:

To provide guidelines for use of FDA-approved medication being prescribed for unlabeled (i.e., “off label” or “unapproved”) use.

II. POLICY:

- This policy is to serve as a reference of addressing requests for FDA-approved drugs prescribed for unlabeled indications or in a manner not included in the approved product labeling.
- All drugs procured for patient use shall be FDA-approved brand name and generic prescription and over-the-counter human drugs and biologic therapeutic products.

III. DEFINITIONS

N/A

IV. PROCEDURE:

A. Definition:

1. Unlabeled use (“off-label use”, “unapproved use”) includes the use of a drug product, which is not reflected in FDA-approved product labeling regarding:
   (1) doses,
   (2) patient populations,
   (3) indications, or
   (4) routes of administration.

B. Background:

1. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations.
2. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to the Food and Drug Administration (FDA) for evaluation.

C. Limits on use of drugs that have been approved for marketing:

1. The Food, Drug and Cosmetic Act does not limit the manner in which a physician may use an approved drug.
2. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling.
3. Such “unlabeled” use may be appropriate and rational in certain circumstances, and may reflect an approach to drug therapy that has been extensively reported in the literature.

D. Pharmacist's responsibility when drugs are ordered for unlabeled indications:

1. Pharmacists may dispense drugs to be used for unlabeled indications.
2. However, unless recognized as safe and legitimate usage, pharmacists shall contact prescribers when drugs are known to be ordered outside the drug's labeled use to request literature references that substantiate a drug's use for the prescribed purpose (including dosage and route of administration).

E. Pharmacy and Therapeutics' (P&T) Role:

1. If safe and effective use cannot be readily substantiated by published reports, the Medical Staff through its Pharmacy and Therapeutics function shall determine if the requested use is permissible.
2. When possible, this determination shall be based on a least two independent studies that have been reported in the literature.
   a. These studies shall attest to an increased efficacy or other medical advantage.

F. Informed Consent:

1. If required by Medical Staff rules and regulations, the prescriber shall obtain the patient's informed consent to administer the drug for an unlabeled use.
2. Informed consent should include the name of the drug (including generic name), route of administration, dosage, intended use, anticipated benefits, known risks (adverse reactions), potential alternative treatments (if any), and any anticipated outcomes should consent be denied.

V. REFERENCE

- Joint Commission Standard: MM.02.01.01 EP-2

VI. STAKEHOLDERS

N/A

Reviewed:	1st	2nd	3rd	4th	5th
Date:	12/10	5/2020			
By:	J.Gavin	J.Gavin			

Revised:	1st	2nd	3rd	4th	5th
Date:	5/13				
By:	J.Gavin				

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Standard (Specification): Medications, Chemicals, and Biologicals	Policy #	PHARM2090
Responsible	Pharmacy Director	Revised/Reviewed	07/2023

~~Policy/Procedure Title~~	~~Standards (Specifications): Medications, Chemicals, and Biologicals~~	~~Manual Location~~	~~Provision of Care~~		
~~Policy/Procedure #~~	~~2090~~	~~Effective~~	~~4/04~~	~~Page~~	~~1 of 2~~
~~Department Generating Policy~~	~~Pharmacy~~	~~Revised~~	~~9/177/2023~~		

I. PURPOSE

To ensure medications provided for use at Watsonville Community Hospital meet national standards of quality.

II. POLICY

- Medications, chemicals, and biologicals used in the facility shall meet national standards of quality [(e.g., the standards and specifications of the United States Pharmacopoeia/National Formulary (USP/NF)].
- Specifications for medications and information on sources of medications used in the facility shall be furnished to the Medical Staff upon request.

III. DEFINITIONS

N/A

IV. PROCEDURE:

A. Provision of drugs by the Pharmacy:

1. All medications used in the facility shall be purchased from FDA-approved manufacturers and provided by the Pharmacy (unless specifically exempted).
2. Visitors shall not supply legend or non-legend medications to patients.
3. Drug preparations compounded or dispensed by an outside pharmacy to a specific patient or physician shall not be used for inpatient treatment unless approved by the Director of Pharmacy and a representative of the Pharmacy and Therapeutics Committee (or equivalent Medical Staff Committee).
4. Professional discretion by the attending physician and Pharmacy may be exercised to allow the patient's home supply to be used in certain circumstances, such as:
   a. Medication is non-formulary, has been identified by Pharmacy, and is needed for immediate use.
   b. Medication is non-formulary, hospital stay is very short, and a supply is not readily obtainable.
   c. Medication is a limited dose drug, and is prescribed for continued therapy as an inpatient (e.g., oral contraceptive).
   d. Refer to Policy# 1577: *Patient Own Medication / Drugs*

B. Non-Official Medications:

1. Non-official medications (i.e., medications not included in the USP/NF) shall be approved for marketing by the Food and Drug Administration (FDA).

C. Compounded Medications:

1. Compounded medications shall be prepared by the Pharmacy from medications and ingredients that meet USP/NF specifications or other national standards of quality.
2. Facility may contract with an approved Pharmacy vendor to compound FDA-approved drugs that meet USP/NF specifications (e.g., total parenteral nutrition solutions and epidural analgesics).
3. Contracted vendors ~~shall~~ should be approved through the Pharmacy and Therapeutics Committee (or equivalent Medical Staff Committee) in compliance with Joint Commission, State and Federal standards.
4. Contracted vendors ~~shall~~ should provide documentation of product testing for those compounded products purchased by the facility.

D. Drugs of Choice:

1. The Medical Staff shall be encouraged to prescribe products that are recognized as medications (drugs) of choice and have demonstrated evidence of effectiveness.
2. Use of herbal or homeopathic products in house are discouraged.

E. Examination of Drugs upon Receipt:

1. Medications shall be examined upon receipt for current dating and evidence of breakage, contamination, and exposure to temperature extremes.
2. Suspect medications shall be isolated until the issue is resolved.
3. Medications that pass this initial examination shall be processed and stored properly as soon as possible.

V. REFERENCE:

Joint Commission Standard: MM.02.01.01 EP 2
MS.05.01.01 EP 4

~~CHS/QHC Policy# 08-01-P (10/15)~~

VI. STAKEHOLDERS

N/A

~~Reviewed:~~	~~1st~~	~~2nd~~	~~3rd~~	~~4th~~	~~5th~~
~~Date:~~	~~5/13~~				
~~By:~~	~~J. Gavin~~				

~~Revised:~~	~~1st~~	~~2nd~~	~~3rd~~	~~4th~~	~~5th~~
~~Date:~~	~~12/10~~	~~7/2023~~			
~~By:~~	~~J. Gavin~~	~~J.Gavin~~			

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Supplying Medications to Other Healthcare Organizations	Policy #	PHARM2095
Responsible	Pharmacy Director	Revised/Reviewed	07/2023

~~Policy/Procedure Title~~	~~Supplying Medications to Other Healthcare Organizations~~	~~Manual Location~~	~~Provision of Care~~		
~~Policy/Procedure #~~	~~2095~~	~~Effective~~	~~4/04~~	~~Page~~	~~1 of 2~~
~~Department Generating Policy~~	~~Pharmacy~~	~~Revised~~	~~9/17~~07/2023		

I. PURPOSE:

To provide consistent guidelines for loaning or selling of medications to other healthcare organizations.

II. POLICY:

- The pharmacy may supply (i.e., loan, sell) medications to other healthcare organizations (e.g., community pharmacies and hospital pharmacies).
- Loans shall be within the limits of the Prescription Drug Marketing Act of 1987.
- The hospital may sell medications at acquisition cost.

III. DEFINITIONS

N/A

IV. PROCEDURE:

A. Containers and Labels:

1. Medications supplied to other healthcare organizations shall be in manufacturer's labeled, original containers or in containers that are identified and labeled so that recalls can be effected as necessary and proper controls established.

B. Quantities to Loan or Sell:

1. The pharmacy may either loan or sell medications that it normally stocks.
2. Quantities loaned or sold shall not exceed five percent of the pharmacy's total annual purchases.

C. Records of Transactions:

1. Records of transactions shall be made on an invoice, cash sales record, borrow/lend record, or similar record.
2. If the medication is returned by a borrower, the transaction record shall be canceled and retained by the Pharmacy.
3. Records of controlled substance as well as other legend drug transactions shall be maintained as required by law.
4. Refer to policy #RX08-05: *Drug Supply Chain Security Documentation*

V. REFERENCES:

- ~~CHS/QHC Policy# 08-06-P (11/15)~~
- Prescription Drug Marketing Act of 1987 (FDA)

~~VI. Reviewed:~~ ~~VII. 1st~~ ~~VIII. 2nd~~ ~~IX. 3rd~~ ~~X. 4th~~ ~~XI. 5th~~

~~XII.~~ ~~XIII. 5/13~~ ~~XIV. 7/2023~~ ~~XV.~~ ~~XVI.~~ ~~XVII.~~

~~Date:~~

~~XVIII. By:~~ ~~XIX. J. Gavin~~ ~~XX. J.Gavin~~ ~~XXI.~~ ~~XXII.~~ ~~XXIII.~~

~~XXIV.~~VI. **STAKEHOLDERS**

N/A

~~Revised:~~	~~1st~~	~~2nd~~	~~3rd~~	~~4th~~	~~5th~~
~~Date:~~	~~12/10~~				
~~By:~~	~~J. Gavin~~				

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Discharge Prescriptions	Policy #	PHARM1578
Responsible	Pharmacy Director	Revised/Reviewed	07/2023

~~Policy/Procedure Title~~	~~Discharge Prescriptions~~	~~Manual Location~~	~~Provision of Care~~		
~~Policy/Procedure #~~	~~1578~~	~~Effective~~	~~09/99~~	~~Page~~	~~1 of 3~~
~~Department Generating Policy~~	~~Pharmacy~~	~~Revised~~	~~5 20207/2023~~		

I. PURPOSE~~:~~

To outline the facility's process for discharge prescriptions.

II. POLICY~~:~~

A. Inpatient Pharmacy shall NOT ~~furnish~~ dispense medications to inpatients upon release from the facility.

B. The physician responsible for the patient shall ~~provide the patient with a prescription that may be filled at an outpatient pharmacy of the patient's choice, may~~ electronically transmit (e.g., fax, e-prescribing) prescription to the patient's preferred pharmacy provider.~~,~~

C. When necessary and appropriate, physician may provide the patient with a prescription that may be filled at an outpatient pharmacy of the patient's choice or may verbally communicate prescriptions to the patient's preferred outpatient pharmacy.

C. The physician should write prescriptions using her/her own personalized prescription forms or a hospital-approved discharge prescription form. Discharge prescriptions must identify the prescriber (e.g., name, office telephone number, office address, and DEA number) should the patient's pharmacist need to contact him/her. Generic (non-personalized) prescription forms are not appropriate for patient discharge prescriptions.

D. Physicians shall not delegate to any hospital or ambulatory surgery center employee (e.g., nurse or pharmacist), in writing or otherwise, his or her authority to verbally communicate prescriptions to external pharmacies for discharged patients.

1. Despite DEA regulations allowing physicians to delegate a nurse as his or her authorized agent, nurses may not enter into a "nurse as agent" agreement with any physician in which a nurse is allowed to verbally communicate a physician's verbally-ordered controlled substance prescription to an outside pharmacy.

III. DEFINITIONS

N/A

IV. ~~III.~~ PROCEDURE~~:~~

A. Physician:

1. Electronically transmit prescription to patient's preferred pharmacy.
2. When necessary and appropriate (e.g., electronic prescribing is not an option), c~~C~~omplete prescription for patient, using either facility discharge form or own personalized prescription form.

B. Nurse:

~~1. If the discharge medication orders are written on a physician order sheet, write the following information on the original copy:~~

~~a. Anticipated time of discharge~~

1. Ensure patient's pharmacy of choice is documented in electronic health record

~~c. Label instructions in English or Spanish~~

~~d. Fax or call the prescription to patient's pharmacy of choice~~

~~2. If the physician leaves a prescription for the medication, give it to the patient, instructing him/her to have it filled at an outside pharmacy upon discharge from the hospital.~~

2. Patients seen in the Emergency Department may be given an initial dose while signed in as a patient then will be referred to the nearest 24 hours retail pharmacy for their prescriptions needs.
3. Provide patient education:
   a. Instruct patients in the administration of medications, which the patient will be taking at home, including last dose given if applicable.
   b. The patient receives:
      1) Copy of discharge instructions
      2) Micromedex information and drug/food interaction information as appropriate
      3) General medication information sheet
      4) Information on discharge medications when available
   c. Document in nurse's note:
      1) Discharge instructions given and patient understands
      2) Medications returned to patient, if appropriate
      3) Information given to patient

V. REFERENCE~~:~~

- Joint Commission Standards: ~~—~~MM.05.01.11 EP 3 MM.05.01.01 EP 1, 4-9
  LD.04.01.01 EP 1 – 2 ~~—~~RC.02.01.01 EP 1-4
- Department of Justice, Drug Enforcement Administration, 21 CFR, Part 193. October 6, 2010. Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies.

VI. STAKEHOLDERS

N/A

Policy Title	Pharmacy Director	Policy #	PHARM1578
~~Policy/Procedure Title~~	~~Discharge Prescriptions~~	~~Manual Location~~	~~Provision of Care~~
~~Policy/Procedure #~~	~~1578~~	~~Page~~	~~3 of 3~~

~~Reviewed:~~	~~1st~~	~~2nd~~	~~3rd~~	~~4th~~	~~5th~~
~~Date:~~	~~04/05~~				
~~By:~~					

~~Revised:~~	~~1st~~	~~2nd~~	~~3rd~~	~~4th~~	~~5th~~
~~Date:~~	~~1/01~~	~~1/04~~	~~8/12~~	~~8/16~~	~~5/2020~~
~~By:~~			~~J.Gavin~~	~~J. Gavin~~	~~J.Gavin~~

	~~6th~~	~~7th~~	~~8th~~	~~9th~~	~~10th~~
~~Date:~~	~~7/2023~~				
~~By:~~	~~J.Gavin~~				

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Adverse Drug Reaction	Policy #	PHARM1429
Responsible	Pharmacy/Administration	Revised/Reviewed	07/2023

~~Policy/Procedure Title~~	~~Adverse Drug Reaction~~	~~Manual Location~~	~~Provision of Care~~		
~~Policy/Procedure #~~	~~1429~~	~~Effective~~	~~1/01~~	~~Page~~	~~1 of 5~~
~~Department Generating Policy~~	~~Pharmacy/Administration~~	~~Revised~~	~~6/157/2023~~		

I. PURPOSE

To provide guidelines for reporting and monitoring of Adverse Drug Reactions (ADR's).

II. POLICY

Adverse (untoward) drug reactions (ADR's) shall be reported using the ~~CHS~~ facility's standardized reporting system and all significant adverse drug reactions reviewed by appropriate medical staff committees.

III. DEFINITIONS

~~i.~~A. Adverse Drug Reaction (ADR):

1. Pharmacy and Therapeutics (P&T) Committee and Medical Executive Committee (MEC) have defined a significant adverse drug reaction as "any unexpected, unintended, undesired or excessive response to a drug that"….
   - Requires discontinuing the drug (therapeutic or diagnostic),
   - Requires changing the drug therapy,
   - Requires modifying the dose (except for minor dosage adjustments),
   - Necessitates admission to a hospital,
   - Prolongs stay in a health care facility,
   - Necessitates supportive treatment,
   - Significantly complicates diagnosis,
   - Negatively affects prognosis, or
   - Results in temporary or permanent harm, disability or death.

B. Allergic Reaction:

1. An ADR that is related to an immunologic hypersensitivity, occurring as the result of unusual sensitivity to a drug.

C. Idiosyncratic Reaction:

1. An ADR that is related to an abnormal susceptibility to a drug that is peculiar to the individual.

D. Side Effect (not an ADR):

1. An expected, well-known reaction resulting in little or no change in patient management; response occurs with predictable frequency and may be dose related.
2. Examples include:
   a. Fever & neutropenia secondary to chemotherapeutic agents
   b. Nausea, vomiting or gastrointestinal upset due to narcotics or antibiotics

c. Hyperglycemia secondary to corticosteroids
d. Confusion secondary to narcotics
e. Constipation secondary to narcotics
f. Itching secondary to narcotics
g. Drowsiness or dry mouth due to antihistamines

E. Drug withdrawal, drug-abuse syndromes, accidental poisoning, and drug-overdose complications **should NOT** be reported as ADR's.

F. Severity Classifications (reported ADR's):

1. **Insignificant:** Bothersome, but requiring no intervention or treatment beyond discontinuation of the medication or decreasing the dose; does not significantly affect the patient's outcome or hospital course.
2. **Mild:** A deterioration of patient status which requires intervention and results in a therapy change and/or minor treatment, including discontinuation of medication; hospital stay is not prolonged.
3. **Significant:** Medical intervention is required. Hospital stay is prolonged.
4. **Severe/Life Threatening:** Disability or hospital stay prolonged by three or more days.

G. Estimating the Probability of an ADR (Naranjo Algorithm- modified *):

Drug:	Yes	No	Not Known	Score
1. Are there previous conclusive reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspended drug was administered?	+2	-1	0	
3. Did the adverse drug reaction improve when the drug was discontinued or a specific antagonist was administered? (Dechallenge)	+1	0	0	
4. Did the adverse reaction reappear when the drug was readministered? (Rechallenge)	+2	-1	0	
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	
6. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
7. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
8. Did the patient have a similar reaction to other same or similar drugs in any previous exposure?	+1	0	0	
9. Was the adverse event confirmed by any objective evidence?	+1	0	0	
TOTAL SCORE				
≥9 = Definite 5-8 = Probable 1-4 = Possible ≤0 = Unlikely				
*modification to table for Naranjo Algorithm: omission of: "Did reaction reappear when placebo was given?"				

H. Adverse Drug Reactions and Medication Variances

1. If a medication administration error (variance) causes an adverse drug reaction, both an adverse drug reaction report and a Medication Variance report shall be completed and processed.

IV. PROCEDURE

A. ~~A.~~ Nursing:

1. Supportive measures to provide for the needs of the patient are paramount.
   a. The patient must be monitored and treated as needed.
2. Stop the medication if still being administered, unless stopping would endanger the health of the patient.
   a. If immediate discontinuation of the drug is questionable, contact the responsible practitioner to ascertain the action that should be taken.
3. Report ADR's immediately to the patient's physician, or the prescribing physician, if different than the patient's physician.
   a. Practitioner notified shall be noted in Nursing Notes and ~~on~~ in ADR ~~Report form~~reporting system.
   b. Reports to the practitioner responsible for the patient or personnel who will treat and support the patient shall be verbal and without delay if there is any risk of harm to the patient.
4. Physician's instructions for follow-up or supportive treatment shall be recorded in the Physician's Orders.
5. Document the reaction and treatment (follow up action) in the patient's medication record (e.g., Nursing Notes).
   a. Nurses shall communicate this information to nursing staff during shift report.
6. If the adverse reaction has been determined to be an allergy to the medication:
   a. Place allergy armband on patient and educate patient of allergic reaction, type and name of medication which caused the reaction.
   b. Notify Pharmacy of new allergy.
   c. Update allergy section of MAR and EMR (electronic medical record).
7. Complete Adverse Drug Reaction via ~~ERS (Event Reporting System).~~facility's reporting system.
   a. The healthcare professional who identifies the suspected ADR shall record the following:
      - Patient's name,
      - Account / ID#,
      - Medical Record Number,
      - Date the reaction was noted,
      - Unit where the patient was located at the time the reaction was noted,
      - Name of the suspected medication,
      - Description of the reaction,
      - Reporter's name/department.
   b. The reporting professional should also include the name of the physician contacted as well as the date/time the physician was notified.
   c. Pharmacy shall complete additional investigation and follow up, if appropriate.
8. If there is an adverse patient outcome, ~~the Chief Quality Officer~~Quality Director must also be notified (x1588).

B. Pharmacy:

1. ADR's from all data sources are reviewed by a pharmacist
   a. ADR ~~Report Form (RX-4101)~~reported via facility reporting system

b. Routine "Adverse Effects of Therapeutic Drugs" report generated by the Health Information Management (HIM or Medical Records).

- This report lists all ADRs identified during coding and is based upon AHA coding guidelines.

c.b. STAT or one time drug orders (with or without laboratory tests) for drugs commonly used to treat ADR's, as identified by pharmacists during chart review and/or order entry process.

1) Examples of these drugs include:

- Antihistamines (e.g., diphenhydramine)
- Atropine
- Benztropine
- Calamine lotion
- Corticosteroids (injectable or topical)
- Dextrose
- Epinephrine
- Fluid boluses
- Flumazenil
- Insulin
- Lorazepam
- Naloxone
- Phenytoin
- Phytonadione (Vitamin K)
- Protamine
- Sodium polystyrene sulfonate

- Dextrose
- Epinephrine
- Fluid boluses
- Flumazenil
- Insulin
- Lorazepam
- Naloxone
- Phenytoin
- Phytonadione (Vitamin K)
- Protamine
- Sodium polystyrene sulfonate

- Antihistamines (e.g., diphenhydramine)
- Atropine
- Benztropine
- Calamine lotion
- Corticosteroids (injectable or topical)

2) Exception includes: drugs used in pre-medication, drugs used in protocols, and drugs used in surgical and emergency procedures.

2. Reports to the FDA:
   a. For reporting purposes, the FDA categorizes a serious adverse event (events relating to drugs or devices) as one in which "the patient outcome is death, life-threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent, or permanent), congenital anomaly, or required intervention to prevent permanent impairment or damage."
   b. Serious or unexpected adverse drug reactions should be reported to the FDA Medical Products Reporting Program (Medwatch) and drug manufacturer, as appropriate.
3. Reactions will be assessed for severity, probability, and outcome (see definition section)

C. Monitoring and Detecting:

1. Physicians, nurses, pharmacists, and others who care for patients shall be alert to signs and symptoms of adverse drug reactions.
2. "High risk" patients (e.g., pediatric, geriatric, renal failure) as well as those patients receiving "high risk" drugs (e.g., amphotericin, phenytoin, thrombolytics) should be monitored.

D. Assessment of the definition and the effectiveness of the detection mechanism:

1. The Medical Staff, in collaboration with the Pharmacy, Nursing, and other staff, as appropriate, shall periodically assess its definition of a significant ADR and the mechanism's effectiveness to detect significant ADR's.
2. Appropriate Medical Staff committee(s) (e.g., Pharmacy and Therapeutics, ~~Quality Coordinating Council,~~ Medical Executive Committee, and Board of Trustees) shall periodically review significant ADR reports as well as trended data.
   a. Trended data should be evaluated to determine any potential improvements in processes (g, drug prescribing or administration) or drug selection (e.g., formulary or appropriate use protocols) to improve patient safety.
   b. Examples of trended data:
      - ADR's causing hospital admission
      - High risk populations
      - High risk classes of drugs
      - Patterns of ADR's
   c. Summary reports should be prepared annually and should include any recommendations to improve processes or the ADR reporting program.
3. This assessment may include a review of expert sources in the published literature, external data sources, or other information regarding occurrence rates of ADR's.

~~V.~~B. REFERENCES:

- Joint Commission Standards: MM.02.01.01 EP 3 ~~—~~MM.06.01.01 EP 9 MM.07.01.03 EP 1 – 3, 5 ~~—~~PI.01.01.01 EP 14 – 15
  RC.02.01.01 EP 1 - 2
- American Society of Health-System Pharmacists. ASHP guidelines on adverse drug reaction monitoring and reporting. *Am J Health-Syst Pharm*. 1995; 52:417-9.
- Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions.
- *Clin Pharmacol Ther*. 1981; 30(2): 239-45.

~~QHC Policy # Rx14-01 (9/12) 14-03-H (2/2/1~~

~~VI.~~C. STAKEHOLDERS

N/A

Reviewed:	1st	2nd	3rd	4th	5th
Date:	7/18	7/19			
By:	J.Gavin	J.Gavin			

Revised:	1st	2nd	3rd	4th	5th
Date:	1/01	11/01	3/04	8/05	3/06

Revised:	6th	7th	8th	9th	10th
Date:	06/09	5/12	4/13	7/2023	
By:			J. Gavin	J.Gavin	

Policy Title	Investigational Drug Studies	Policy #	PHARM1565
Responsible	Pharmacy Director	Revised/Reviewed	07/2023

~~Policy/Procedure Title~~	~~Investigational Drug Studies~~	~~Manual Location~~	~~Provision of CarePharmacy~~		
~~Policy/Procedure #~~	~~1565~~	~~Effective~~	~~8/97~~	~~Page~~	~~1 of 4~~
~~Department Generating Policy~~	~~Pharmacy~~	~~Revised~~	~~5/20207/2023~~		

I. PURPOSE

To provide guidelines for participation in investigational drug studies.

II. POLICY

A. Watsonville Community Hospital may participate in investigational drug studies and clinical trials only after such participation is approved by the Pharmacy and Therapeutics (P&T) Committee (or equivalent Medical Staff Committee). ~~and the Institutional Review Board (IRB).~~ The Pharmacy Director should be informed of participation.

B. The Pharmacy shall ensure that these drugs are properly stored, distributed, and controlled and that records are maintained according to the approved study protocol and FDA requirements.

C. The hospital may only participate in studies approved by the US Food and Drug Administration (FDA) or National Cancer Institute (NCI).

D. Patients enrolled in investigational studies from unaffiliated IRB's (Institutional Review Board) or drug studies may be administered their own investigational drug(s) providing sufficient information for the safe use of the investigational drug is provided in advance of any doses administered and approval for the use is approved by the attending physician, the Director of Pharmacy, Pharmacy and Therapeutics Chairperson, and/or equivalent Medical Staff Committee~~the Investigational Review Board (IRB).~~

1. The patient shall supply the drug and copies of the patient's consent form, the study protocol, and an IRB approval letter.
2. A pharmacist shall validate the patient's own investigational drug prior to any doses administered.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Protocols:

1. Approved protocols for investigational drug use must address patient selection, informed consent, pharmacological information (including known potential side effects), and correct use and administration of the drugs.
2. Protocols must be approved by the Pharmacy and Therapeutics Committee (or equivalent Medical Staff Committee) ~~and Institutional Review Board~~ prior to patient enrollment or administration of investigational drugs within the hospital.

B. Roles of Sponsors and Investigators:

1. Investigational drugs shall be used under the direction of an investigator (usually a physician) who is authorized by a sponsor (usually a manufacturer).
2. Sponsors must have filed Form FDA-1571 ("Investigational New Drug Application [IND]" form) with the Food & Drug Administration and investigators must have filed a Form FDA-1572 ("Statement of Investigator" form) with the sponsor.
3. **Patients already enrolled in investigational studies:**
   a. Sufficient information for safe use of the investigational drug, including copies of the subject's signed consent form, the study protocol, and the IRB approval letter, shall accompany the drug.
   b. The responsibilities of the facility are based on whether the facility is providing care incidental to or as a participant in the research protocol.

C. Emergency Protocol Approval:

1. If the patient's attending physician determines that a patient must be enrolled in an investigational drug study (or is already enrolled in an approved study and must be admitted to the hospital) and time does not allow for Medical Staff committees (i.e., P&T) ~~and IRBs~~ to meet and approve a protocol, the attending physician may declare an emergency and request an expedited review by the Chairperson of the P&T committee (or other authorized officer of the Medical Staff).
2. The ~~IRB and the~~ Director of Pharmacy must be notified.
3. Only approved FDA and NCI studies may be considered for approval.

D. Role of the Pharmacy:

1. The Pharmacy shall participate as required in investigational drug studies.
2. Participation shall include development of policies and procedures for handling, storage, distribution, labeling, monitoring, security, control, disposal, and accountability of investigational drugs.
3. With the approval of the facility administrator, the Pharmacy may charge the study sponsor (or principal investigator) reasonable fees associated with dispensing of study medications as well as related time required for proper record keeping and control of study medications.

E. Drug Information:

1. Essential information related to approved study drugs shall be maintained in the Pharmacy.
2. Information shall include the dosage form, dosage range, storage requirements, route of administration, strength, actions, uses, adverse effects, contraindications, interactions, and symptoms of toxicity.
3. The Pharmacy shall supply this information to nurses and others who handle, dispense, and administer these drugs.

F. Storage:

1. Investigational drugs shall be kept in locked storage within the Pharmacy and at patient care areas prior to administration.

G. Ordering:

1. Only authorized practitioners may prescribe approved investigational drugs for patients.

2. Orders for investigation drugs must be written clearly in the patient's medical record and reviewed by a pharmacist knowledgeable of the investigational protocol.

H. Dispensing:

1. Investigational drugs may only be dispensed by a pharmacist knowledgeable of the investigational protocol.

I. Distribution:

1. Investigational drugs shall be dispensed from the Pharmacy only upon receipt of an order by a physician authorized to order the approved investigational drugs.
2. The Director of Pharmacy is responsible for ~~insuring~~ensuring that all documentation related to investigational drugs is maintained in compliance with FDA and study sponsor requirements.

J. Labeling:

1. Investigational drugs shall be properly labeled in accordance with current FDA requirements.
2. Labels of investigational drugs shall contain at least the following:
   - Patient name and location
   - Name of prescriber
   - Name and strength of drug (or code)
   - Complete directions for use (affixed to the container or available to the person administering the drug)
   - Number of dosage units in container when dispensed
   - Lot number
   - Expiration date
   - Name or initials of dispensing pharmacist
   - Notation that the medication is investigational and/or of the study protocol

K. Administration:

1. Administration of investigational drugs must comply with the approved protocol.

L. Persons Who May Administer Investigational Drugs:

1. Investigational drugs may be administered by those professionals granted privileges to practice within the hospital and licensed by the state to administer medications to patients.
2. Investigational drugs may not be administered to a patient until the professional authorized to administer the drug has been properly educated on both the study protocol and investigational drug.
3. This professional should demonstrate understanding of the investigational drug and study protocol prior to administering the drug to a patient.

M. Education for Persons Who Administer Investigational Drugs:

1. The Pharmacy shall participate in ensuring that education for persons who administer these drugs includes the following, but not limited to:
   - The benefits and risks to the patient enrolled in the drug study
   - How to administer the drugs
   - Pharmacologic action of the drugs
   - Expected response to the drugs
   - Possible adverse effects of the drugs

- Appropriate response to adverse effects of the drugs
- Other clinical implications associated with the use of the drugs
- Proper documentation of drug administration, outcome, and potential side effects

2. Educational methods may include written materials, skills tests, and skills checklists.

N. Monitoring:

1. Pharmacists should work with study investigators and others who provide care to patients enrolled in investigational drug studies to monitor the effects of study medications.

O. Informed Consent:

1. Protocols for the use of investigational drugs and devices used in clinical trials shall include a requirement for the patient's informed consent before administration or use of the drug or device.
2. The form used for the patient's consent must be approved by ~~an IRB and~~the Pharmacy and Therapeutics Committee (or other authorized Medical Staff committee).
3. Patient's informed consent shall include at a minimum:
   - The identity of the patient
   - The date the informed consent was signed
   - The treatment (in layman terminology when possible)
   - The name(s) of the individual(s) who are the principal investigators as well as their contact information
   - An indication that alternate means of therapy and the possibility of risks or complications have been explained to the patient
   - A description of the potential discomfort and risks
   - A description of the expected benefits
   - The patient's right to privacy, confidentiality, and safety
   - An indication that the patient has been informed that he/she may refuse to participate and that refusal will not compromise access to services
   - The signature of the patient or other individual empowered to give consent
   - The name(s) of the individual(s) who provided the information

P. Witnessing Informed Consent:

1. Signatures on informed consent records shall be witnessed.

Q. RESPONSIBILITY FOR OBTAINING INFORMED CONSENT

1. The principal investigator or person granted authority to conduct the approved study within the facility is responsible for obtaining informed consent from patients enrolled in the study.
2. A copy of the informed consent must be maintained in the patient's medical record.

R. Control of Investigational Drugs:

1. When the patient is discharged or therapy is discontinued, all unused investigational drugs shall be returned to the Pharmacy which shall ensure return to the principal investigator or study sponsor.
2. These drugs shall not remain at patient care areas.

S. Records of Dispensing, Administration, and Destruction / Disposition:

1. The Pharmacy shall keep records or receipts of doses dispensed, administered, and destroyed.

2. Records shall be as required by the sponsor and shall meet current FDA requirements.

T. Confidentiality:

1. The Principal Investigator and facility must maintain the confidentiality of research data, patient information, and the patient's medical record.

V. REFERENCES:

- Joint Commission Standards: R1.01/03/05 EP 2-4
- American Society of Health-System Pharmacists. ASHP guidelines for the use of drugs in clinical research. Am J Health-Syst Pharm. 1998;55:369-76.
- Food and Drug Administration. Use of investigational products when subjects enter a second institution. IRB operations and clinical investigation information sheet. www.fda.gov/oc/oha/use ofinv.html

VI. STAKEHOLDERS

N/A

~~Reviews:~~	~~1st~~	~~2nd~~	~~3rd~~	~~4th~~	~~5th~~
~~Date:~~	~~4/04~~	~~4/08~~			
~~By:~~		~~J.Gavin~~			

~~Revised:~~	~~1st~~	~~2nd~~	~~3rd~~	~~4th~~	~~5th~~
~~Date:~~	~~9/11~~	~~11/2014~~	~~5/2020~~	~~7/2023~~	
~~By:~~	~~J.Gavin~~	~~J.Gavin~~	~~J.Gavin~~	~~J.Gavin~~	

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Warfarin (Coumadin) Protocol - Administration and Monitoring	**Policy #**	PHARM0274
Responsible	Pharmacy Director	**Revised/Reviewed**	07/2022

~~**Policy/Procedure Title**~~	~~Warfarin (Coumadin) Protocol - Administration and Monitoring~~	~~**Manual Location**~~	~~Provision of Care~~		
~~**Policy/Procedure #**~~	~~0274~~	~~**Effective**~~	~~4/04~~	~~**Page**~~	~~1 of 12~~
~~**Department Generating Policy**~~	~~Pharmacy~~	~~**Revised**~~	~~3/16~~		

I. PURPOSE:

To establish guidelines for the administration and monitoring of oral anti-coagulants.

II. POLICY:

Warfarin is used to prevent and treat thromboembolic complications of a variety of medical conditions. Because of warfarin's narrow therapeutic window and numerous drug interactions, initiating and optimizing therapy with warfarin may be problematic. Structured inpatient anticoagulation programs focusing on warfarin have been shown to minimize risks while achieving goals related to anticoagulation therapy.[1-4] This policy describes standards for use of warfarin within Watsonville Community Hospital.

III. DEFINITIONS

~~III.~~IV. PROCEDURE:

Physician:

A. Any credentialed provider may order warfarin.
   1. Order for inpatient warfarin protocol may be initiated by provider – ~~ege~~.g., "Warfarin per Pharmacy."
   2. Under the inpatient warfarin protocol, Pharmacist will manager warfarin therapy according to the Medical Staff approved procedures, as described below in section A.
   3. Alternatively, any credentialed provided may order warfarin independent of the warfarin protocol. The provision of warfarin therapy independent of the warfarin protocol will be according to the procedures described in section B below.

B. All patients being newly started on warfarin should have a laboratory confirmed baseline INR, and hemoglobin (Hgb), and hematocrit (Hct) within 48 hours prior to initiating therapy.
   1. Patients taking warfarin at the time of admission will have their INR, and Hgb, and Hct checked upon admission.
   2. In addition, INR will be checked daily for 3 days at the start of warfarin therapy in the hospital.
      a. If there is not a current order for INR daily for 3 days, Pharmacist will order INR daily for 3 days for any patient, protocol or non-protocol, starting or continuing on warfarin in the hospital.
   3. Subsequent INRs should be checked every 1 to 3 days depending on the clinical situation.
      a. Recommend daily INR for 5 days.
      b. INR may be reduced to every 3 days, when 3 consecutive INR's are within appropriate therapeutic range with NO dosage adjustments.
   4. Subsequent Hgb and Hct should be checked periodically depending on the clinical situation.

C. All patients receiving warfarin should have a desired INR range associated with their warfarin therapy.
   1. Physician may specify a desired INR range on the original warfarin order.
      a. If noted, this range will be documented in the Pharmacy order entry system for lab tracking purposes.

D. Warfarin should be ordered in doses that require the administration of one tablet strength per dose whenever possible.

E. Any INR ≥ 4 is considered critical.
   1. Lab personnel will call all critical INR results to the ordering clinician.

Pharmacist:

A. Pharmacist(s) role in Physician managed/directed warfarin therapy is to ensure that these patients receive timely INRs and that the results are reasonable for the dose of warfarin being administered.

B. Warfarin will be dispensed in unit dosed packages.
   1. All available tablet strengths will be stocked.

C. Upon receipt of an order for warfarin, Pharmacist will assess the patient for the following:
   - Indication for warfarin
   - Past medical history
   - Concomitant medications
   - Current and anticipated risks of warfarin therapy including drug-drug and drug-disease interactions
   - Potential contraindications to warfarin therapy.

   1. Pharmacist will contact the consulting Physician for any clarifications.
   2. Pharmacist will contact the consulting Physician for any of the following, if not already addressed in orders and progress notes:
      - INR >4
      - Anytime clinically significant bleeding or other adverse effects related to warfarin occur
      - Anytime a clarification on the patient's clinical status is necessary.

D. Pharmacist will review the current (within previous 48 hours) INR for patients with an active warfarin order.
   1. Pharmacist will order an INR for any patient with no INR in >48 hours and no pending order for an INR.
   2. INR may be ordered STAT if necessary to avoid a potential delay in therapy.
   3. If there is not a current order for INR daily for 3 days, Pharmacist will order INR daily for 3 days for any patient, protocol or non-protocol, starting or continuing on warfarin in the hospital.
   4. Pharmacist will contact the Physician if the INR is above 3.4 and there is no order to hold at least the next scheduled warfarin dose.
   5. If the INR is not reported by the time the Pharmacy is scheduled to close, Pharmacist will notify the patient's Nurse of the pending lab result.

E. Initial warfarin order will not be profiled or administered until the INR result is reported and reviewed and called to the prescriber if necessary.

F. A verbal order will be written if the Physician desires to modify the existing order.

Nurse:

A. As above, if the INR is not reported by the time the Pharmacy is scheduled to close, Pharmacist will coordinate with the patient's Nurse of the pending lab result.

B. If the INR is > 3.4, Nurse will contact the Physician to verify that the next schedule dose of warfarin should be administered.

C. Nurse will be prompted by the ADC to enter the current INR that has been reported within the last 48 hours, and also prompted to verify that the physician has been contacted for INR >3.4.

D. If no current INR is available, Nurse will cancel the transaction in Pyxis.

1. A "STAT" INR will be ordered unless a previous level is pending.
2. When the INR result is available, the Nurse will follow the process described above.

E. As above, the initial warfarin order will not be profiled or administered until the INR result is reported and reviewed and called to the prescriber if necessary.

F. A verbal order will be written if the Physician desires to modify the existing order.

Education:

A. Dietary personnel will be notified of all warfarin patients and automatically consulted to provide patient dietary education, food-drug interaction reviews, and other warfarin related dietary information.

B. A Pharmacist and/or Nurse will educate the patient on warfarin therapy, either within 24 hours of initiation of inpatient therapy, in preparation for hospital discharge, or both.

~~I~~V. PROTOCOL vs NON-PROTOCOL:

A. Warfarin protocol:

Physician directed and Pharmacist managed warfarin therapy

1. Upon receipt of an order to initiate warfarin protocol, Pharmacy will assess the patient for the following:
   - Indication for warfarin
   - Past medical history
   - Concomitant medications
   - Current and anticipated risks of warfarin therapy, including drug-drug and drug-disease interactions
   - Potential contraindications to warfarin therapy

   Pharmacist will contact the consulting physician for any clarifications.
2. If the goal INR is not defined by the consulting physician, the Pharmacist will target the INR goal form the Medical Staff approved reference ranges (table 1), based on the indication for therapy.
   a. The consulting physician retains the authority to increase or decrease the desired INR range and will inform the Pharmacist of this decision in order to ensure appropriate, coordinated care.
3. After the initial assessment, Pharmacist will initiate and/or adjust and monitor warfarin therapy throughout the hospitalization according to the Medical Staff approved protocols described below.

4. Clinical situations may arise that require slight deviation from the warfarin protocol dosing. The Pharmacist may deviate from the protocol, if necessary, based on clinical judgment. Significant deviations will be discussed with the consulting physician.
5. Pharmacist will assess the patient's status as often as necessary to adequately evaluate progress and identify any changes in the patient's clinical care that may alter the existing anticoagulation plan. Pharmacist will provide documentation in the Progress Notes after each assessment in order to inform each provider of the patient's anticoagulation therapy.
6. Pharmacists following the warfarin protocol are authorized to order laboratory tests necessary to adequately evaluate the status of the patient, adjust warfarin dosing, and monitor for complications of therapy.
7. Pharmacist will contact the consulting physician for any of the following:
   a. Patient with an INR > 5
   b. Anytime clinically significant bleeding or other adverse effects related to warfarin occur
   c. Anytime a clarification on the patient's clinical status is necessary
8. If a patient develops an elevated INR and is a candidate for vitamin K reversal, according to table 5, the Pharmacist will contact the consulting physician to discuss the situation. Pharmacist may order vitamin K (PO or IV) ONLY after discussion and agreement from the consulting physician.
9. The provisions of the warfarin protocol do not extend beyond the management of warfarin therapy.
10. Pharmacist following warfarin patients will remain current with the literature pertaining to anticoagulation management as it develops and make adjustments to the warfarin protocol as appropriate.

B. **Non-protocol:**

Physician directed and Physician managed warfarin therapy

1. Pharmacist role in physician directed and physician managed warfarin therapy is to ensure that these patients receive timely INR's and that the results are reasonable for the dose of warfarin being administered.
2. Pharmacist will review the current (within previous 72 hours) INR for physician directed and physician managed patients with an active warfarin order.
3. Pharmacist will order an INR for any patient with no INR in > 72 hours and no pending order for an INR. The INR may be ordered STAT if necessary to avoid a potential delay in therapy.
4. Pharmacist will contact the physician if the INR is above 3.5 and there is no order to hold at least the next scheduled warfarin dose.
5. If the INR is not reported by the time the Pharmacy is scheduled to close, then the Pharmacist will notify the patient's nurse of the pending lab result. If the INR is > 3.5 the Nurse will contact the physician to verify that the next scheduled dose of warfarin should be administered.
6. When the Pharmacy is closed, the Nurse will remove warfarin from Pyxis MedStation as per approved override policy. Additionally, the Nurse will be prompted by Pyxis to enter the current INR that has been reported within the last 72 hours.
7. If no current INR is available, the Nurse will cancel the transaction and a STAT INR will be ordered, unless a previous level is pending. When the INR result is available, the Nurse will ~~floow~~follow the process described in step 5 above.
8. The initial warfarin order will not be profiled or administered until the INR result is reported and reviewed and called to the prescriber if necessary.

The following guidelines will be used for monitoring and evaluating anticoagulation therapy for patients on warfarin.

1. <u>Desired INR ranges for oral anticoagulation therapy</u>

Table 1.

Indication	**INR**
VTE prophylaxis VTE treatment PE treatment Prevention of SE Bioprosthetic mitral heart valves*† AMI Rheumatic mitral valve disease, NSR, left atrial diameter > 5.5 cm MAC with history of non-calcific SE MVP with SE or recurrent TIAs on ASA Atrial fibrillation	Goal 2.5; range = 2 to 3
Mechanical prosthetic valves mitral position† Caged-ball or caged-disk mechanical valve† Mechanical valves in any position plus additional thromboembolic risk factors† Antiphospholipid syndrome	Goal 3; range = 2.5 to 3.5
Bileaflet mechanical or Medtronic Hall tilting-disk valve in aortic position, NSR, normal LA size†	Goal 2.5; range 2 to 3

ACCP CHEST Vol. 133, No. 6, June, 2008 Supplement; SE = systemic embolism; AMI = acute myocardial infarction; NSR = normal sinus rhythm; MAC = mitral annular calcification; TIA = transient

ischemic attack; ASA = aspirin; LA = left atrium; MVP = mitral valve prolapse; * warfarin for 3 months then ASA unless another indication for warfarin exists; † Initial IV UFH or LMWH until INR is within desired range for 2 consecutive days.

2. Inpatient warfarin initiation for warfarin naïve patients (new starts)

a. All patients being newly started on warfarin will have a baseline INR, Hgb, and Hct checked within 72 hours prior to initiating therapy.
b. Initial doses will generally be according to table 2. While the initial doses may be higher than subsequent maintenance doses, a traditional loading dose (i.e., 20 mg) of warfarin will not be routinely used.
c. A starting dose of 5 mg to 10 mg daily will be typical as this dose range is sufficient to achieve an INR of ≥ 2 in 4 or 5 days for most patients and minimizes the risk of excessive anticoagulation compared to higher starting doses.
d. Patients < 40 years old and patients receiving medications known to decrease the INR may benefit from higher starting doses (i.e., 7.5 mg to 10 mg).
e. Patients > 60 years old, patients with impaired nutrition, patients with liver disease, patients with congestive heart failure, and patients at a high risk of bleeding should not typically receive starting doses > 5 mg.
f. Concomitant unfractionated heparin (UFH), low-molecular weight heparin (LMWH), or factor Xa inhibitor therapy may be discontinued after 5 days and when the INR has been found to be within the desired range on 2 measurements at least 24 hours apart.
g. The decision to use UFH, LMWH, or factor Xa inhibitor as initial concomitant therapy in patients requiring a rapid anticoagulant effect or in patients with known hypercoagulable conditions will be left to the consulting Physician(s).

h. Concurrent UFH, LMWH, or factor Xa inhibitor therapy is not routinely necessary for outpatient warfarin initiation in low risk conditions (i.e., chronic stable atrial fibrillation). The decision to use these therapies in hospitalized patients will be left to the consulting Physician(s).

i. After the patient has received 7 days of warfarin therapy refer to section 3 below for dosing guides.

Table 2. Initiation of warfarin therapy for warfarin naïve patients

Rapid Anticoagulation Necessary and low bleeding risk	**Warfarin Dose**
Day 1	7.5 - 10 mg
Day 2	5 - 10 mg
INR on Day 3*	
Day 3	2.5 mg – 10 mg per day & INR every 1-3 days until INR is within desired range
Normal Anticoagulation and/or high bleeding risk	**Warfarin Dose**
Day 1	2.5 - 5 mg
Day 2	2.5 - 5 mg
INR on Day 3*	
Day 3	2.5 mg – 7.5 mg per day & INR every 1-3 days until INR is within desired range

*It is acceptable to check the INR daily on any given hospitalized patient if desired

3. <u>Inpatient therapy for patients admitted on warfarin therapy</u>

a. All patients receiving warfarin must have a baseline INR, Hgb, and Hct checked as soon as possible upon admission.

b. Add each daily dose that the patient received for the past **7** days prior to admission to determine the total weekly dose (e.g., 5mg daily x 7 days/week = 35 mg/week).

c. Determine if the measured INR is within, above, or below the desired INR range.

d. Depending on the desired INR range, use Table 3 or Table 4 below to determine the most appropriate dose adjustment with consideration of the patient's clinical status.

e. If patient specific issues exist that are anticipated to increase or decrease the effects of warfarin, deviations from the recommended adjustments in the tables may be required.

Table 3. Warfarin dosing for desired INRs of 2 to 3 (after at least 7 days of continuous dosing)

INR	**Suggested dosage change**
<1.5	Give extra daily dose times 1 and increase weekly dose by 10%-20%

1.5 to 2	Increase weekly dose by 5%-15% (may give extra daily dose times 1) †
3 to 4*	Hold up to 1 daily dose & decrease weekly dose by 5%-10%†
4 to 5*	Hold up to 2 daily doses & decrease weekly dose by 10%-15%†
≥ 5	See "Management of patient with high INR"

*assumes no active bleeding; †If transient cause identified may not need to increase/decrease weekly dose

Table 4. Warfarin dosing for desired INRs of 2.5 to 3.5 (after at least 7 days of continuous dosing)

INR	Suggested dosage change
<1.5	Give extra daily dose times 1 and increase weekly dose by 10%-20%
1.5 to 2.5	Increase weekly dose by 5%-15% (may give extra daily dose times 1) †
3.5 to 4.5*	Hold up to 1 daily dose & decrease weekly dose by 5%-10%†
4.6 to 5*	Hold up to 2 daily doses & decrease weekly dose by 10%-15%†
≥ 5	See "Management of patient with high INR"

*assumes no active bleeding; †If transient cause identified may not need to increase/decrease weekly dose

4. **Management of patients with high INR**
   a. The goals of anticoagulation reversal are to reduce the bleeding risk (as reflected by a decrease in the INR) and to avoid excessive reversal resulting in an INR below the desired range.
   b. Identify the most likely etiology for the increased INR and determine if etiology is transient or persistent.
   c. Evaluate the patient for signs and symptoms of bleeding.
   d. Determine the appropriate course of action according to Table 5 below.
   e. The INR should be checked daily for several days after initiating anticoagulation reversal.
   f. Subcutaneous vitamin K is discouraged since it has not been shown to be more effective than holding oral anticoagulation in clinical studies.

g. Based on the clinical situation, the use of lower doses of vitamin K than are listed in Table 5 may be acceptable.
h. Bridge therapy with a LMWH or factor Xa inhibitor should be considered if overcorrection of INR occurs in a patient with a high thromboembolic risk condition. Refer to Table 6 and Table 7.

Table 5.

INR and clinical situation	**Suggested action(s)**
INR above desired range but < 5 and no significant bleeding	Lower the dose or omit the next dose. Monitor more frequently and resume therapy at a lower dose when the INR is within the desired range. If only minimally above the desired range, or elevation is due to a transient factor, no dose reduction may be necessary.
INR ≥ 5 but < 9 *and* No clinically significant bleeding	Hold 1-2 doses, frequent follow-up, resume at lower dose when INR in desired range. Alternatively, omit dose and give vitamin K (1-2.5mg po), particularly if at increased risk for bleeding. If more rapid reversal is required because the patient requires urgent surgery, vitamin K (< 5mg po) can be given with the expectation that a reduction of the INR will occur in 24 h. If the INR is still high, additional vitamin K (1-2mg po) can be given.
INR ≥ 9 without significant bleeding	Hold warfarin therapy and give higher dose of vitamin K (2.5-5mg po) with the expectation that the INR will be reduced substantially in 24-48 h. Monitor more frequently and use additional vitamin K if necessary. Resume therapy at an appropriate dose when the INR is in the desired range.
Serious or life-threatening bleeding at any INR	Hold warfarin, contact referring physician and/or medical director, 10 mg IV vitamin K slow IV infusion with FFP or prothrombin complex concentrate or rVIIa, depending on the urgency of the situation. Vitamin K can be repeated q 12 h
Administration of vitamin K	In patients with mild to moderately elevated INRs without major bleeding, give vitamin K orally rather than subcutaneously.

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5. Anticoagulation Bridging Guidelines

Table 6. Risk of Thromboembolic Complications

Low	**Intermediate**	**High**
Acute VTE > 12 months ago	Acute VTE within past 3-12	Recurrent VTE within past 3

	months; non severe thrombophilic conditions (heterozygous factor V Leiden, heterozygous factor II mutation); recurrent VTE, active cancer (treated within 6 months or palliative)	months; severe thrombophilia (protein C or S deficiency, antithrombin, antiphospholipid antibodies, or multiple abnormalities)
AF with $CHADS_2$ score of 0-2 (and no prior stroke or TIA).	AF with $CHADS_2$ Score of 3 or 4	AF with $CHADS_2$ score of 5 or 6; recent (within 3 months) stroke or TIA, rheumatic valvular heart disease
Bileaflet mechanical valve in the aortic position, and no other stroke risk factors.	Bileaflet mechanical heart valve in the aortic position and one of the following: AF, prior stroke or TIA, HTN, DM, CHF, Age > 75 yr.	Mechanical heart valve in the mitral position; older (caged-ball or tilting disk) aortic valves; recent (within 6 months) stroke or TIA.

ACCP *Chest.* Vol. 133, No. 6, June, 2008 Supplement; AF=atrial fibrillation; TIA=transient ischemic attack; HTN=hypertension; DM=diabetes mellitus; CHF=congestive heart failure; $CHADS_2$=congestive heart failure-hypertension-age-diabetes-stroke

Table 7. Bridge Therapy Based on Risk for Thromboembolic Complications

Low	Intermediate	High
Discontinue warfarin therapy approximately 5 days prior to surgery, and allow INR to decline to near normal. Two days prior to the procedure give low dose SC LMWH** or no bridging. Consider low dose PO vitamin K if the INR is > 1.5 one to two days before procedure. Resume warfarin 12 to 24 hours and heparin or LMWH 24 to 72 hours after the procedure, according to bleeding risks and when the patient achieves adequate hemostasis.	Discontinue warfarin therapy approximately 5 days prior to surgery and allow INR to decline to near normal. Two days prior to the procedure give therapeutic dose IV UFH†, therapeutic dose SC LMWH††, or low dose SC LMWH**. Stop IV UFH 4 hours before procedure or give the last dose of LMWH 24 hours before the procedure – at half the total daily dose. Consider low dose PO vitamin K if the INR is > 1.5 one to two days before procedure. Resume warfarin 12 to 24 hours and heparin or LMWH 24 to 72 hours after the procedure, according to bleeding risks and when the patient achieves adequate hemostasis.	Discontinue warfarin therapy approximately 5 days prior to surgery and allow INR to decline to near normal. Two days prior to the procedure give therapeutic dose IV UFH† or SC LMWH.†† Stop IV UFH 4 hours before procedure or give the last dose of LMWH 24 hours before the procedure – at half the total daily dose. Consider low dose PO vitamin K if the INR is > 1.5 one to two days before procedure. Resume warfarin 12 to 24 hours and heparin or LMWH and 24 to 72 hours after the procedure, according to bleeding risks and when the patient achieves adequate hemostasis.

ACCP *Chest.* Vol. 133, No. 6, June, 2008 Supplement; **enoxaparin 40 mg daily subcutaneously; †Standard intensity IV unfractionated heparin; ††enoxaparin 1.5 mg/kg/d or 1mg/kg q 12 hours subcutaneously

Table 8. Bridging Guidelines

Days or hours relative to surgery	Anticoagulation management
-10 to -7	Assess thrombosis and bleeding risk. Determine appropriate bridging plan. Evaluate aspirin or other antiplatelet therapy†. Obtain baseline hematology, and serum creatinine. Screen for heparin induced thrombocytopenia (HIT). Obtain INR.
-5 to -4	Stop Warfarin.
-3 to -2	Start heparin or LMWH. Obtain labs if not already performed.
-48 hours to -24 hours	Obtain INR. Consider po vitamin K if INR > 1.5. Stop IV heparin 4 hours prior to procedure or give last LMWH dose (at half the total daily dose) 24 hours before procedure.
0 (procedure)	
+ 24 hours to +72 hours	Resume warfarin at usual maintenance dose 24 h to 72 h post procedure when there is adequate hemostasis. Resume antiplatelet (e.g., aspirin, clopidogrel) 24 h post procedure when hemostasis is adequate. Start heparin or LMWH, if indicated, and hemostasis achieved. Obtain INR and CBC. Modify warfarin dose if needed.
≥ 4	Obtain INR and adjust warfarin dose, if needed. Stop heparin or LMWH if INR > 2.

† for patients not at high risk of cardiac events, stopping antiplatelet drugs is recommended. For patients at a high risk for cardiac events undergoing noncardiac surgery, aspirin may be continued up to and beyond the time of surgery; clopidogrel should be stopped at least 5 days and, preferably, within 10 days prior to surgery; ACCP *Chest.* Vol. 133, No. 6, June, 2008 Supplement

NOTE: for warfarin patients who require anticoagulant effect reversal for an urgent procedure, consider IV or PO vitamin K (2.5 to 5mg). If a more immediate reversal is desired, consider fresh-frozen plasma or another prothrombin concentrate in addition to the IV or PO vitamin K.

V. REFERENCES:

1. Joint Commission National Patient Safety Goal 3E.
2. Willey ML, Chagan L, Sisca TS, et al. A pharmacist-managed anticoagulation clinic: Six-year assessment of patient outcomes. *Am J Health-Syst Pharm*. 2003;60:1033-7.
3. Chiquette E, Amato MG, Bussey HI. Comparison of an anticoagulation clinic with usual medical care. Anticoagulation control, patient outcomes, and health care costs. *Arch Intern Med*. 1998;158:1641-1647
4. Chamberlain MA, Sageser NA, Ruiz, D. Comparison of anticoagulation clinic patient outcomes with outcomes from traditional care in a family medicine clinic. *J Am Board Fam Pract*. 2001;14:16-21.
5. Witt DM, Sadler MA, Shanahan RL, et al. Effect of a Centralized clinical pharmacy anticoagulation service on the outcomes of anticoagulation therapy. *Chest*. 2005;127:1515-1522.
6. Eighth ACCP Conference on Antithrombotic and Thrombolytic Therapy. *Chest*. 2008 June 133 (Suppl): 67S-968S.
7. CHS Policy #14-10-P (2008)

VI. STAKEHOLDERS

N/A

~~**Reviewed:**~~	~~1st~~	~~2nd~~	~~3rd~~	~~4th~~	~~5th~~
~~Date:~~	~~10/08~~	~~6/12~~	~~7/19~~	~~7/2022~~	
~~By:~~		~~J.Gavin~~	~~J.Gavin~~	~~J.Gavin~~	
~~**Revised:**~~	~~1st~~	~~2nd~~	~~3rd~~	~~4th~~	~~5th~~
~~Date:~~	~~10/09~~				
~~By:~~	~~J.Gavin~~				

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Anticoagulant Management	Policy #	PHARM004
Responsible	Pharmacy Director	Revised/Reviewed	07/2022

~~Policy/Procedure Title~~	~~Anticoagulant Management~~	~~Manual Location~~	~~Provision of Care~~		
~~Policy/Procedure #~~	~~PHARM004~~	~~Effective~~	~~7/19~~	~~Page~~	~~1 of 7~~
~~Department Generating Policy~~	~~Pharmacy~~	~~Revised~~			

I. PURPOSE:

A. To develop and implement standardized practices for anticoagulant therapy that optimizes therapeutic benefits and minimizes associated risks to reduce the likelihood of patient harm associated with this type of therapy~~.~~.

B. Our organization strives to improve medication management across the continuum of care while reducing the potential for adverse outcomes

II. POLICY:

A. Evidence-based guidelines shall be used to develop a comprehensive anticoagulant management program.

B. Policies and procedures shall be utilized to ensure the safe and effective use of anticoagulant therapy and reduce the harm associated with use~~.~~.

C. Policies and procedures direct safe and effective measures to be used throughout the medication use process that includes anticoagulant procurement, storage, ordering/prescribing, preparing/dispensing, administration, and monitoring.

D. Approved protocols or guidelines shall be available for:

- Initiation and maintenance of anticoagulant therapy that are appropriate to the medication used, the condition being treated, and the risk for serious drug interactions.
- Reversal of anticoagulant and management of bleeding events related to each anticoagulant medication, including the use of reversal agents and bleeding management modalities.

E. The hospital shall use evidence-based practice guidelines to develop a process for the perioperative management of all patients on oral anticoagulants.

F. Education shall be provided to prescribers, staff, patients, and families involved with anticoagulant therapy.

G. Anticoagulant use shall be evaluated, assessed, and improved through ongoing performance improvement activities aimed at assuring safe and effective use of these medications.

III. PROCEDURE:

A. Procurement

1. Oral anticoagulants shall be purchased or packaged in unit dose form only in available strengths to meet all dosing needs.

2. Formulary choices shall be limited as clinically acceptable to reduce potential for medication errors.
3. Parenteral anticoagulants shall be purchased or packaged to meet all dosing needs.
4. Standard facility defined concentrations shall be used for intravenous anticoagulation.

B. Storage

1. Pharmacy Storage

a. Containers shall be labeled with high alert stickers and shall be used within the pharmacy to signal the high alert nature of selected anticoagulants identified on the high alert medication list.

2. Patient Care Area Storage

a. Storage of anticoagulant medication shall be limited to containment in automated dispensing machines.

b. Patient Home Medications: Individual patient doses (non-formulary items) shall be stored in a patient labeled bag located in the designated space for your facility (e.g., automated dispensing device) (see Policy #1577: *Patient Own Medications/Drugs*).

C. Ordering and Prescribing:

1. Protocols and Guidelines

a. Hospital approved protocols and evidence-based practice guidelines shall be available for the initiation, maintenance and monitoring of anticoagulant therapy that address medication selection; dosing, including adjustments for age and renal or liver function; drug-drug interactions; and other risk factors as applicable.

b. Approved protocols and guidelines for reversal of anticoagulation and management of bleeding events related to each anticoagulant medication, including the use of reversal agents and bleeding management modalities shall be available.

c. Approved protocols and evidence-based practice guidelines shall be available for the perioperative management of all patients on oral anticoagulants, including situations in which the oral anticoagulant is stopped, the duration it is held, and the timing and dosing for restarting the medication.

2. General

a. Before initiating anticoagulant therapy, a patient's baseline coagulation status shall be assessed and documented.

b. Anticoagulant therapy shall be initiated pursuant to a licensed practitioner order utilizing medical staff approved, evidence-based, established paper and/or electronic order sets and protocols.

c. **Warfarin:** A current International Normalization Ratio (INR) shall be used to adjust and monitor therapy~~—~~. Baseline status and current INRs are documented in the medical record. Warfarin dosing is managed by pharmacy per Warfarin Inpatient Protocol unless otherwise specified by the physician.

d. **Non-warfarin anticoagulants:** Dosing is based on indication, shall be weight-based when indicated and adjusted for age, renal or hepatic function as appropriate.

e. Orders for anticoagulants shall be checked against the electronic health record (EHR) for relevant patient data, including current weight, allergies, age, pregnancy and/or lactation status and labs, as appropriate prior to approval by the pharmacist.

f. Alerts for all patients, including elderly and pediatric patients, on anticoagulants shall be reviewed by a pharmacist prior to final approval. Interventions shall be documented.

g. Order review by the pharmacist shall include, but is not limited to, the following:
   - Appropriate indication for use
   - Weight-based dosing as indicated
   - Potential drug-drug and drug-food interactions
   - Lab values (to include baseline and current INR for warfarin and baseline labs as required for other anticoagulants)
   - Therapeutic duplications

h. Dose adjustments shall be based on age, renal and/or hepatic function

i. Evidence-based resources (i.e. Clinical Pharmacology, LexiComp, Micromedex etc.) shall be accessible by pharmacists to manage potential drug-drug and drug-food interactions.

j. Anticoagulants requiring renal dose adjustment shall be monitored and adjusted by pharmacy per policy #1957: *Adult Renal Dosing Guidelines*.

k. Changes in dosing made by pharmacy pursuant to established protocols shall be entered by the pharmacist under the ordering physician. Therapy changes shall be documented in the medical record.

D. Preparation and Dispensing

1. Oral anticoagulants shall be dispensed in ready to use unit dose packaging.
2. Splitting tablets on nursing units is discouraged.
3. Parenteral anticoagulation shall be prepared or purchased in accordance with established facility standard concentrations.
4. Parenteral doses that do not correspond to available product sizes shall have auxiliary labeling to display the correct dose amount to administer.
5. Commercially prepared heparin flushes shall be dispensed by pharmacy per patient order and are stored in automated dispensing device. They shall not be available as unsecured floor stock, and shall be contained within the automated dispensing machine. Flushes are excluded from anticoagulant management policy and procedures.
6. Baseline and maintenance labs shall be verified by the pharmacist prior to dispensing.
7. Required labs may be entered per specified medication protocols if not ordered by the physician.
8. Anticoagulants are considered high-alert medications and should include high-alert labeling.
9. High-alert anticoagulants should require acknowledgement of alert status.

E. Administration

1. Standard administration times for daily doses shall be used unless otherwise ordered by physician. Please refer to policy #1569: *Administration of Drug: Medication Administration Times.*
2. Nurse shall review and acknowledge appropriate laboratory parameters prior to administration. Physician should be alerted prior to administration for critical laboratory parameters.

3. Anticoagulants given by intravenous infusion shall be administered using a programmable infusion pump.
4. Bolus/loading doses should be programmed to deliver from the pump when applicable.
5. Nurse shall use a facility approved protocol to verify rate and dosing adjustments for intravenous infusions.—. Nurse double check shall be required prior to heparin administration to verify the correct patient, drug, concentration, dose, rate, pump settings, and IV-line are chosen.
6. High-alert anticoagulants should require acknowledgement of alert status. Rate and rate changes shall be double checked and documented in the patient record.
7. Subcutaneous anticoagulants shall be administered with appropriate site documentation in the medical record.—. Sites for deep subcutaneous injections should be rotated. (i.e. enoxaparin – anterolateral and left and right posterolateral abdominal wall; heparin – above the iliac crest or abdominal fat layer)

F. Monitoring

1. Baseline laboratory tests (e.g., hemoglobin, hematocrit, serum creatinine, platelet count, INR, aPTT, CBC CMP, SCr, etc.) as defined below are obtained prior to anticoagulant administration.—. Baseline laboratory tests should be obtained within 24 hours before initiation of therapy.
2. Ongoing required laboratory monitoring shallbeshall be obtained as defined below or as defined in appropriate facility policy/procedure.
3. For baseline and ongoing anticoagulant monitoring parameters for intravenous anticoagulants, please refer to applicable policies and procedures (Policy #2449: *MedicationPolicyMedication Policy: Unfractionated Heparin (UFH) Drip Protocols*)
4. Anticoagulant-associated lab values shall be communicated in a timely manner to the provider or the person managing the anticoagulation therapy.
5. Required laboratory tests may be entered per protocol if not ordered by physician.

Facility-Established Required Anticoagulant Monitoring Parameters*		
Medication	**Baseline Requirements**	**Ongoing Inpatient Monitoring Requirements**
Intravenous anticoagulants	PT/aPTT, CBC,CMP	PT/aPTT CBC, CMP daily
Heparin Subcutaneous	CBC	CBC every 48 hours
LMWH	CBC, BMP, SCr	CBC, BMP, SCr daily for therapeutic dosing
Warfarin	PT/INR, CBC	Daily
Other oral anticoagulants	CBC, SCr, CMP	Not required

***CBC- contains: hemoglobin, hematocrit, and platelet count; CMP- contains: BUN, Creatinine, AST, ALT, ALP; BMP- contains: BUN, creatinine.**

6. Pharmacy

a. All anticoagulation therapy shall be screened and monitored by the pharmacist for high risk and significant drug interactions. Drug interactions that are identified as high risk are communicated directly to the prescriber.

7. Dietary

a. All anticoagulation therapy subject to drug-food interactions shall be screened by the Clinical dietitian for high risk and significant drug-food interactions. The dietitian shall reference evidence-based guidelines (i.e. American Dietetic Association Nutritional Care Manual).

8. Laboratory

a. Laboratory shall be responsible for communication of the heparin therapeutic range annually and any time a reagent change occurs. This information shall be communicated to the Medical Staff, Nursing Units, and Pharmacy.

b. Laboratory shall be responsible for notification in accordance with the guidelines set in the laboratory policy for critical laboratory parameters.

9. Nursing

a. Nursing shall monitor the patient receiving anticoagulation for potential adverse reactions including signs/symptoms of bleeding in addition to the required laboratory markers. The ordering practitioner shall be alerted by Nursing immediately for the following parameters:

Alarm Parameters/ Critical Laboratory Parameters	
Hemoglobin (Hgb)	≤ 7.0 gm/dl or ≥ 20gm/dl
Platelets (PLT)	≤ 50 K/uL or ≥ 1000 K/uL
Any signs or symptoms of clotting or bleeding	Presence
Critical INR	≥ 4.0
aPTT	facility specific

G. Education

1. Staff Education

a. The hospital shall educate staff and licensed independent practitioners involved in the management of anticoagulants as identified by the facility.

2. Patient and Family Education

a. Nursing personnel are the primary patient/family educators, but they may be assisted by various clinical staff. Pharmacy may also be consulted to provide anticoagulant education.

b. Prior to implementation of patient teaching, the provider must assess and address potential learning barriers.

c. Patient/family education shall be specific to the anticoagulant medication prescribed and includes at minimum the following:

- Name, strength, dose, and description of anticoagulant medication

- Indication for therapy
- Goals of therapy and desired INR range (if applicable)
- Adherence to medication dosing and schedule
- Potential drug-drug and drug-food interactions
- Potential for adverse drug reactions, including: signs and symptoms of embolic events and what to do, and signs and symptoms of bleeding and what to do
- Importance of laboratory blood tests (if required)
- Potential risks during pregnancy and lactation, if applicable.
- Importance of follow-up physician office appointments

d. Provision of anticoagulation education shall be documented in the medical record.

e. Written educational materials may be provided.
   - The Institute of Safe Medication Practices provides consumer education sheets for high-alert medications such as anticoagulants copies may be found via https://consumermedsafety.org/

H. Performance Measurements

1. The facility shall evaluate its anticoagulation management safety practices, takes appropriate action to improve its practices, and measures the effectiveness of those practices on a regular basis through performance improvement activities.
2. This evaluation shall include identification and reporting (including outcomes and actions taken) of at minimum:
   - Medication errors
   - Adverse drug reactions
3. Review of reported events and evaluation of the effectiveness of those actions shall occur at least quarterly by the Pharmacy and Therapeutics Committee.
4. Examples of process Measures could include any of the following:
   - Rate of use of anticoagulation protocols
   - Percentage of patients receiving anticoagulation education prior to discharge
   - Percentage of patients with appropriate VTE prophylaxis
   - Percentage of patients with appropriate duration of overlap anticoagulation therapy
   - Percentage of patients with appropriate lab monitoring of anticoagulation parameters
   - Percentage of patients with supratherapeutic INRs
   - Number of days to therapeutic INR
   - Percentage of patients with follow-up appointment scheduled prior to discharge
5. Outcome measures could include any of the following:
   - Incidence of thrombotic events
   - Incidence of bleeding events
   - Incidence of incidental effects (e.g. HIT)

REFERENCES:

- Horner MA, Duane TM, Ehlers AP. et al. et al. American College of Surgeons' Guidelines for the Perioperative Management of Antithrombotic Medication. J Am Coll Surg. November 2018.
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- Ageno W, Gallus AS, Wittkowsky A, Crowther M, Hylek EM, Palareti G; American College of Chest Physicians. Oral anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012 Feb;141(2 Suppl):e44S-88S. doi: 10.1378/chest.11-2292. Review.
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- Morton C. Marshall P. P. Pearl of knowledge evidence based summary documents: dabigatran (Pradaxa) guidelines. [Internet]. Health Partners. 2011. Cited 2015 Feb 13. 6 pgs. Available at: https://www.healthpartners.com/ucm/groups/public/@hp/@public/@ime/@content/documents/documents/cntrb_010830.pdf
- 2017 ACC Expert Consensus Decision Pathway on Management of Bleeding in Patients on Oral Anticoagulants: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways. J Am Coll Cardiol 2017;Dec 1.
- 2017 ACC Expert Consensus Decision Pathway for Periprocedural Management of Anticoagulation in Patients With Nonvalvular Atrial Fibrillation John U. Doherty, Ty J. Gluckman, William J. Hucker, James L. Januzzi, Thomas L. Ortel, Sherry J. Saxonhouse, Sarah A. Spinler. Journal of the American College of Cardiology Feb 2017, 69 (7) 871-898; DOI: 10.1016/j.jacc.2016.11.024
- 2011 clinical practice guide on anticoagulant dosing and management of anticoagulant-associated bleeding complications in adults [homepage on the Internet]. American Society of Hematology. 2011 [cited 2 September 2016]. Available from: http://www.hematology.org/Clinicians/Guidelines-Quality/Quick-Ref/525.aspx
- Most recent available drug monographs were referenced for each product listed – available upon request.
- The Joint Commission National Patient Safety Goal NPSG.03.05.01
- CMS Conditions of Participation §482.25(b)
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3815430

Policy/Procedure Title	Anticoagulant Management	**Manual Location**	Provision of Care
Policy/Procedure #	PHARM004	**Page**	8 of 8

Policy Title	Anticoagulant Management	**Policy #**	PHARM004

Revised Date: _____ _____ _____ _____ _____
By: _____ _____ _____ _____ _____

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: July 26, 2023
Report Type: Discussion

Title: Medical Committees Reports July 2023

Recommendation: Pass a **Motion** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of July 2023; 2) OPPE template for Pediatric Physicians; 3) Reappointment Application Attestation Questions; and 4) 2023 Surgical Quality Review Indicators

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

Analysis

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

Financial Impact: None.

Attachments:

1-Medical Executive Committee Reports
2-OPPE Template Pediatrics Physicians
3-Reappointment Attestation Questions
4- 2023 Surgical Quality Review Indicators

WATSONVILLE COMMUNITY HOSPITAL

Medical Executive Committee Summary – July 26, 2023
ITEMS FOR BOARD APPROVAL

Credentials Committee

INITIAL APPOINTMENTS: (3)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Avelar, Taurino, MD	Nephrology / Provisional	Medicine	Telemedicine Nephrology	07/27/2023 – 06/30/2025
Hubner, Gwendolyn, MD	Pediatric Hospitalist / Provisional	Pediatrics	Pediatrics	07/27/2023 – 06/30/2025
Yellin, Rachelle, DO	Emergency Medicine / Provisional	Emergency Medicine	Emergency Medicine Sedation	07/27/2023 – 06/30/2025

REAPPOINTMENTS: (6)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Harkins, Andrew, MD	Pediatric Hospitalist	Pediatrics	Pediatrics	08/01/2023 - 07/31/2025
Harraher, Ciara, MD	Surgery-Neurological	Surgery	Neurosurgery; Fluoroscopy	08/01/2023 - 07/31/2025
McHugh, Kevin, MD	Diagnostic Radiology	Medicine	Radiology	08/01/2023 - 07/31/2025
Patel, Saharsh, MD	Pediatric Hospitalist	Pediatrics	Pediatrics	08/01/2023 - 07/31/2025
Surdock, Nicole, MD	Podiatry	Surgery	Podiatry; Fluoroscopy	08/01/2023 - 07/31/2025
Yousefi, Arian, MD	Internal Medicine Hospitalist	Medicine	Internal Medicine; Critical Care, Non-Intensivist	08/01/2023 – 11/30/2024

MODIFICATION / ADDITION OF PRIVILEGES: (3)

NAME	SPECIALTY / STATUS	Privileges
Alexander, Charlotte, MD	OBGYN / Provisional	GYN Surgery
Harmon, Liv, MD	General Surgery / Active	Robotic General Surgery Privileges
Goodstein, Monica, MD	General Surgery / Provisional	Robotic General Surgery Privileges

STAFF STATUS MODIFICATIONS: (11)

NAME	SPECIALTY / DEPARTMENT	RECOMMENDATION
Sharma, Shikha, MD	Pain Management / Surgery	Release from Proctoring
Amoussou, Dela, MD	Telemedicine Neurology / Medicine	Voluntary Resignation, effective 6/27/2023
Bojedla, Sundeep, DO	Telemedicine Neurology / Medicine	Voluntary Resignation, effective 6/27/2023
Cheung, Tyler, MD	Telemedicine Neurology / Medicine	Voluntary Resignation, effective 6/27/2023
Chow, Matthew, MD	Telemedicine Neurology / Medicine	Voluntary Resignation, effective 6/27/2023

Gadient, Paul, MD	Telemedicine Neurology / Medicine	Voluntary Resignation, effective 6/27/2023
Hudson, Kristen, MD	Telemedicine Neurology / Medicine	Voluntary Resignation, effective 6/27/2023
Minazad, Yafa, DO	Telemedicine Neurology / Medicine	Voluntary Resignation, effective 6/27/2023
Moghbel, Shahla, DO	Telemedicine Neurology / Medicine	Voluntary Resignation, effective 6/27/2023
Noya Santana, Monica, MD	Telemedicine Neurology / Medicine	Voluntary Resignation, effective 6/23/2023
Shahid, Noor-E-Ain, MD	Telemedicine Neurology / Medicine	Voluntary Resignation, effective 6/27/2023

TEMPORARY PRIVILEGES: (3)

NAME	SPECIALTY / DEPARTMENT	DATES
Alexander, Charlotte, MD	OBGYN / GYN Surgery	07/14/2023 – 07/26/2023
Goodstein, Monica, MD	General Surgery / Robotic General Surgery	07/14/2023 – 07/26/2023
Harmon, Liv, MD	General Surgery / Robotic General Surgery	07/14/2023 – 07/26/2023
Hubner, Gwendolyn, MD	Pediatric Hospitalist / Pediatrics	07/17/2023 – 07/27/2023
Yellin, Rachelle, DO	Emergency Medicine / Emergency Medicine	07/14/2023 – 07/27/2023

INTERDISCIPLINARY PRACTICE CREDENTIALS REPORT

Initial Appointment: (1)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Radcliffe, Collin, CRNA	Nurse Anesthetist / Allied Health Professional	Surgery	Nurse Anesthetist	07/27/2023 – 06/30/2025

REAPPOINTMENT: (1)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Bernatsky, Vania, PA-C	Physician Assistant / Allied Health Professional	Surgery	Physician Assistant Surgery	08/01/2023-07/31/2025

Temporary Privileges: (1)

NAME	SPECIALTY / DEPARTMENT	DATES
Radcliffe, Collin, CRNA	Nurse Anesthetist / Allied Health Professional	**06/30/2023 - 07/10/2023**

STAFF STATUS MODIFICATIONS: (1)

NAME	SPECIALTY / DEPARTMENT	RECOMMENDATION
Lamm, Zachary, PA-C	Physician Assistant / Surgery	Release from Proctoring

WATSONVILLE COMMUNITY HOSPITAL

PEDIATRIC PHYSICIAN OPPE REPORT

Metrics	Source/ Triggers	Physician Name			
Unplanned Readmission within 48 hours of discharge (Excluding hyperbilirubinemia < 22 mg/dl)	**Peer Review 100%**				
Appropriateness of pediatric and IICN transfers	**Peer Review 100%**				
Medical Record Delinquencies (Suspensions)	**HIM Trend**				
CPOE Compliance	**HIM 80%**				
Peer Review Cases: Rated 3 or 4, PI Plan or FPPE	**2 level 4 or 4 level 3 & 4 in 24 months**				
Validated Patient Complaints	**2 incidents in 8 months**				
Validated Disruptive Physician Complaints	**3 significant incidents in 12 months**				

☐ No issues identified; continue unrestricted current privileges

☐ Track and trend for pattern analysis

☐ Refer to MQRC for possible FPPE

☐ Other _____

Department Chair: Carmin Powell, MD Date

PROPOSED UPDATED REAPPOINTMENT ATTESTATION QUESTIONS

The current reappointment application has 5-sections of attestation questions. Most are redundant and unnecessary. **MEC recommendation is to follow the initial application attestation questions with the statement: <u>When answering the following questions, please reference the time-period since your last appointment unless indicated elsewise</u>:**

If the answer to the below is YES, please provide additional detailed information

<u>LICENSURE / CERTIFICATION ATTESTATION</u>

1. **Has your professional** license to practice medicine, or registration in any jurisdiction, ever been challenged, voluntarily or involuntarily relinquished, suspended, limited, revoked, denied, restricted, non-renewed, surrendered or subjected to probationary conditions or have your voluntarily or involuntarily relinquished any such license or registration or voluntarily or involuntarily accepted any such actions or conditions or have you been fined or received a letter of reprimand or is such action pending?

2. **Has your DEA license** or state narcotics registration ever been voluntarily or involuntarily relinquished, suspended, limited, revoked, denied, or restricted for reasons other than non-completion of medical records or are any such actions pending?

<u>APPOINTMENT / PRIVILEGES ATTESTATION</u>

3. **Has your application for appointment or reappointment** to the medical staff or any other health care facility ever been denied?

4. **Have you ever surrendered**, allowed to expire, voluntarily or involuntarily withdrawn or had terminated a request for membership or clinical privileges, terminated contractual participation or employment, or voluntarily or involuntarily resigned from any medical organization, including while under investigation for possible incompetence or improper professional conduct, or breach of contract, or in return for such an investigation not being conducted, or is any such action pending?

5. **Has your medical** staff membership ever been voluntarily or involuntarily terminated, suspended, limited, revoked, denied or surrendered for any reason, including reasons related to professional competence or conduct or are any such actions pending?

6. **Have your clinical privileges at** any medical organization ever been voluntarily or involuntarily terminated, suspended, limited, restricted, revoked, denied or surrendered for any reason, including reasons related to professional competence or conduct or are any such actions pending?

7. **Have you ever been subjec**t to a Focused Professional Practice Review for cause at any medical organization, or subject to probationary conditions other than for non-completion of medical records or are any such actions pending?

MEDICARE / MEDICAL / ETHICAL SANCTIONS

8. **Have you ever been charged**, suspended, fined, disciplined, or otherwise sanctioned, subjected to probationary conditions, restricted or excluded, or have you voluntarily or involuntarily relinquished eligibility to provide services or accepted conditions on your eligibility to provide services, for reasons relating to possible incompetence, or improper professional conduct, or breach of contract or program conditions by Medicare, Medicaid, or any federal program or is any such action pending?

9. **Have you** ever been disciplined for a violation of ethical standards by a professional organization?

TRAINING ATTESTATION

10. **During your internship**, residency, fellowship and/or formal clinical appointment were you ever disciplined, suspended, placed upon probation, formally reprimanded, requested or compelled to relinquish your status as a student in good standing or asked to resign? During training, did you incur a leave for thirty (30) or more consecutive days?

BOARD CERTIFICATION

11. **Have you ever been denied** certification or recertification by a specialty board or chosen not to recertify, or have you ever voluntarily or involuntarily surrendered your board certification while under investigation?

LEGAL ATTESTATION

12. **Have you ever been arrested**, accused or convicted of, or pled guilty to a criminal offense (e.g., felony or misdemeanor) and/or placed on deferred adjudication or probation for a criminal offense other than a misdemeanor traffic offense? Or are any such actions pending?

INSURANCE MALPRACTICE ATTESTATION

13. **Have any judgments** been entered against you, or settlements been agreed to by you in any professional liability cases? Or are there any professional liability lawsuits and/or arbitrations against you that have been dismissed or are currently pending? If yes, please complete the attached form

14. **Has your professional liability** insurance ever been terminated, not renewed, restricted, or modified (e.g. reduced limits, restricted coverage, surcharged), or have you ever been denied professional liability insurance, or has any professional liability carrier provided you with written notice of any intent to deny, cancel, not renew, or limit your professional liability insurance or its coverage of any procedures?

15. Has your professional liability insurance been in continuous coverage for the prior 5-years?

HEALTH ATTESTATION

Are you currently suffering from any condition for which you are not being appropriately treated that impairs your judgment or that would otherwise adversely affect your ability to practice medicine in a competent, ethical, and professional manner? (Yes/No)

**For ADA compliance, If YES, please describe any accommodations that could reasonably be made to facilitate your practice without risk of compromise to patients or staff.

WATSONVILLE COMMUNITY HOSPITAL

Surgical Quality Review Indicators for 2023

1. All post-op deaths prior to discharge
2. Unplanned removal or injury, repair of organ during operative procedure
3. Unplanned return to OR within 15 days
4. Wound dehiscence with rupture
5. SSI
6. Post-op DVT/PE
7. Post-op PNA

Approved by Surgical Quality Review Committee, 7/12/2023

Approved by Medical Executive Committee, 7/18/2023

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: July 26 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: July 26, 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.

Attachments
A: Financial Performance Report
B: Presentation

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

CURRENT PERIOD					YTD			
Jun-23	BUDGET	VARIANCE	% VARIANCE		ACTUAL	BUDGET	VARIANCE	% VARIANCE
				Operating Revenues				
30,546,468	35,733,376	(5,186,908)	-14.5%	Inpatient Revenue	176,653,428	211,562,780	(34,909,352)	-16.5%
55,987,005	53,458,883	2,528,122	4.7%	Outpatient Revenue	317,366,735	290,423,394	26,943,341	9.3%
86,533,473	**89,192,259**	**(2,658,786)**	**-3.0%**	**Total gross patient revenue**	**494,020,163**	**501,986,174**	**(7,966,011)**	**-1.6%**
				Deductions From Revenue:				
77,192,426	77,300,407	(107,981)	-0.1%	Contractual Allowances	436,296,762	435,517,613	779,148	0.2%
(1,599,179)	(1,599,179)		0.0%	QAF	(9,595,076)	(9,595,076)		0.0%
(128,059)	(128,059)		0.0%	Disproportionate Share DSH	(768,351)	(768,351)		0.0%
75,465,188	**75,573,169**	**(107,981)**	**-0.1%**	**Total Deductions From Rev**	**425,933,335**	**425,154,187**	**779,148**	**0.2%**
11,068,285	**13,619,090**	**(2,550,805)**	**-18.7%**	**Net Revenue**	**68,086,828**	**76,831,987**	**(8,745,159)**	**-11.4%**
184,462	116,145	68,317	58.8%	Provision for Bad Dbt	(345,805)	655,196	(1,001,001)	-152.8%
10,883,823	**13,502,944**	**(2,619,121)**	**-19.4%**	**Collectible Patient Revenue**	**68,432,633**	**76,176,791**	**(7,744,158)**	**-10.2%**
84,476	132,138	(47,662)	-36.1%	Other Revenue	3,394,488	797,232	2,597,256	325.8%
10,968,299	**13,635,082**	**(2,666,783)**	**-19.6%**	**Total Net Operational Revenue**	**71,827,121**	**76,974,023**	**(5,146,902)**	**-6.7%**
				Operating Expenses				
5,314,821	6,303,459	(988,638)	-15.7%	Salaries & Wages	34,753,947	34,982,411	(228,464)	-0.7%
1,730,221	2,028,835	(298,614)	-14.7%	Benefits	9,920,041	12,280,513	(2,360,472)	-19.2%
594,517	506,000	88,517	17.5%	Contract Labor	3,432,256	3,356,000	76,256	2.3%
7,639,559	**8,838,294**	**(1,198,735)**	**-13.6%**	**Subtotal Salaries Wages & Benefits**	**48,106,244**	**50,618,925**	**(2,512,681)**	**-5.0%**
606,012	828,940	(222,928)	-26.9%	Medical Spec Fees	3,977,817	5,022,317	(1,044,500)	-20.8%
801,712	991,447	(189,735)	-19.1%	Supplies	5,598,590	5,488,453	110,137	2.0%
124,252	100,945	23,307	23.1%	Repairs & Maintenance	623,397	609,036	14,361	2.4%
156,209	161,358	(5,149)	-3.2%	Utilities	1,359,999	974,343	385,656	39.6%
886,998	1,185,825	(298,827)	-25.2%	Purchased Services	7,193,840	8,701,717	(1,507,877)	-17.3%
154,162	210,739	(56,577)	-26.8%	Lease Cost and Rent	946,084	1,254,928	(308,844)	-24.6%
203,964	290,020	(86,056)	-29.7%	Prop Taxes & Ins	1,119,267	1,656,035	(536,768)	-32.4%
825	4,167			Marketing	-	25,000		
653,947	926,779	(272,832)	-29.4%	Other Operating Exp	3,918,966	5,922,674	(2,003,708)	-33.8%
11,227,640	**13,538,515**	**(2,310,875)**	**-17.1%**	**Total Operating Exp**	**72,844,204**	**80,273,429**	**(7,429,225)**	**-9.3%**
(259,341)	**96,568**	**(355,909)**	**-368.6%**	**EBITDA**	**(1,017,083)**	**(3,299,406)**	**2,282,323**	**-69.2%**
82,465	96,850	(14,385)	-14.9%	Depreciation and Amortization	534,624	578,578	(43,954)	-7.6%
382,375	402,641	(20,266)	-5.0%	Interest	2,322,816	2,411,267	(88,451)	-3.7%
464,840	**499,491**	**(34,651)**	-6.9%	**Total Other Expenses**	**2,857,440**	**2,989,845**	**(132,405)**	-4.4%
(724,181)	**(402,923)**	**(321,258)**	79.7%	**Net Income/Loss from Operations**	**(3,874,523)**	**(6,289,251)**	**2,414,728**	-38.4%

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

CURRENT PERIOD					YTD			
Jun-23	BUDGET	VARIANCE	% VARIANCE		ACTUAL	BUDGET	VARIANCE	% VARIANCE
				Operating Revenues				
30,546,468	35,733,376	(5,186,908)	-14.5%	Inpatient Revenue	176,653,428	211,562,780	(34,909,352)	-16.5%
55,408,782	52,946,847	2,461,935	4.6%	Outpatient Revenue	314,231,209	287,540,197	26,691,012	9.3%
85,955,250	**88,680,223**	**(2,724,973)**	**-3.1%**	**Total gross patient revenue**	**490,884,637**	**499,102,978**	**(8,218,341)**	**-1.6%**
				Deductions From Revenue:				
76,844,551	77,016,763	(172,212)	-0.2%	Contractual Allowances	434,374,037	433,910,018	464,019	0.1%
(1,599,179)	(1,599,179)		0.0%	QAF	(9,595,076)	(9,595,076)		0.0%
(128,059)	(128,059)		0.0%	Disproportionate Share DSH	(768,351)	(768,351)		0.0%
75,117,313	**75,289,525**	**(172,212)**	**-0.2%**	**Total Deductions From Rev**	**424,010,610**	**423,546,591**	**464,019**	**0.1%**
10,837,937	**13,390,698**	**(2,552,761)**	**-19.1%**	**Net Revenue**	**66,874,027**	**75,556,386**	**(8,682,359)**	**-11.5%**
180,002	113,562	66,440	58.5%	Provision for Bad Dbt	(340,689)	640,769	(981,458)	-153.2%
10,657,935	**13,277,136**	**(2,619,201)**	**-19.7%**	**Collectible Patient Revenue**	**67,214,716**	**74,915,617**	**(7,700,901)**	**-10.3%**
17,271	113,024	(95,753)	-84.7%	Other Revenue	2,978,031	681,912	2,296,119	336.7%
10,675,206	**13,390,160**	**(2,714,954)**	**-20.3%**	**Total Net Operational Revenue**	**70,192,747**	**75,597,529**	**(5,404,782)**	**-7.1%**
				Operating Expenses				
5,079,315	6,022,137	(942,822)	-15.7%	Salaries & Wages	33,262,012	33,326,059	(64,047)	-0.2%
1,690,574	1,971,538	(280,964)	-14.3%	Benefits	9,644,516	11,894,945	(2,250,429)	-18.9%
594,517	506,000	88,517	17.5%	Contract Labor	3,432,256	3,356,000	76,256	2.3%
7,364,406	**8,499,675**	**(1,135,269)**	**-13.4%**	**Subtotal Salaries Wages & Benefits**	**46,338,784**	**48,577,004**	**(2,238,220)**	**-4.6%**
593,815	816,758	(222,943)	-27.3%	Medical Spec Fees	3,930,478	4,927,772	(997,294)	-20.2%
794,177	985,000	(190,823)	-19.4%	Supplies	5,558,264	5,450,914	107,350	2.0%
124,221	100,828	23,393	23.2%	Repairs & Maintenance	623,255	608,332	14,923	2.5%
155,231	160,394	(5,163)	-3.2%	Utilities	1,352,391	967,713	384,678	39.8%
1,050,958	1,152,275	(101,317)	-8.8%	Purchased Services	7,162,186	8,499,631	(1,337,445)	-15.7%
130,676	189,964	(59,288)	-31.2%	Lease Cost and Rent	801,262	1,146,115	(344,853)	-30.1%
192,534	263,544	(71,010)	-26.9%	Prop Taxes & Ins	1,072,357	1,590,050	(517,693)	-32.6%
825	-	825		Marketing	3,019	-	3,019	
-	-			Management Fees	-	150,000	(150,000)	-100.0%
650,775	924,419	(273,644)	-29.6%	Other Operating Exp	3,902,300	5,754,028	(1,851,728)	-32.2%
11,057,618	**13,092,857**	**(2,035,239)**	**-15.5%**	**Total Operating Exp**	**70,744,296**	**77,671,559**	**(6,927,263)**	**-8.9%**
(382,412)	**297,303**	**(679,715)**	**-228.6%**	**EBITDA**	**(551,549)**	**(2,074,030)**	**1,522,481**	**-73.4%**
-	-			Depreciation and Amortization	-	-		
3,936	16,183	(12,247)	-75.7%	Interest	37,788	92,515	(54,727)	-59.2%
3,936	**16,183**	**(12,247)**	-75.7%	**Total Other Expenses**	**37,788**	**92,515**	**(54,727)**	-59.2%
(386,348)	**281,120**	**(667,468)**	-237.4%	**Net Income/Loss from Operations**	**(589,337)**	**(2,166,546)**	**1,577,209**	-72.8%

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

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

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: July 26, 2023

Report Type: Discussion

Title: California Department of Health Care Access and Information (HCAI) Hospital Distressed Loan Program

Recommendation: Pass a **Resolution** authorizing the execution and delivery of a promissory note, Loan and Security Agreement, and certain actions in connection therewith for a loan in an aggregate amount not to exceed $6,500,000 from the California Health Facilities Financing Authority under the Distressed Hospital Loan Program.

Contact: Julie Peterson, Chief Financial Officer

Summary
The Distressed Hospital Loan Program (Program) was established through Chapter 6, Statutes of 2023 (Assembly Bill 112). The legislation requires the Department of Health Care Access and Information (HCAI) and the California Health Facilities Financing Authority (CHFFA) to collaboratively develop the Distressed Hospital Loan Program to offer interest-free, working capital loans to non-profit and publicly-operated financially distressed hospitals, including hospitals that belong to integrated health care systems with no more than two separately licensed hospitals in California that are facing a risk of closure, while they implement turnaround strategies to regain financial viability.

HCAI will contract with CHFFA through an Inter-Agency Agreement to administer the loan program. HCAI and CHFFA are developing a loan application and criteria to make loans to financially distressed hospitals seeking assistance. Some details of the Program are as follows:

- The legislation authorizes up to $150 million in one-time funding to implement the Program, including administrative costs. Loans will be offered at zero-percent interest.
- Loans are repayable over 72-months, with an initial 18-month grace period at the beginning of the loan term.
- Lending parameters will be focused on financially distressed hospitals in areas where demand for services and service adequacy are of concern.
- The Program will sunset on December 31, 2031. Loans are secured using Medi-Cal checkwrite payments for participating hospitals.
- The legislation also includes provisions for requiring hospitals to submit quarterly financial data to HCAI, for use in monitoring the financial health of hospitals throughout the state. This will enable HCAI to better prepare for and identify developing fiscal challenges at hospitals statewide.

Timeframe for Funding
Based on stakeholder responses, applications will be open until July 31 to allow adequate time for hospitals to provide all the information. If you would like to determine program eligibility, you are encouraged to send all information except the turnaround plan by June 30. If eligibility is determined, applicants must submit a turnaround plan by July 31. Applications received after June 30 must contain a turnaround plan. We will likely fund the loans two-three weeks after applications are awarded.

Evaluation Methodology
The application evaluation methodology will apply equally to all hospitals and all applications will be reviewed in aggregate after the application deadline.

Attachments:
A: Resolution

RESOLUTION NO. xx-xx

RESOLUTION OF **PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION** AUTHORIZING EXECUTION AND DELIVERY OF A PROMISSORY NOTE, LOAN AND SECURITY AGREEMENT, AND CERTAIN ACTIONS IN CONNECTION THEREWITH FOR A LOAN UNDER THE DISTRESSED HOSPITAL LOAN PROGRAM

DISTRESSED HOSPITAL LOAN PROGRAM

WHEREAS, Pajaro Valley Health Care District Hospital Corporation (the "Borrower") is a not-for-profit hospital, as defined in Section 129381 of the Health and Safety Code;

WHEREAS, Borrower does not belong to an integrated health care system with more than two separately licensed hospital facilities.

WHEREAS, Borrower has determined that it is in its best interest to borrow an aggregate amount not to exceed $6,500,000.00 from the California Health Facilities Financing Authority (the "Lender") under the Distressed Hospital Loan Program, with that loan to be funded with the proceeds in the Distressed Hospital Loan Program Fund; and

WHEREAS, the Borrower intends to use the loan in order to prevent closure and further stabilize operations of the hospital;

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

Section 1. The Board of Directors of Borrower hereby approves the submission of an application for a loan from the Distressed Hospital Loan Program.

Section 2. Julie L. Peterson (Chief Financial Officer), Matko Vranjes (Interim Chief Executive Officer), John Friel (Board Chairman), Marcus Pimentel (Board Treasurer) {each} an "Authorized Officer" are hereby authorized and directed, for and on behalf of the Borrower, to do any and all things and to execute and deliver any and all documents that the Authorized Officer(s) deem(s) necessary or advisable to consummate the borrowing of moneys from the Lender and otherwise to effectuate the purposes of this Resolution and the transactions contemplated hereby.

Section 3. The proposed form of Loan and Security Agreement (the "Agreement"), which contains the terms of the loan, is hereby approved. The loan shall be in a principal amount not to exceed $6,500,000.00, shall not bear interest, and shall mature 72 months from the date of the executed Loan and Security Agreement between the Borrower and the Lender. The {Each} Authorized Officer(s) is (are) hereby authorized and directed, for and on behalf of the Borrower, to execute the Agreement in substantially that form, which includes the Loan Funds Disbursement Certification, as well as the redirection of up to twenty percent (20%) of Medi-Cal reimbursements (checkwrite payments) to Lender in the event of default in accordance with Health and Safety Code section 129384, with those changes therein as the Authorized Officer(s) may require or approve, that approval to be conclusively evidenced by the execution and delivery thereof.

Section 4. The proposed form of Promissory Note (the "Note") as evidence of the Borrower's obligation to repay the loan is hereby approved. The Authorized Officer is hereby authorized and directed, for and on behalf of the Borrower, to execute the Note in substantially said form, with those

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

PASSED AND ADOPTED at a regular meeting of the Board of Directors of Pajaro Valley Health Care District Hospital Corporation held on the 26th day of July, 2023.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: July 26, 2023

Report Type: Discussion

Title: Line of Credit-Santa Cruz County Bank

Recommendation: Pass a **Motion** 1) authorizing staff to negotiate a $5.0 million Line of Credit agreement between the Pajaro Valley Health Care District Hospital Corporation (the "Hospital") and Santa Cruz County Bank and 2) directing staff to place a Resolution approving the final agreement on a future Pajaro Valley Health Care District Hospital Corporation agenda.

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: July 26, 2023
Report Type: Discussion

Title: Watsonville Community Hospital (WCH) Strategic Plan Approval

Recommendation: 1) Provide Chartis with input on a) mission, vision, and values statements, and b) strategic priorities and tactics, and c) strategic plan roadmap and accountable leaders and 2) Pass a Motion approving the mission, vision and values statements and Strategic Plan.

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

Background:

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

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

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

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

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

Attachments:

A: Chartis Presentation

CHARTIS

Watsonville Community Hospital & Pajaro Valley Healthcare District

STRATEGIC PLAN SUMMARY AND ROADMAP

July 26, 2023

WATSONVILLE COMMUNITY HOSPITAL

Mission, Vision and Values

Our Mission

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

Our Vision

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

Our Values

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

WATSONVILLE COMMUNITY HOSPITAL

WCH and PVHCD Strategies

PVHCD-FOCUSED STRATEGIES

Community Health & Advocacy

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

Provider Recruitment

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

WCH-FOCUSED STRATEGIES

Clinical Quality & Patient Experience

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

Talent & Culture

Recruit, retain and support exceptional teams who advance a culture of trust, compassion, and integrity

Clinical Services & Access

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

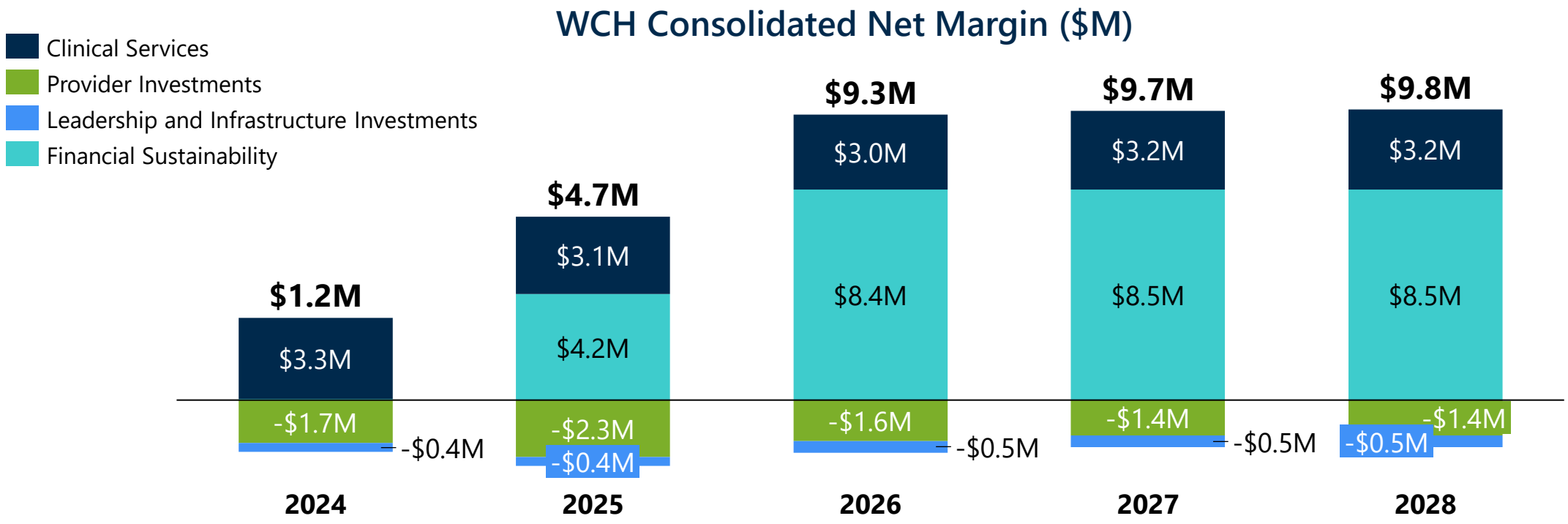
Financially Sustainable Services

Ensure **efficient operations and financial sustainability** to achieve PVHCD's mission and ensure services for generations to come

Health Equity Across All Strategies

WCH Consolidated Net Margin by Strategy

The combined strategic initiatives result in $9.8M of annual additional net margin for WCH and PVHCD by 2028.



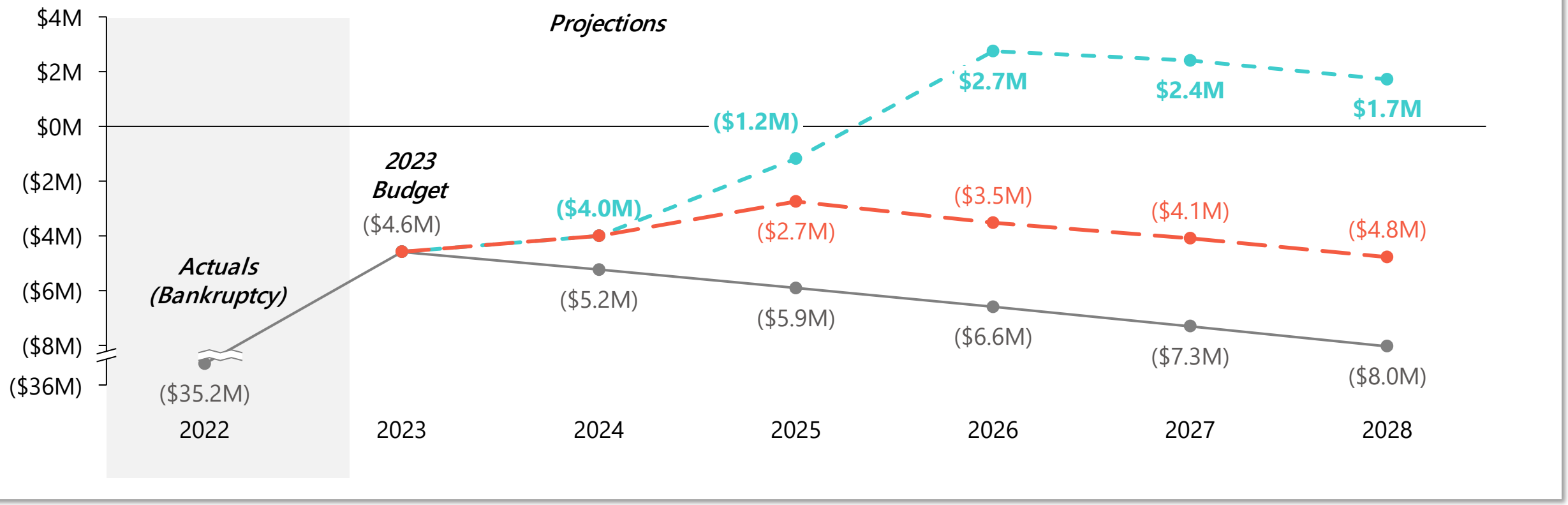
	2024	2025	2026	2027	2028
Annual Additional IP Discharges	58	185	226	253	280
Annual Additional OP Surgeries	158	171	184	200	217

WCH Consolidated Financial Projections

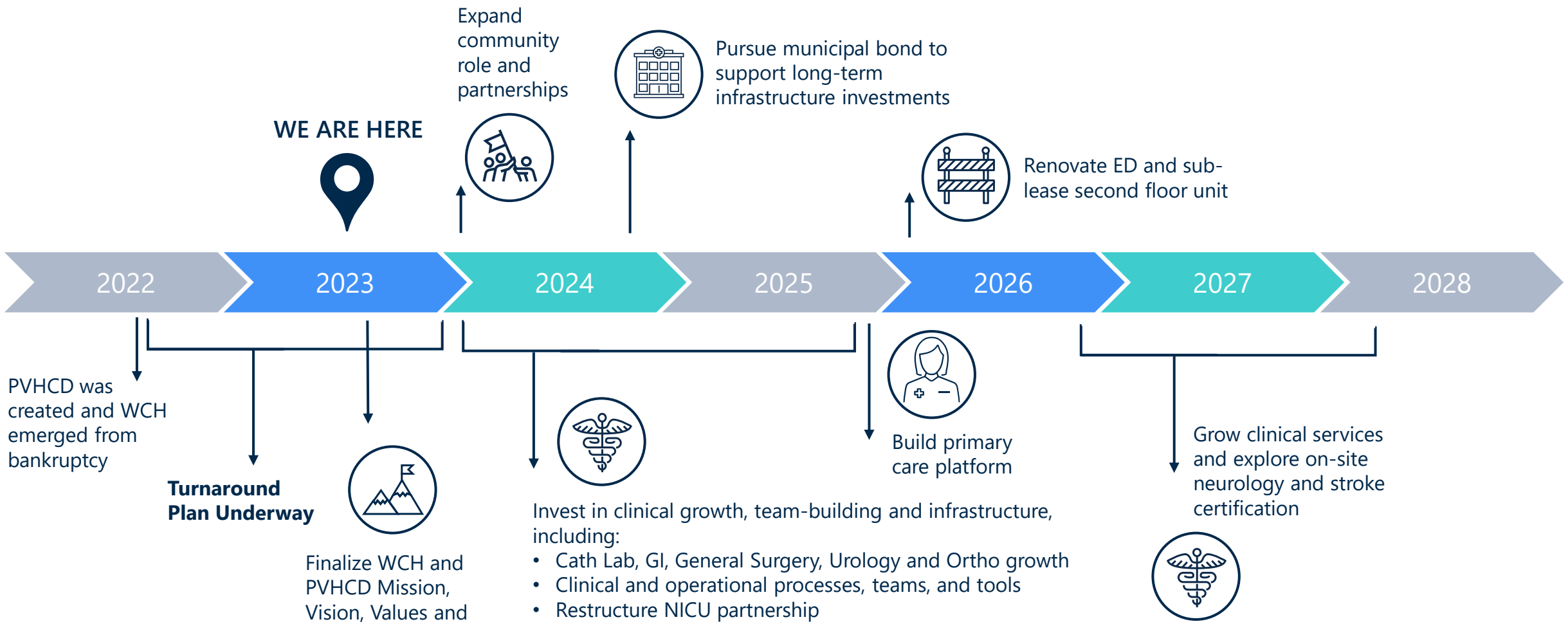
Despite net margin improvements from the strategic plan, WCH and PVHCD will need to pursue additional revenue sources, including federal, state, and local funding.

WCH Consolidated Net Margin, FY22 Historic-FY28 Projected

Do Nothing | Strategic Plan w/ Bond | Strategic Plan w/o Bond



Strategic Plan Roadmap Highlights



Community Health & Advocacy Roadmap

Accountable Leaders

- Matko Vranjes
- Board of Directors
- June Ponce
- Nancy Gere

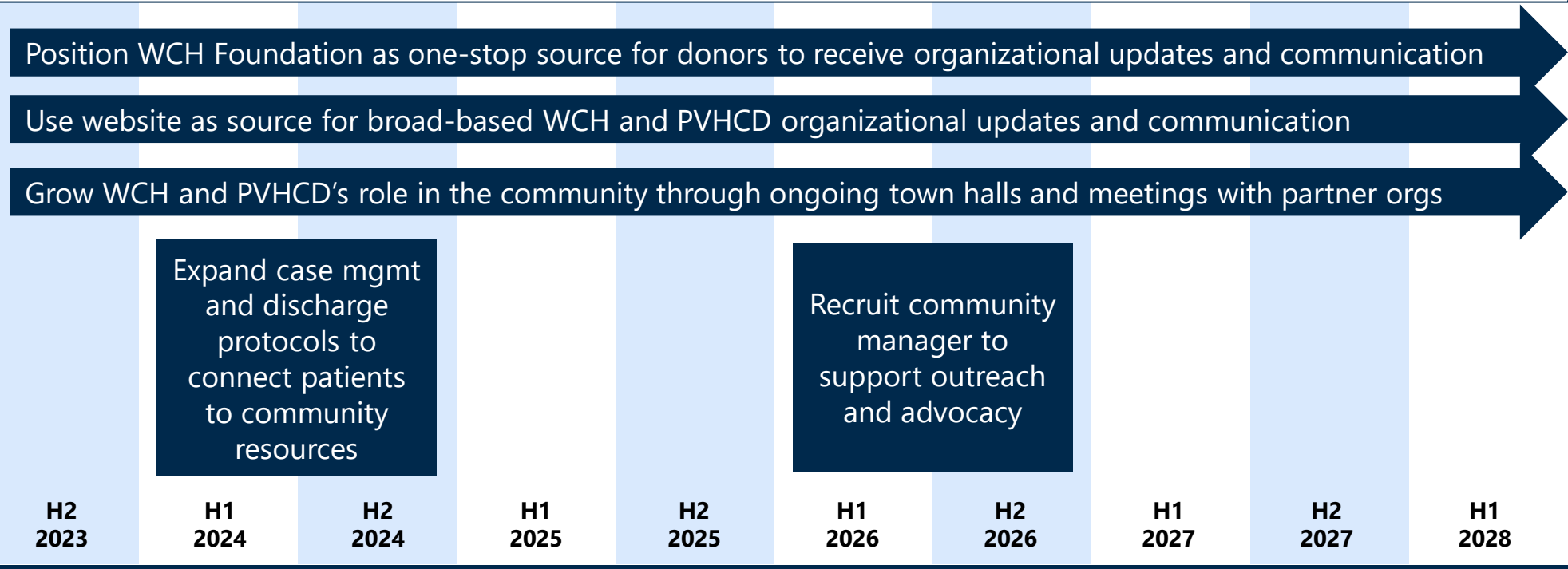
Requirements for Success

- ✓ Dedicated WCH communications and community outreach leaders
- ✓ Collaboration and coordination from community-based organizations in the region
- ✓ Community advocacy capabilities to address social determinants of health

How Will We Know We are Successful?

- Greater trust and awareness of WCH and PVHCD's role in the community
- Greater coordination and collaboration with community partners
- Increased navigation and support for WCH patients who may benefit from community and social services

Timeline and Key Milestones



WATSONVILLE COMMUNITY HOSPITAL

Provider Recruitment Roadmap

Accountable Leaders

- Matko Vranjes
- Dr. Clay Angel
- Lupe Mendoza

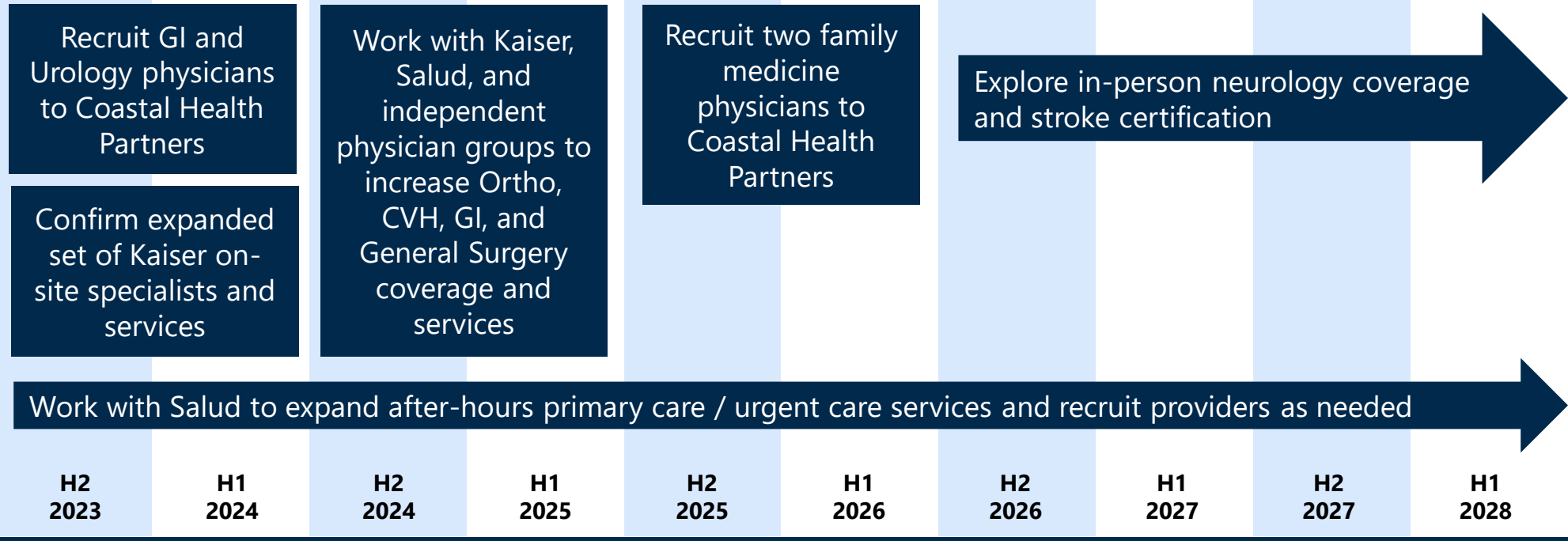
Requirements for Success

- ✓ Ability to recruit and retain high-quality, engaged providers to Coastal Health Partners
- ✓ Commitment from Kaiser to expand on-site specialists and ancillary services
- ✓ Commitment from Salud Para La Gente to expand primary care access and recruit select specialist providers as needed

How Will We Know We are Successful?

- Reduced transfers due to comprehensive specialist call coverage
- Increased care coordination between Salud patients and Coastal Health Partners physicians
- Fewer patients leaving the region for primary care and specialist services

Timeline and Key Milestones



WATSONVILLE COMMUNITY HOSPITAL

Clinical Quality & Patient Experience Roadmap

Accountable Leaders

- Matko Vranjes
- Sherri Stout Torres
- Tracy Trail-Mahan

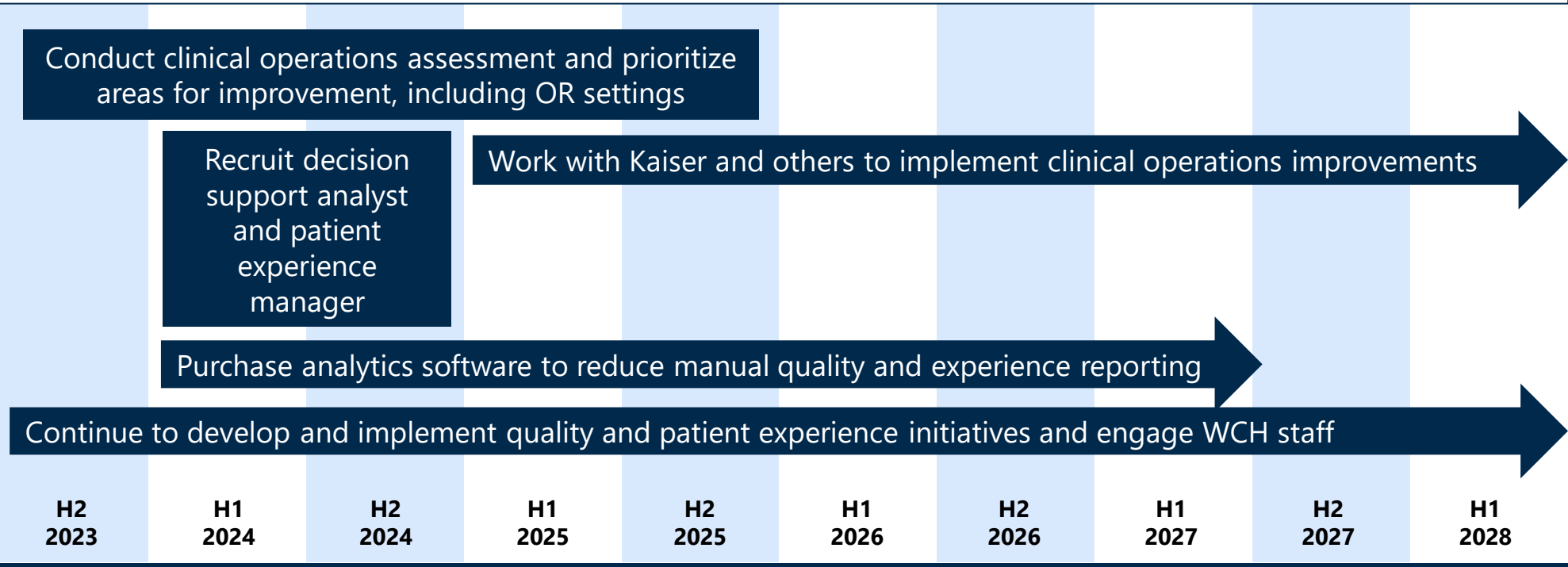
Requirements for Success

- ✓ WCH care teams, providers, and staff are committed to their role supporting quality and patient experience
- ✓ Operational support to lead clinical operations improvement initiatives
- ✓ Software, tools, and dedicated roles to improve reporting and documentation

How Will We Know We are Successful?

- Improved Leapfrog and patient satisfaction scores
- Greater staff engagement around quality initiatives and performance improvement
- Improved clinical operations across key areas (e.g., patient throughput, clinical documentation, revenue cycle, etc.)
- Processes are automated where possible

Timeline and Key Milestones



Talent & Culture Roadmap

Accountable Leaders

- Matko Vranjes
- Dr. Clay Angel
- Sherri Stout Torres
- Allyson Hauck

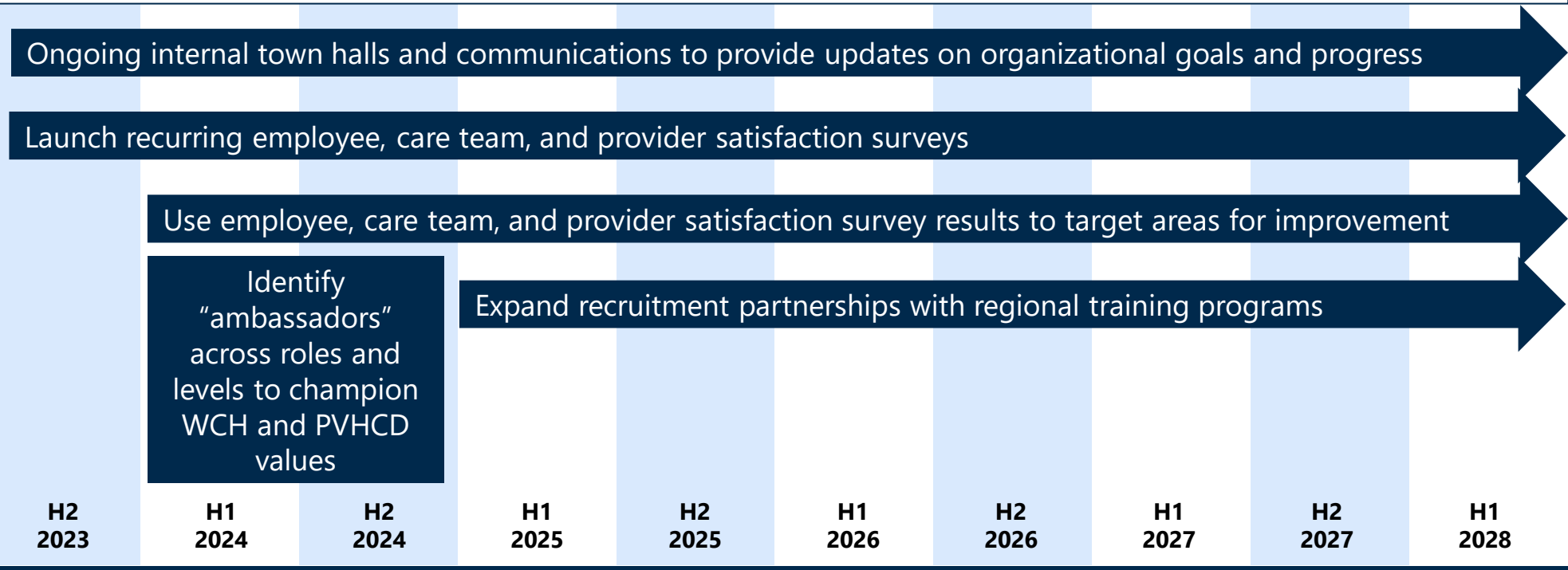
Requirements for Success

- ✓ Enhanced training and development to support employees, care teams, and providers
- ✓ Adequate resources and tools to ensure employee, care team, and provider success
- ✓ Individual performance management and clear behavioral expectations
- ✓ Support from regional training programs to partner with WCH

How Will We Know We are Successful?

- Increased staff and care team satisfaction and retention
- Greater trust and collaboration between WCH care teams, providers, staff, and leaders
- Greater proportion of employees recruited from regional training programs

Timeline and Key Milestones



Clinical Services & Access Roadmap

Accountable Leaders

- Matko Vranjes
- Dr. Clay Angel
- Sherri Stout Torres

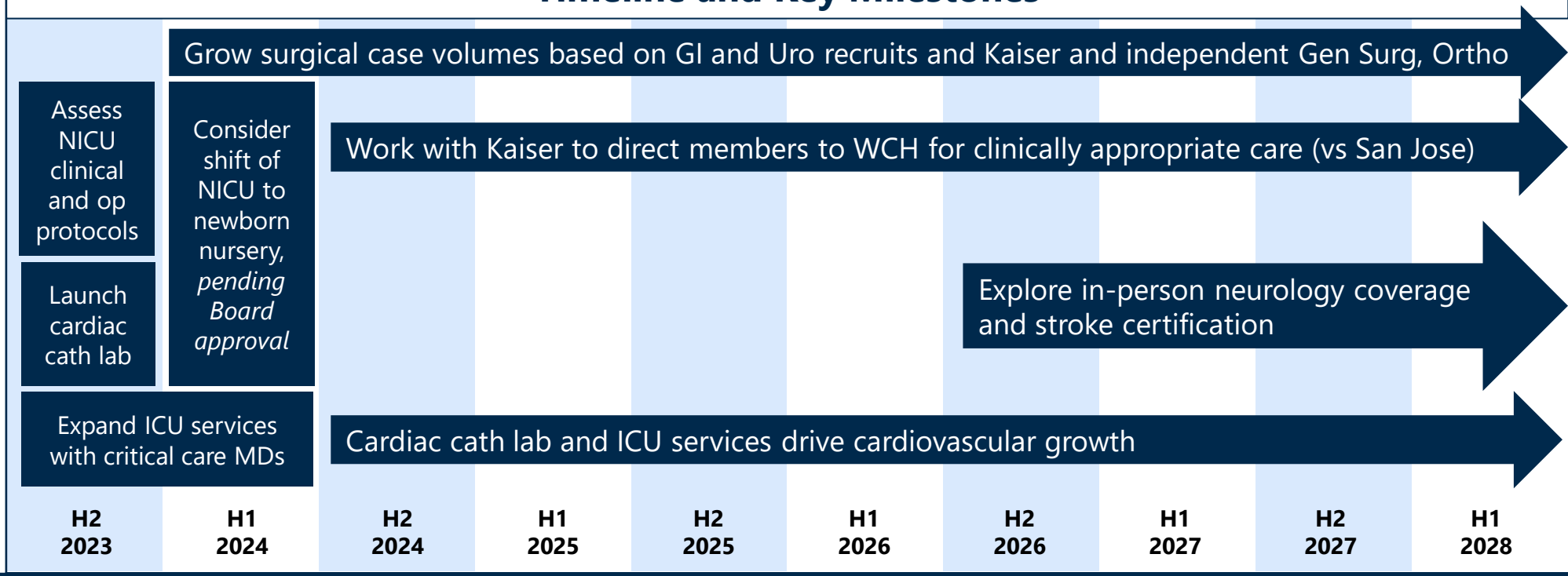
Requirements for Success

- ✓ Commitment from Kaiser to expand on-site specialists and ancillary services
- ✓ Capital to support cardiac catheterization lab opening
- ✓ Clinical and operational protocols to support newborn nursery services
- ✓ Adequate specialist recruitment (described in provider recruitment strategy)

How Will We Know We are Successful?

- Clinical growth for key service lines: Cardiac, GI, Gen Surg, Ortho
- IP and OP surgical volume growth
- Increased patient acuity (CMI)
- Increased Kaiser deliveries
- WCH maintaining its role as a primary facility for obstetrics services in the region

Timeline and Key Milestones



Financially Sustainable Services Roadmap

Accountable Leaders

- Matko Vranjes
- Julie Peterson
- June Ponce

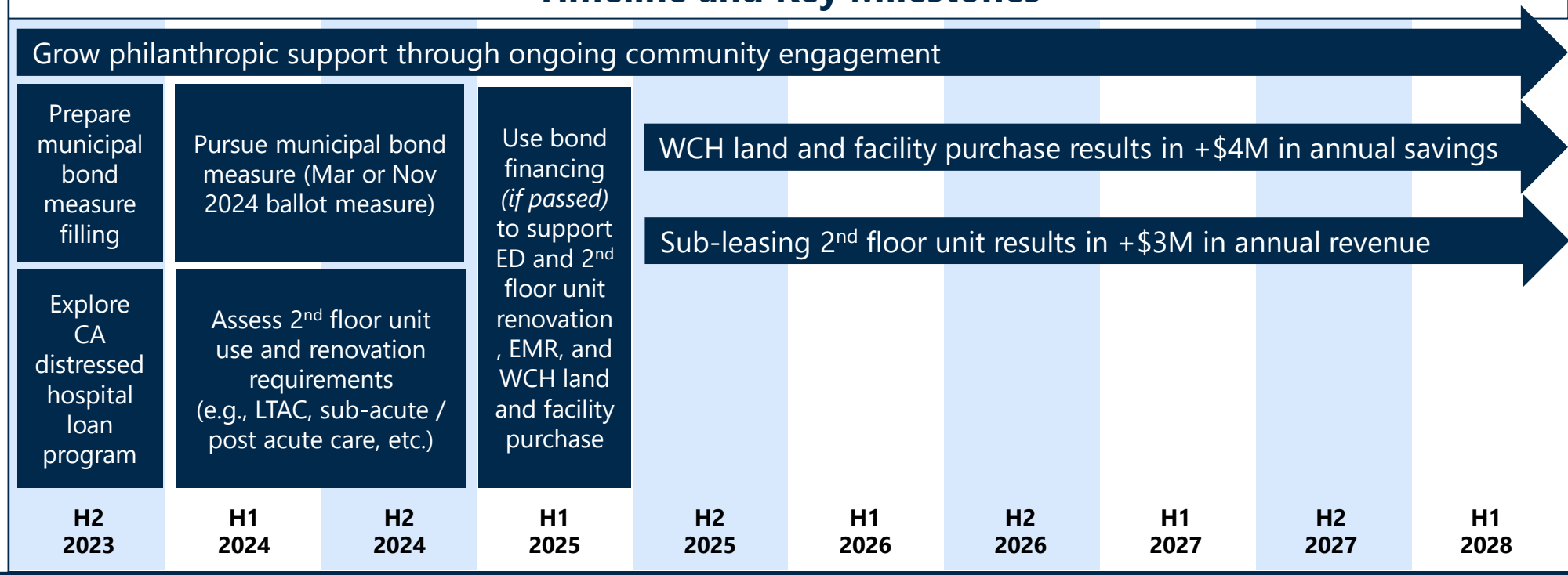
Requirements for Success

- ✓ Municipal bond approval required to support infrastructure and facility investments
- ✓ Funds from CA distressed hospital program can support near-term cash flow needs
- ✓ Ongoing monitoring of WCH and PVHCD financial performance

How Will We Know We are Successful?

- Achieve net margin targets for consolidated financials
- Purchase land and facility from real estate investment trust
- Standardize financial reporting to inform strategic initiatives and decision making
- Grow the number and amount of philanthropic donations

Timeline and Key Milestones



Thank You! & Discussion

Appendix Materials for Reference

WCH and PVHCD Tactics

Strategies	Tactics
Community Health & Advocacy	1. Grow WCH's role in the community and relationships with local organizations and partners 2. Advocate for equitable policies and legislation at the federal, state, and local level to improve health and wellbeing 3. Partner with Salud and other organizations to design a population health delivery model for the community 4. Expand partnership with Kaiser to ensure shared clinical, operational, and financial success
Provider Recruitment	1. Fill gaps in core specialty services (e.g., GI, Urology) 2. Contract with select specialists to offer coverage for distinct populations and services (e.g., Ortho. Gen Surgery) 3. Create an integrated primary care base for WCH through recruitment, succession planning, and provider alignment
Clinical Quality & Patient Experience	1. Expand clinical and operational processes to improve quality outcomes and patient experience 2. Deepen data and analytics capabilities to ensure consistent quality and experience monitoring and reporting 3. Optimize clinical operations including access / throughput, clinical documentation improvement, and revenue cycle
Talent & Culture	1. Support and retain employees through a focus on care team experience, competitive compensation, and access to resources that enable success 2. Expand staff, care team, and physician engagement, ownership, and collaboration, and foster employee pride as "ambassadors" for WCH 3. Ensure leaders and staff embody a culture of transparency and accountability to achieve WCH's mission and vision 4. Partner with regional programs to grow the talent pipeline and support local care team members and employees
Clinical Services & Access	1. Grow select clinical programs and aligned services (e.g., Cardiovascular, GI, General Surgery, and Orthopedics) 2. Grow WCH OB program and explore NICU programs and partnerships to ensure financial sustainability and access 3. Establish seamless tertiary/quaternary care partnerships to ensure coordinated care across the continuum 4. Sub-lease available second floor unit to inpatient rehab or long-term acute care service provider
Financially Sustainable Services	1. Assess the financial implications for all organizational initiatives to improve operating margins and performance 2. Continue to engage community donors and identify philanthropic funding opportunities 3. Pursue federal, state, and local government funding to support ongoing capital and operational expenses 4. Identify longer-term technology and infrastructure investments and financing strategy

Strategic Plan Process Overview

Phase I

Assess Current State & Articulate Vision / Goals

Market Landscape and Watsonville Community Hospital Assessment

Internal and External Stakeholder Engagement

Draft Mission, Vision, Values and Goals

Phase II

Plan Strategies & Tactics

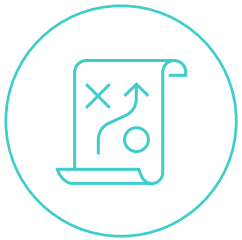
Develop Strategies and Tactics, such as:

- *Clinical Services*
- *Community Health & Access*
- *Provider & Facility Network*
- *Workforce Engagement*
- *Partnerships*

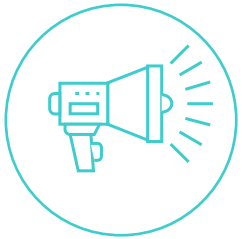
Phase III

Create Roadmap & Synthesized Plan

High-Level Financial Impact and Projections



Strategic Plan and Implementation Roadmap



Communications Strategy for Internal and External Audience

WATSONVILLE COMMUNITY HOSPITAL

LISTENING TO OUR TEAMS AND COMMUNITY

Mission, Vision, Values Development Process

342

Survey Respondents

80+

Focus Group Participants

- The survey included 331 English and 11 Spanish submissions
- Focus groups included physicians, frontline employees, directors, partners, donors and administrators

WATSONVILLE COMMUNITY HOSPITAL

Driving Assumptions of Clinical and Financial Projections

Revenue Assumptions

Category	Metric	Assumption
Volumes & Growth Rate	Overall annual growth rate	IP: 4% / OP: 2%
	Kaiser annual growth rate	IP: 14% / OP: 6%
	Market share increase**	42% → 48%
Revenue Rates	Reimbursement rate growth	3%
	Kaiser rate increase*	26%
	Commercial rate increase*	20%
	DSH/QAF payment growth	27% of Medicare / Medicaid revenue
Payer Mix	Payor Mix Change *(due to increased Kaiser cases, not decreased MediCal/Medicare)*	Comm: 13% → 19% MediCal: 50% → 46% Medicare: 35% → 34%

Expense Assumptions

Category	Metric	Assumption
Resource Requirements	Primary Care Provider annual investment (2 PCPs) GI, Urology recruitment support and practice costs	$1.4M annual investment plus recruitment support
Expense Rates	Annual expense inflation	3%
Leadership & Infrastructure	New roles and investments to focus on clinical quality, patient experience, talent and culture, financial sustainability, and community health initiatives	

*Kaiser and other commercial rates reflect a one-time increase from contract negotiations that were implemented in 2023. **Market share zips = 95076, 95019, 95077