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, September 27, 2023-5:00 pm

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

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

Kathleen King Community Room - 85 Nielson Street, Watsonville

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Email: info@pvhcd.org

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- Please include the agenda item number

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

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Pajaro Valley Health Care District Hospital Corporation
Regular Meeting Agenda- Wednesday, September 27, 2023

Call to Order

Roll Call

Closed Session Report

Agenda Modification Consideration

Public Comment on Matters Not on the Agenda

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

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

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

Comments from Board Members

Consent

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

1. **Minute Approval: August 30, 2023**
   Recommendation: Pass a **Motion** approving the minutes for August 30, 2023.
   Contact: Dawn Bullwinkel, Consultant Clerk of the Board

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

Discussion

3. **Medical Executive Committees Report September 2023**
   Recommendation: Receive the Quality Report and pass a **Motion** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of September 2023; and 2) addition of Fluoroscopy and Sedation Privilege to Gastroenterology Privilege Delineation List.
   Contact: Executive Sponsor-Dr. Angel, Chief of Staff, Medical Executive Committee

4. **Chief Executive Officer (CEO) Employment Agreement with Stephen Gray and Related Actions**
   Recommendation: Pass a **Resolution**:1) approving the CEO Employment Agreement to appoint Stephen Gray as the CEO of Pajaro Valley Health Care District Hospital Corporation dba Watsonville Community Hospital (Hospital); 2) authorizing the Board Chair to executive the agreement and 3) approving the market study findings and confirming the reasonableness of Mr. Gray's compensation package.
   Contact: Ad Hoc CEO Selection Committee (Board Chair John Friel and Director Pimentel); Staff Contact, Allyson Hauck, Chief Human Resources Officer.

5. **Chief Executive Officer Report**
   Recommendation: Receive and file.
   Contact: Matko Vranjes, Interim Chief Executive Officer

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

7. **Santa Cruz County Bank Business Loan Agreement**
   Recommendation: Pass a **Resolution** 1) authorizing the execution and delivery of a business loan agreement with Santa Cruz County Bank and approving related documents and actions; 2) authorizing the interim Chief Executive Officer, Matko Vranjes and Chief Financial Officer, Julie Peterson (or any interim) or either of their designees (each, an "Authorized Officer") and directing them to execute and deliver the Loan Agreement, the related Security Agreement, and all other related documents on behalf of the Pajaro Valley Health Care District Hospital Corporation.
   Contact: Julie Peterson, Chief Financial Officer

Adjourn

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

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: September 27, 2023
Report Type: Consent

Title: Minute Approval: August 30, 2023

Recommendation: Pass a **Motion** approving the minutes for August 30, 2023.

Contact: Dawn Bullwinkel, Consultant Board Clerk

Analysis

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

Financial Impact: None

Attachments:

A: August 30, 2023

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

Call to Order at 7:31 pm.

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

Public Comment on Matters on the Agenda

a. Fred Castillo-chief Executive Officer

Adjourn to Closed Session at 7:37 pm.

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

2. **Public Employment Recruitment Update** (Government Code 54957(b)(1)) and **Conference with Labor Negotiators** (Government Code 54957.6)
   Title-Chief Executive Officer
   Contact: Allyson Hauck, Chief Human Resources Officer

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

Call to Order at 5:00 pm.

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

Closed Session Report

a. Chair Friel announced the Board of Directors has selected a final candidate for the Chief Executive Officer (CEO) position and the Board has provided Ad Hoc committee authority to engage in discussions with the Candidate. The Board hopes to publicly report on the appointment of the Watsonville Community Hospital CEO in the very near future.

Agenda Modification Consideration

a. Chair Friel requested that the Pajara Valley Health Care District Update be heard first to accommodate guest presenter.

Public Comment on Matters Not on the Agenda

a. Jennifer Gavin, Pharmacy Director announced the International Overdose Awareness and thanked Matko Vranjes, Nancy Gere and June Ponce for their efforts supporting the event.

Comments from Board Members-None

Consent

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

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

1. **Minute Approval: June 28, 2023, July 25, 2023, July 26, 2023, July 27, 2023, July 28, 2023, August 2, 2023, August 10, 2023, and August 17, 2023**
   Action: Passed **Motion No. 044-2023** approving the minutes for June 28, 2023, July 25, 2023, July 26, 2023, July 27, 2023, July 28, 2023, August 2, 2023, August 10, 2023 and August 17, 2023.
   Contact: Dawn Bullwinkel, Consultant Clerk of the Board

2. **Policies/Policy Summary Approval: August 2023**
   Action: Item pulled for discussion by Director Gallagher.
   Moved/Seconded: Nunez/Gallagher
   Yes: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel
   Passed **Motion No. 045-2023** approving all policies except the Sepsis Nursing Policy for further discussion.
   Moved/Seconded: Nunez/Cox
   Yes: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel
   Passed **Motion No. 046-2023** approving the Sepsis Nursing Policy.
   Contact: Sherri Torres, Chief Nursing Officer

3. **Finance Committee Member Appointments**
Action: Passed a **Motion No. 047-2023** approving 1) Matko Vranjes, CEO (Senior Executive); 2) Julie Peterson, CFO (Senior Executive); and Jessica Dixon, Controller (Director/Manager) to serve on the Finance Committee.
Contact: Julie Peterson, Chief Financial Officer

Discussion

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

5. **Medical Executive Committees Report August 2023**
Action: Passed **Motion No. 048-2023** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of August 2023; 2) OPPE template for Pediatric Physicians; 3) Reappointment Application Attestation Questions; and 4) 2023 Surgical Quality Review Indicators.
Contact: Executive Sponsor-Dr. Angel, Chief of Staff, Medical Executive Committee

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

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

8. **Watsonville Community Hospital (WCH) Strategic Plan Approval**
Action: 1) Reviewed the Strategic Plan with edits from July 26, 2023 Pajaro Valley Health Care District Hospital Corporation meeting with public comment from unnamed, Javier, Angio Arroyo, Jane Murphy, Louise Pierce, Ruth Ann Ferris, Ms. Meyer, Mary, Fred Castillo, S Martin, Mary Boyd and 2) Passed **Motion No. 049-2023** approving the mission, vision and values statements and Strategic Plan.
Contact: Matko Vranjes, Interim Chief Executive Officer (CEO)

Adjourn at 7:29 pm.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: September 27, 2023

Report Type: Consent

Title: Policy/Summaries September 2023

Recommendation: Pass a **Motion** approving the Policies and Summary Report of September 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
POLICY APPROVAL SUMMARY REPORT

Committee: BOD

Reporting Period: September 27, 2023

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

Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Pharmacy (PHARM)				
Master Formula & Compounding Records	PHARMXXXX	New Policy		Author: Pharmacy Director 09/2023 CNO/Vp Sr leader/CEO:09/2023 PTIC: 09/06/2023 MEC: 09/19/2023 BOD:
Certification and Recertification of Sterile Compounding Areas	PHARMXXXX	New Policy		Author: Pharmacy Director 09/2023 CNO/Vp Sr leader/CEO:09/2023 PTIC: 09/06/2023 MEC: 09/21/2023 BOD:
Handling, Storage, Packaging, & Transport of CSPs	PHARMXXXX	New Policy		Author: Pharmacy Director 09/2023 CNO/Vp Sr leader/CEO:09/2023 PTIC: 09/06/2023 MEC:0 9/21/2023 BOD:
Workflow and Aseptic Technique	PHARM2727	P#PHARM2727 – replace with: USP Workflow and Aseptic Technique		Author: Pharmacy Director 09/2023 CNO/Vp Sr leader/CEO:09/2023 PTIC: 09/06/2023 MEC: 09/19/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOD

Reporting Period: September 27, 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
Beyond-Use Dating and Stability Considerations	PHARM2728	P#PHARM2728 – replace with: USP 797 Beyond-Use Dating and Stability Considerations		Author: Pharmacy Director 09/2023 CNO/Vp Sr leader/CEO:09/2023 PTIC: 09/06/2023 MEC: 09/19/2023 BOD:

Watsonville Community Hospital	**Master Formula & Compounding Records**
Policy Number/ Version:	797-2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the documentation elements and record keeping requirements for Master Formulation Records and Compounding Records for Compounded Sterile Preparations (CSPs) prepared for within Watsonville Community Hospital.

1.2. In addition to *USP <797> Pharmaceutical Compounding – Sterile Preparations* requirements, Watsonville Community Hospital follows all regulations issued by the California State Board of Pharmacy, including record keeping and record retention.

1.3. Master Formula and Compounding Records create a detailed and reproduceable compounding procedure and historical record of each CSP compounded ensuring patients receive a consistent, high quality CSPs. The Compounding Record also provides the documentation framework to quickly implement a recall or patient review if needed.

- A **Master Formula Record (MFR)** is a detailed procedural record describing how a unique CSP is prepared, verified, packaged, and labeled. A MFR provides a precise roadmap allowing any compounder to, without assistance or interpretation, prepare a consistent and replicable CSP each time.

- A **Compounding Record (CR)** documents each instance of CSP compounding including specifics about the manufacture, measurement, and use of Active Pharmaceutical Ingredients (APIs), added substances, supplies, and dispensing devices in the preparation and quality control of the final dosing or yield unit(s).

2. Policy

2.1 [USP 797] A Master Formula Record (MFR) is created for each unique Category 1 and Immediate-Use CSP formulation when one or both of the following conditions exist:

- CSPs prepared for more than one patient (i.e. batch compounding or repackaging)
- CSPs prepared from one or more nonsterile ingredient(s) or component(s)

2.2 [USP 797] MFRs include at least the following per USP <797>:

- Name, strength or activity, and dosage form of the CSP
- Identities and amounts of all ingredients, active and inactive; if applicable, relevant characteristics of components (e.g. particle size, salt form, purity grade, solubility)
- Type and size of container closure system(s)
- Complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions (e.g., hazardous material handling instructions)
- Physical description of the final CSP
- Beyond use dating (BUD) and storage requirements

- If applicable, calculations or conversions to determine and verify quantities and/or concentrations of components and strength or activity of API
- Stability reference source for the CSP
- Quality control (QC) procedures (e.g., visual inspection) and expected results
- Other information as needed to describe the compounding process and ensure repeatability, as appropriate
- [Best Practice] Labeling requirements
- [Best Practice] Reference source(s) for CSP formulation, compounding techniques, and physiochemical considerations

2.3 [Best Practice] Two (2) qualified compounding personnel including Designated Person and qualified designee(s) review and sign-off on all new or revised MFRs and associated calculations prior to initial use.

2.4 [USP 797] A Compounding Record (CR) is created for all Category 1 CSPs and for Immediate Use batched or repackaged CSPs intended for use in more than one patient and compounded according to an MFR.

2.5 [USP 797] CRs include at least the following per *USP <797>:*

- Name, strength or activity, and dosage form of the CSP
- Date and time of preparation of the CSP
- Assigned internal identification number (e.g., prescription, order, or lot number)
- A method to identify the individuals involved in the compounding process and individuals verifying the final CSP
- Name of each component including Active Pharmaceutical Ingredients (APIs), excipients, and other added substances
- [Conditional: If pharmacy batches CSPs for use by more than one patient] Vendor, lot number, and expiration date for each component used in the preparation of CSPs (e.g. as appropriate, APIs, excipients, diluents, components, containers)
- Weight or volume of each component
- Strength or activity of each component
- Total quantity compounded
- Final yield (e.g., quantity, containers, number of units)
- Assigned BUD and storage requirements
- Results of QC procedures (e.g., visual inspection)

If applicable:

- MFR reference (if retained separately)
- Calculations and conversions made to determine and verify quantities and/or concentrations of components, if applicable

2.6 [USP 797] MFRs and CRs are retained and readily accessible for review.

3. Roles & Responsibilities

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

- Ensures MFRs are created, reviewed, and approved for each unique CSP formulation prepared for more than one patient (including repackaging).

- Provides education and communication for new or revised MFRs and CRs to compounding personnel.
- Ensures CRs are completed, retained, and readily accessible for required CSPs.
- Ensures MFRs and CRs meet minimum documentation standards.

3.2 Compounding Personnel:

- Follow the exact specifications and directions in the MFR and ensure complete and accurate documentation within the CR.

4. Procedures

4.1. Creation and Revisions of Master Formula Records (MFRs)

- Submit requests for new or revised MFRs to the Designated Person.
- The Designated Person and/or qualified designee(s) reviews the request to determine the feasibility and viability the requested formulation including, but not limited to:
  - Supporting references for the formulation, CSP stability and BUD, and compounding methods and techniques
  - Availability and cost of needed ingredients, dispensing devices, equipment, and supplies
  - BUD assignment, storage, transport, and labeling requirements
  - Quality control procedures and tests based on the dosage form, route/location of administration, and drug stability
  - Impact to workflow and staffing
- If the request is approved, the DP or a qualified designee creates (or revises) the MFR.
- [BEST PRACTICE] An independent review of the MFR is conducted by two compounding personnel with the appropriate expertise. Both the MFR author and reviewer(s) sign off on the final MFR version prior to use.
- The DP or designee provides education and communication about the new/revised MFR with an effective date to Sterile Compounding Personnel.
- The DP retains a revision history of the MFR.

4.2. Creation of Compounding Records (CRs)

- Compounding personnel creates a CR for all Category 1 CSPs and for immediate use compounds made for more than one patient.
- CRs are allowed in the following formats that are fully compliant with the CR documentation requirements stated above in section 2.5
  - MFR designed to allow for the manual entry of the information needed to complete the CR

4.3. Use of MFR and CR

- Prior to starting the compounding process, compounding personnel review the MFR and compounding procedure in detail; initiate the CR; complete and record all required calculations; and confirm necessary ingredients, devices, equipment, and supplies are readily available.
- Update the CR during the preparatory, compounding, and QC processes to ensure accurate and complete documentation of the compounding process.
- Ensure all components of the CR are complete and accurate including, but not limited to:
  - Formulation Name

- Name/ID, manufacturer (or wholesaler), lot number, expiration, weight/volume, and strength of each API and added substance incorporated into the CSP
- Calculations and conversions
- Anticipated and actual final yield (including total quantity compounded, number of containers, and/or number of final dose units)
- Anticipated and actual results of QC procedures and tests (e.g., final yield unit weight/volume) and verifying Pharmacist's initials.

- Validate the CSP label, prescription or med order and Master Formulation Records and Compounding record are consistent and conform with each other,
- Ensure signatures of the compounder(s) and verifying Pharmacist are indelibly written on each CR.
- Ensure compounding date, time compounding started, and assigned internal ID number are indelibly written on each CR.
- Submit final CR to the DP or qualified designee(s) for final review and approval prior to storage in a readily retrievable format.

5. Definitions

5.1 Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation, and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

5.2 Added substance: An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms: inactive ingredient, excipient, and pharmaceutical ingredient.

5.3 Beyond-Use Date (BUD): The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.

5.4 Category 1 CSP: A CSP that is assigned a BUD of 12 hour or less at controlled room temperature or 24 hour or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in USP 797.

5.5 Category 2 CSP: A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in USP 797.

5.6 Category 3 CSP: A CSP that may be assigned a BUD exceeding the limits for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in USP.

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

5.8 Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication.

5.9 Container closure system: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components if the latter are intended to provide additional protection.

5.10 Designated Person (DP) is one ore more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CSPs.

5.11 Final yield/Final yield unit: The total number of containers prepared at the end of the compounding process prior to release testing.

5.12 Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

5.13 Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.

5.14 Release inspection and testing: Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.

5.15 Repackaging: The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation

5.16 Workflow management system: Technology comprised of hardware and software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

6. Related Policies, Documents, References

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

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

7. Approval and Review Summary

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

7.1 Initial version published by Wolters Kluwer 2022.

7.2 *Revised/adapted by* Watsonville Community Hospital 9/2023.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Master Formula & Compounding Records	Policy #	PHARMXXXX
Responsible	Pharmacy Director	Revised/Reviewed	09/06/2023

I. PURPOSE

1. This policy describes the documentation elements and record keeping requirements for Master Formulation Records and Compounding Records for Compounded Sterile Preparations (CSPs) prepared for within Watsonville Community Hospital.
2. In addition to *USP <797> Pharmaceutical Compounding – Sterile Preparations* requirements, Watsonville Community Hospital follows all regulations issued by the California State Board of Pharmacy, including record keeping and record retention.
3. Master Formula and Compounding Records create a detailed and reproduceable compounding procedure and historical record of each CSP compounded ensuring patients receive a consistent, high quality CSPs. The Compounding Record also provides the documentation framework to quickly implement a recall or patient review if needed.
    - A **Master Formula Record (MFR)** is a detailed procedural record describing how a unique CSP is prepared, verified, packaged, and labeled. A MFR provides a precise roadmap allowing any compounder to, without assistance or interpretation, prepare a consistent and replicable CSP each time.
    - A **Compounding Record (CR)** documents each instance of CSP compounding including specifics about the manufacture, measurement, and use of Active Pharmaceutical Ingredients (APIs), added substances, supplies, and dispensing devices in the preparation and quality control of the final dosing or yield unit(s).

II. POLICY

A. A Master Formula Record (MFR) is created for each unique Category 1 and Immediate-Use CSP formulation when one or both of the following conditions exist:
    - CSPs prepared for more than one patient (i.e. batch compounding or repackaging)
    - CSPs prepared from one or more nonsterile ingredient(s) or component(s)

B. MFRs include at least the following per USP <797>:
    - Name, strength or activity, and dosage form of the CSP
    - Identities and amounts of all ingredients, active and inactive; if applicable, relevant characteristics of components (e.g. particle size, salt form, purity grade, solubility)
    - Type and size of container closure system(s)
    - Complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions (e.g., hazardous material handling instructions)
    - Physical description of the final CSP
    - Beyond use dating (BUD) and storage requirements
    - If applicable, calculations or conversions to determine and verify quantities and/or concentrations of components and strength or activity of API
    - Stability reference source for the CSP
    - Quality control (QC) procedures (e.g., visual inspection) and expected results
    - Other information as needed to describe the compounding process and ensure repeatability, as appropriate
    - Labeling requirements
    - Reference source(s) for CSP formulation, compounding techniques, and physiochemical considerations

C. Two (2) qualified compounding personnel including Designated Person and qualified designee(s) review and sign-off on all new or revised MFRs and associated calculations prior to initial use.

D. A Compounding Record (CR) is created for all Category 1 CSPs and for Immediate Use batched or repackaged CSPs intended for use in more than one patient and compounded according to an MFR.

E. CRs include at least the following per *USP <797>:*

- Name, strength or activity, and dosage form of the CSP
- Date and time of preparation of the CSP
- Assigned internal identification number (e.g., prescription, order, or lot number)
- A method to identify the individuals involved in the compounding process and individuals verifying the final CSP
- Name of each component including Active Pharmaceutical Ingredients (APIs), excipients, and other added substances
- Vendor, lot number, and expiration date for each component used in the preparation of CSPs (e.g. as appropriate, APIs, excipients, diluents, components, containers)
- Weight or volume of each component
- Strength or activity of each component
- Total quantity compounded
- Final yield (e.g., quantity, containers, number of units)
- Assigned BUD and storage requirements
- Results of QC procedures (e.g., visual inspection)

If applicable:

- MFR reference (if retained separately)
- Calculations and conversions made to determine and verify quantities and/or concentrations of components, if applicable

F. MFRs and CRs are retained and readily accessible for review.

III. ROLES & RESPONSIBILITIES

1. The Designated Person (DP):
   - Ensures MFRs are created, reviewed, and approved for each unique CSP formulation prepared for more than one patient (including repackaging).
   - Provides education and communication for new or revised MFRs and CRs to compounding personnel.
   - Ensures CRs are completed, retained, and readily accessible for required CSPs.
   - Ensures MFRs and CRs meet minimum documentation standards.
2. Compounding Personnel:
   - Follow the exact specifications and directions in the MFR and ensure complete and accurate documentation within the CR.

IV. DEFINITIONS

1. **Active pharmaceutical ingredient (API):** Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation, and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.
2. **Added substance:** An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms: inactive ingredient, excipient, and pharmaceutical ingredient.

3. **Beyond-Use Date (BUD):** The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
4. **Category 1 CSP**: A CSP that is assigned a BUD of 12 hour or less at controlled room temperature or 24 hour or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in USP 797.
5. **Category 2 CSP:** A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in USP 797.
6. **Category 3 CSP:** A CSP that may be assigned a BUD exceeding the limits for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in USP.
7. **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.
8. **Compounding:** The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication.
9. **Container closure system:** Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components if the latter are intended to provide additional protection.
10. **Designated Person (DP)** is one ore more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CSPs.
11. **Final yield/Final yield unit:** The total number of containers prepared at the end of the compounding process prior to release testing.
12. **Quality assurance (QA):** A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
13. **Quality control (QC):** The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.
14. **Release inspection and testing:** Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
15. **Repackaging:** The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation
16. **Workflow management system:** Technology comprised of hardware and software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

V. PROCEDURE

A. Creation and Revisions of Master Formula Records (MFRs)
- Submit requests for new or revised MFRs to the Designated Person.
- The Designated Person and/or qualified designee(s) reviews the request to determine the feasibility and viability the requested formulation including, but not limited to:
  - Supporting references for the formulation, CSP stability and BUD, and compounding methods and techniques
  - Availability and cost of needed ingredients, dispensing devices, equipment, and supplies
  - BUD assignment, storage, transport, and labeling requirements
  - Quality control procedures and tests based on the dosage form, route/location of administration, and drug stability

  - Impact to workflow and staffing
- If the request is approved, the DP or a qualified designee creates (or revises) the MFR.
- An independent review of the MFR is conducted by two compounding personnel with the appropriate expertise. Both the MFR author and reviewer(s) sign off on the final MFR version prior to use.
- The DP or designee provides education and communication about the new/revised MFR with an effective date to Sterile Compounding Personnel.
- The DP retains a revision history of the MFR.

B. Creation of Compounding Records (CRs)
- Compounding personnel creates a CR for all Category 1 CSPs and for immediate use compounds made for more than one patient.
- CRs are allowed in the following formats that are fully compliant with the CR documentation requirements stated above in section 2.5
  - MFR designed to allow for the manual entry of the information needed to complete the CR

C. Use of MFR and CR
- Prior to starting the compounding process, compounding personnel review the MFR and compounding procedure in detail; initiate the CR; complete and record all required calculations; and confirm necessary ingredients, devices, equipment, and supplies are readily available.
- Update the CR during the preparatory, compounding, and QC processes to ensure accurate and complete documentation of the compounding process.
- Ensure all components of the CR are complete and accurate including, but not limited to:
  - Formulation Name
  - Name/ID, manufacturer (or wholesaler), lot number, expiration, weight/volume, and strength of each API and added substance incorporated into the CSP
  - Calculations and conversions
  - Anticipated and actual final yield (including total quantity compounded, number of containers, and/or number of final dose units)
  - Anticipated and actual results of QC procedures and tests (e.g., final yield unit weight/volume) and verifying Pharmacist's initials.
- Validate the CSP label, prescription or med order and Master Formulation Records and Compounding record are consistent and conform with each other,
- Ensure signatures of the compounder(s) and verifying Pharmacist are indelibly written on each CR.
- Ensure compounding date, time compounding started, and assigned internal ID number are indelibly written on each CR.
- Submit final CR to the DP or qualified designee(s) for final review and approval prior to storage in a readily retrievable format.

VI. REFERENCES

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

VII. STAKEHOLDERS

N/A

Watsonville Community Hospital	**Certification and Recertification of Sterile Compounding Areas**
Policy Number/ Version:	797 – 2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the procedures for certification and recertification of Primary Engineering Controls (PECs) and Secondary Engineering Controls (SECs) within Watsonville Community Hospital. Certification indicates that the equipment and compounding area is meeting its design and air quality specifications.

Refer to the **Facility and Engineering Controls policy** for design specifications and acceptance criteria for Primary Engineering Controls (PECs), Secondary Engineering Controls (SEC) and compounding areas.

2. Policy

2.1. [USP 797] Before a compounding area is used to compound either Category 1, Category 2, or Category 3 Compounded Sterile Preparations (CSPs), it must be independently certified following the requirements in this policy and when applicable, manufacturer specifications.

2.2. [USP 797] Certification of the classified areas including the PEC must be performed initially, and recertification must be performed at least every 6 months, and must include:

- **Airflow testing**: to determine acceptability of the air velocity, room air exchange rate, and room pressure differential in doorways between adjacent rooms to ensure consistent airflow; and that the appropriate quality of air is maintained under dynamic operating conditions.
- **Air changes per hour (ACPH)** and their sources e.g., HVAC, PEC and total, must be documented on the certification report.
- **HEPA filter integrity testing**: HEPA filters must be leak tested at the factory, after installation, and as part of recertification.
- **Total particle count testing**: performed under dynamic operating conditions using calibrated electronic equipment.
- **Dynamic airflow smoke pattern testing**: performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s).

2.3. [USP 797] The Designated Person (DP) immediately addresses any out of specification results determined by the certification professional or vendor at the time of recertification per **Out of Specifications policy** and **QA/QC policy**.

2.4. [USP 797] Classified areas additionally must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.

- [Best Practice] Before any of the above activities, the DP(s) consults with the certification professional to confirm need for recertification and schedule availability.

2.5. [USP 797] All certification and recertification records are reviewed by the DP(s) to ensure the classified environments meet USP <797> requirements and documents are readily retrievable.

2.6. [BEST PRACTICE] All certification activities are completed or supervised by vendors and professionals that are credentialed by the Controlled Environment Testing Association (CETA) National Board of Testing (CNBT). Credentials are readily available from the vendor and/or Designated Person.

2.7. All equipment for testing and certification is calibrated per Intitute of Environmental Sciences and Technology (IEST) standards or manufacturer's recommendations and calibration dates are included in the certification report.

3. Roles & Responsibilities

3.1. Designated Person(s) (DP):

- [USP 797] Review all certification and recertification records) to ensure the classified environments meet USP <797> requirements and documents are readily retrievable.
- [USP 797] Initiate a corrective action for any out-of-specification results and ensures the actions taken have been effective.
- Determine dynamic operating conditions for each PEC and SEC in use.

3.2. Certification professional or vendor:

- Coordinates schedule for certification with DP or designee to ensure completion within due time and for minimal disruption of pharmacy workflow.
- Follows facility hand hygiene and garbing and material handling and cleaning procedures.
- Reviews facility sampling diagram with DP or designee prior to each certification activity to ensure consistent sampling plan.
- Notifies DP of any out-of-specification criteria and any immediate corrective actions completed before leaving the facility.

4. Procedures

4.1 Initial Certification of Compounding Areas

- Prior to certification, all construction areas are thoroughly cleaned and approved by the DP or qualified designee.
- At completion of construction, compounding areas are certified under static or as-built conditions. The goal of this certification is to ensure airflow and air exchanges are functioning as designed and that PECs and SECs meet ISO classification.

4.2 Recertification of Compounding Areas

- Routine recertification of PECs and SECs occurs at a minimum of every 6 months. Recertification is considered on time if completed by the last day of the month when certification is due.
- Recertification occurs under dynamic operating conditions.
- DP determines the maximum number of personnel normally working in the classified area. Recertification is performed with that determined number of personnel.
- Ensure the number of personnel in the space at the time of recertification is recorded on the recertification report.

- Recertify PECs whenever the equipment requires a signficant move such that the air quality or function may be disturbed. Consult with a certification professional if uncertain of the impact.
- Recertify SECs following construction, redesign, or alteration of the configuration of the room that could affect airflow or quality.

4.3 Review of Certification Report

- The DP reviews preliminary and final certification reports for every PEC and SEC under the scope of Watsonville Community Hospital's sterile compounding program within 3 business days of receipt.
- DP completes all applicable parts of the **Certification Report Review Form: Appendix 1.**
    - Ensure the report includes all components and a pass or fail indication for all PEC and SEC certification criteria as described in this policy.
    - Further review all pass indications for elements that may have minimally exceeded passing criteria.
- The DP begins a corrective action plan for all certification criteria items that are found to be out of specification on the certification report.
    - See **Out of Specifications policy** and **QA/QC policy** for procedures when review of certification report features sterile compounding areas out of compliance with USP <797> and USP <800> design specifications and acceptance criteria.
- Once corrective action plan remediations are complete, schedule recertification testing to determine effectiveness of remediation efforts.
- Review certification report after remediation to determine if all areas found out of specification are now within acceptable design specifications and acceptance criteria. Record successful remediation on corrective action.
- Document the review by signature and date and file for regulatory review

4.4 PEC Certification Criteria

- Airflow velocity testing, including verifying unidirectional airflow utilizing smoke pattern testing under static and dynamic conditions
- Nonviable particle counts meeting ISO class 5 or better air quality
- HEPA filter integrity test
- Induction/back streaming test
- [Conditional: CAI/CACI] Chamber pressure test
- [Conditional: CAI/CACI] Site installation assessment test
- [Conditional: CAI/CACI] Preparation ingress and egress test

4.5 Segregated Compounding Area (SCA) Certification Criteria:

- Non-Hazardous SCA: no minimum air requirements

5. Definitions

5.1 **Biologic safety cabinet (BSC):** A ventilated cabinet that may be used or compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).

5.1 **Dynamic operating conditions:** Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations.

5.2 **High-efficiency particulate air (HEPA) filtration (HEPA Filter):** Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.

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

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

6. Related Policies, Documents, References

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

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

6.3 Controlled Environment Testing Association (CETA) Application Guide CAG-003:2022. Certification of Sterile Compounding Facilities for USP Compliance.

7. Approval and Review Summary

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

8.1. Initial version published by Wolters Kluwer 2023.

7.2 Revised 9/2023.

Appendix 1: Certification Report Review Form

Watsonville Community Hospital		**Certification Report Review Form**	
Pharmacy Location			
Date of Certification		**Certification Performed By (name and vendor)**	
Date Report Received		**Reviewed By**	

All certification reports reviewed by Designated Person and/or qualified designee

	Unit(s) Tested	**Pass**	**Fail**	**N/A**	**Comments/Actions**
PECs *Add additional rows for additional PECs*	CAI/CACI model and serial # _____ • Airflow test • Smoke pattern test • Chamber pressure test • Site installation assessment test • HEPA filter integrity test • Particle containment integrity and enclosure leak test • Preparation ingress and egress test				

Action Items Reviewed With (who/date)

Action Plan for Correction of Any Deficiencies:
i.e. What/Who/By When

File copy on site with final certification reports for regulatory inspection. Forward completed review to Designated Person or qualified designee for review and/or escalation if needed.

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Certification and Recertification of Sterile Compounding Areas	Policy #	PHARMXXXX
Responsible	Pharmacy Director	Revised/Reviewed	09/06/2023

I. PURPOSE

This policy describes the procedures for certification and recertification of Primary Engineering Controls (PECs) and Secondary Engineering Controls (SECs) within Watsonville Community Hospital. Certification indicates that the equipment and compounding area is meeting its design and air quality specifications.

Refer to the **Facility and Engineering Controls policy** for design specifications and acceptance criteria for Primary Engineering Controls (PECs), Secondary Engineering Controls (SEC) and compounding areas.

II. POLICY

A. Before a compounding area is used to compound either Category 1, Category 2, or Category 3 Compounded Sterile Preparations (CSPs), it must be independently certified following the requirements in this policy and when applicable, manufacturer specifications.

B. Certification of the classified areas including the PEC must be performed initially, and recertification must be performed at least every 6 months, and must include:

- **Airflow testing**: to determine acceptability of the air velocity, room air exchange rate, and room pressure differential in doorways between adjacent rooms to ensure consistent airflow; and that the appropriate quality of air is maintained under dynamic operating conditions.
- **Air changes per hour (ACPH)** and their sources e.g., HVAC, PEC and total, must be documented on the certification report.
- **HEPA filter integrity testing**: HEPA filters must be leak tested at the factory, after installation, and as part of recertification.
- **Total particle count testing**: performed under dynamic operating conditions using calibrated electronic equipment.
- **Dynamic airflow smoke pattern testing**: performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s).

C. The Designated Person (DP) immediately addresses any out of specification results determined by the certification professional or vendor at the time of recertification per **Out of Specifications policy** and **QA/QC policy**.

D. Classified areas additionally must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.

- Before any of the above activities, the DP(s) consults with the certification professional to confirm need for recertification and schedule availability.

E. All certification and recertification records are reviewed by the DP(s) to ensure the classified environments meet USP <797> requirements and documents are readily retrievable.

F. All certification activities are completed or supervised by vendors and professionals that are credentialed by the Controlled Environment Testing Association (CETA) National Board of Testing (CNBT). Credentials are readily available from the vendor and/or Designated Person.

G. All equipment for testing and certification is calibrated per Intitute of Environmental Sciences and Technology (IEST) standards or manufacturer's recommendations and calibration dates are included in the certification report.

III. ROLES & RESPONSIBILITIES

1. Designated Person(s) (DP):
   - Review all certification and recertification records) to ensure the classified environments meet USP <797> requirements and documents are readily retrievable.
   - Initiate a corrective action for any out-of-specification results and ensures the actions taken have been effective.
   - Determine dynamic operating conditions for each PEC and SEC in use.
2. Certification professional or vendor:
   - Coordinates schedule for certification with DP or designee to ensure completion within due time and for minimal disruption of pharmacy workflow.
   - Follows facility hand hygiene and garbing and material handling and cleaning procedures.
   - Reviews facility sampling diagram with DP or designee prior to each certification activity to ensure consistent sampling plan.
   - Notifies DP of any out-of-specification criteria and any immediate corrective actions completed before leaving the facility.

IV. DEFINITIONS

1. **Biologic safety cabinet (BSC):** A ventilated cabinet that may be used or compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
2. **Dynamic operating conditions:** Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations.
3. **High-efficiency particulate air (HEPA) filtration (HEPA Filter):** Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.
4. **Primary Engineering Control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
5. **Secondary Engineering Control (SEC):** The area where the PEC is placed (e.g. a cleanroom suite or SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

V. PROCEDURE

A. Initial Certification of Compounding Areas
   - Prior to certification, all construction areas are thoroughly cleaned and approved by the DP or qualified designee.
   - At completion of construction, compounding areas are certified under static or as-built conditions. The goal of this certification is to ensure airflow and air exchanges are functioning as designed and that PECs and SECs meet ISO classification.

B. Recertification of Compounding Areas
   - Routine recertification of PECs and SECs occurs at a minimum of every 6 months. Recertification is considered on time if completed by the last day of the month when certification is due.
   - Recertification occurs under dynamic operating conditions.
   - DP determines the maximum number of personnel normally working in the classified area. Recertification is performed with that determined number of personnel.

- Ensure the number of personnel in the space at the time of recertification is recorded on the recertification report.
- Recertify PECs whenever the equipment requires a signficant move such that the air quality or function may be disturbed. Consult with a certification professional if uncertain of the impact.
- Recertify SECs following construction, redesign, or alteration of the configuration of the room that could affect airflow or quality.

C. Review of Certification Report
- The DP reviews preliminary and final certification reports for every PEC and SEC under the scope of Watsonville Community Hospital's sterile compounding program within 3 business days of receipt.
- DP completes all applicable parts of the **Certification Report Review Form: Appendix 1.**
  - Ensure the report includes all components and a pass or fail indication for all PEC and SEC certification criteria as described in this policy.
  - Further review all pass indications for elements that may have minimally exceeded passing criteria.
- The DP begins a corrective action plan for all certification criteria items that are found to be out of specification on the certification report.
  - See **Out of Specifications policy** and **QA/QC policy** for procedures when review of certification report features sterile compounding areas out of compliance with USP <797> and USP <800> design specifications and acceptance criteria.
- Once corrective action plan remediations are complete, schedule recertification testing to determine effectiveness of remediation efforts.
- Review certification report after remediation to determine if all areas found out of specification are now within acceptable design specifications and acceptance criteria. Record successful remediation on corrective action.
- Document the review by signature and date and file for regulatory review

D. PEC Certification Criteria
- Airflow velocity testing, including verifying unidirectional airflow utilizing smoke pattern testing under static and dynamic conditions
- Nonviable particle counts meeting ISO class 5 or better air quality
- HEPA filter integrity test
- Induction/back streaming test
- Chamber pressure test
- Site installation assessment test
- Preparation ingress and egress test

E. Segregated Compounding Area (SCA) Certification Criteria:
- Non-Hazardous SCA: no minimum air requirements

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.
- Controlled Environment Testing Association (CETA) Application Guide CAG-003:2022. Certification of Sterile Compounding Facilities for USP Compliance.

VII. STAKEHOLDERS

N/A

Appendix 1: Certification Report Review Form

Watsonville Community Hospital		**Certification Report Review Form**	
Pharmacy Location			
Date of Certification		**Certification Performed By (name and vendor)**	
Date Report Received		**Reviewed By**	

All certification reports reviewed by Designated Person and/or qualified designee

	Unit(s) Tested	**Pass**	**Fail**	**N/A**	**Comments/Actions**
PECs *Add additional rows for additional PECs*	CAI/CACI model and serial # _____ • Airflow test • Smoke pattern test • Chamber pressure test • Site installation assessment test • HEPA filter integrity test • Particle containment integrity and enclosure leak test • Preparation ingress and egress test				

Action Items Reviewed With (who/date)

Action Plan for Correction of Any Deficiencies:
i.e. What/Who/By When

File copy on site with final certification reports for regulatory inspection. Forward completed review to Designated Person or qualified designee for review and/or escalation if needed.

Watsonville Community Hospital	**Handling, Storage, Packaging, & Transport of CSPs**
Policy Number/ Version:	797-2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the handling, storage, packaging, and transportation requirements and procedures for Compounded Sterile Preparations (CSPs) prepared at Watsonville Community Hospital.

1.2. CSP quality and integrity can be adversely affected by inappropriate handling, storage, packaging, and transport methods. Care and consideration are given to the determination and selection of these methods and personnel and/or vendors to carry out these duties. Proper training, processes, and quality assurance and control measures are integral to maintaining the quality of CSP during these processes.

1.3. Refer to **Label, Packaging, and Transport of Hazardous Drugs policy** for procedures to hazardous medication handling, storage, packaging, transporting, and shipping.

2. Policy

2.1. [USP 797] Personnel handling, storing, packaging, and transporting CSPs are trained in the knowledge and skills needed to perform job-related responsibilities. Refer to **Sterile Compounding Personnel Training & Evaluation policy** for further information.

2.2. [USP 797] CSPs are handled in a manner that maintains CSP quality and packaging integrity and are stored in temperature controlled designated storage areas to ensure storage temperatures remain within the appropriate range.

2.3. Designated CSP storage area temperatures are monitored and logged daily on days of operation either manually or by a continuous recording device.

2.4. [USP 797] Temperature monitoring systems are verified for accuracy at least every 12 months or as required by the manufacturer.

2.5. [USP 797] Temperature excursions above or below the required limits are investigated and CSPs are discarded if available literature or analytical testing does not verify the affected CSP(s) are expected to retain integrity or quality.

2.6. [USP 797] CSP packaging materials protect CSPs from damage, leakage, contamination, degradation, and adsorption as well as prevent accidental exposure to transport personnel.

2.7. [USP 797] Tamper evident closures are used for all controlled substance CSPs and all other CSPs shipped outside of Watsonville Community Hospital.

2.8. [USP 797] Light-resistant packaging materials are used for light-sensitive CSPs.

2.9. [USP 797] Shipping and transportation methods and vendors are selected that reasonably and reliably deliver properly packaged CSPs in an undamaged, sterile, and stable condition.

2.10. [USP 797] CSPs delivered or shipped outside of Watsonville Community Hospital bear the appropriate visible and legible labeling on the outer packaging or container conveying in-transit

storage requirements, special handling instructions (if applicable), and immediate storage requirements (if appropriate) upon receipt. Refer to the **Labeling of CSPs policy** for further information.

3. Roles & Responsibilities

3.1 The Designated Person(s) (DP):

- Provide appropriate training and competency evaluations for personnel performing CSP handling, storage, packaging, and transport
- Ensure CSP storage locations are appropriately monitored, and temperature is recorded daily or readily accessible
- Research CSP stability and integrity when drug storage temperature excursions occur and determine if CSPs have retained quality and can be dispensed or must be destroyed due to a lack of uncertainty in the available stability and sterility data in the event of an excursion
- Ensure packaging procedures and materials are appropriate to help retain the quality of the CSP

3.2. Internal Personnel Handling, Storing, Packaging, & Transporting CSPs:

- Personnel successfully complete and remain current on training and competency assessments required to perform job functions. Refer to **Sterile Compounding Personnel Training & Evaluation policy** for further information.

3.3. Third Party Delivery and Shipping Vendors:

- Maintain appropriate CSP storage conditions during transit per labeling and delivery or shipping instructions.

4. Procedures

4.1. [USP 797] CSP Handling and Storage

- After CSPs have been compounded and transferred to final dispensing containers, minimize jostling, shaking, or inverting CSPs unless labeling or literature promotes these actions to maintain or reestablish homogeneity of mixture.
- Transport CSPs to drug storage locations on carts or in sanitized bins to minimize the risk of jostling, dropping, or damaging packaging and container closure systems and, as result, potentially impacting CSP integrity.
- Move CSPs to the designated storage areas within controlled compounding areas corresponding with the labeled storage conditions upon pharmacist final verification, when delays in final verification exceed 30 minutes from completion of compounding of CSPs requiring refrigeration or pending release testing results.
- Move CSPs to designated storage areas within or outside of controlled areas when CSPs have been released for dispensing or administration, packaging, transport, or shipping.

- Store CSPs in the following storage locations:

Storage Condition	Within Controlled Area(s)	Outside of Controlled Area(s)
Prior to Final Verification *(including CSPs that have not undergone final verification or pending release testing results)*		
Controlled Room Temperature: 20°C - 25°C	Inpatient Pharmacy	N/A
Refrigerated: 2°C - 8°C	Inpatient Pharmacy	N/A
Frozen: -25°C to -10°C	N/A	N/A
After Final Verification *(CSPs released for dispensing, delivery, or shipping)*		
Controlled Room Temperature: 20°C - 25°C	Inpatient Pharmacy	Automated Dispensing Cabinet at Nursing Station
Refrigerated: 2°C - 8°C	Inpatient Pharmacy	Refrigerator associated with Automated Dispensing Cabinet at Nursing Station
Frozen: -25°C to -10°C	N/A	N/A

4.2. [USP 797] CSP Packaging

- Select CSP container closure systems and packaging that do not interact physically or chemically (e.g., adsorption) with the CSP and that protect the CSP's sterility, identity, potency, purity, and similar quality criteria (e.g., light sensitivity).
  - Refer to the USP-NF drug monograph, manufacturer's packaging data, or similar literature to determine appropriate container closure systems and packaging.
  - Record container closure system and packaging requirements and references on the Master Formulation Record (MFR), if applicable, for future reference.
- Use tamper evident CSP containers or closure systems for the following:
  - Controlled substance CSPs
  - Ophthalmic and Otic CSPs
  - CSPs for use via high-risk routes of administration (e.g., intrathecal, epidural)
  - CSPs delivered, transported, or shipped by a third party vendor

4.3. [USP 797] CSP Transport, Delivery, & Shipment

- Transport CSPs to drug storage locations within the immediate facility on well-organized carts to minimize the risk of jostling, dropping, or damaging packaging and container closure systems and potentially impacting CSP integrity.
  - If multiple CSP deliveries occur simultaneously, sort CSPs into sanitized and labeled bins or totes to reduce the risk of mix up or missed delivery of time-sensitive medications.
  - Transport medications in appropriate packaging and storage conditions (see table below).

Transport Scenario / Storage Conditions	Required Packaging Materials		
	Controlled Room Temp (20°C - 25°C)	**Refrigerated: 2°C - 8°C**	**Frozen: -25°C to - 10**
Transport within immediate facility via cart	• CSP(s) placed in sanitized bins	• CSP(s) placed in clear zippered bag • Transported in cooler with ice packs	N/A

- Watsonville Community Hospital does not transport or ship CSPs outside of the immediate facility.

4.4. [USP 797] Monitoring & Logging Storage Temperatures

- Monitor and log temperatures of all drug storage locations and devices daily on days of operation or via continuous monitoring device.
- Temperatures are recorded; e.g., manual temperature log or electronically via recording system [e.g., Simplifi].
- Temperature monitoring devices are maintained, and accuracy validated at least once every 12 months or per manufacturer instructions.
- Retain readily retrievable records of temperature logs and accuracy validations.

4.5. [USP 797] CSP Storage Location Temperature Excursions

- Report out of range temperatures or continuous temperature monitoring system alarms immediately to the Designated Person or Designee. Temperature deviations in drug storage locations are considered urgent maintenance events and are remediated as quickly as possible.
- When deviations exceed ±3°C (±37.4°F) of the required storage conditions for longer than 30 minutes, quarantine CSPs located in the affected drug storage areas(s) in appropriate comparable storage conditions. Refer to the **Release Inspections & Testing policy** for CSP quarantine procedures.
- As soon as possible, the DP or responsible party conducts necessary research to determine if the affected CSP quality and integrity has been compromised.
  - If CSPs are determined to have retained quality and integrity, move CSPs back to the appropriate storage location.
  - If CSP quality or integrity cannot be determined or has been compromised, log or remove CSPs from dispensable inventory and destroy and/or dispose of per facility drug disposal policy.
- Investigate the temperature excursion to determine root cause(s) and implement corrective actions if appropriate. Consider historical trends in the investigation. Refer to the **Quality Assurance and Quality Control policy** for procedures related to conducting investigations and corrective actions.

4.6. CSPs Exposed to Temperature Deviation during Transport or Shipping

- Provide delivery personnel and vendors transporting CSPs within and outside of the immediate facility with training and instructions regarding:
  - Monitoring CSP temperatures, packaging, and storage conditions before, during, and immediately after transit
  - Managing and reporting temperature deviations and excursions
- When temperature excursions are reported to the Pharmacy, log the issue per the Complaints, Adverse Drug Reactions, & CSP Recall policy.

5. Definitions

5.1. **Closure:** A material that seals an otherwise open space of a *Container* and provides protection for the contents. It also provides access to the contents of the *Container* (e.g., screw caps and stoppers).

5.2. **Container:** A receptacle that holds an intermediate compound, API, excipient, or dosage form, and is in direct contact with the article (e.g., ampules, vials, bottles, syringes, and pen injectors).

5.3. **Controlled room temperature:** The temperature maintained thermostatically that encompasses the usual and customary working environment of 20°–25° (68°–77° F).

5.4. **Freezer:** A place in which the temperature is controlled between −25° and −10° (−13° and 14° F)

5.5. **Room temperature** (also referred to as Ambient temperature)**:** The temperature prevailing in a working environment.

5.6. **Tamper-evident packaging:** A *Packaging system* that may not be accessed without obvious destruction of the seal or some portion of the *Packaging system*

6. Related Policies, Documents, References

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

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

6.3. United States Pharmacopeial Convention, Inc. <659> Packaging and Storage Requirements. Current version.

7. Approval and Review Summary

Approved by/date:	PTIC, Date of approval (9/2023)
Next review:	Month/year

7.1. Initial version published by Wolters Kluwer 2023.

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

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Handling, Storage, Packaging, & Transport of CSPs	Policy #	PHARMXXXX
Responsible	Pharmacy Director	Revised/Reviewed	09/06/2023

I. PURPOSE

This policy describes the handling, storage, packaging, and transportation requirements and procedures for Compounded Sterile Preparations (CSPs) prepared at Watsonville Community Hospital.

CSP quality and integrity can be adversely affected by inappropriate handling, storage, packaging, and transport methods. Care and consideration are given to the determination and selection of these methods and personnel and/or vendors to carry out these duties. Proper training, processes, and quality assurance and control measures are integral to maintaining the quality of CSP during these processes.

Refer to **Label, Packaging, and Transport of Hazardous Drugs policy** for procedures to hazardous medication handling, storage, packaging, transporting, and shipping.

II. POLICY

1. Personnel handling, storing, packaging, and transporting CSPs are trained in the knowledge and skills needed to perform job-related responsibilities. Refer to **Sterile Compounding Personnel Training & Evaluation policy** for further information.
2. CSPs are handled in a manner that maintains CSP quality and packaging integrity and are stored in temperature controlled designated storage areas to ensure storage temperatures remain within the appropriate range.
3. Designated CSP storage area temperatures are monitored and logged daily on days of operation either manually or by a continuous recording device.
4. Temperature monitoring systems are verified for accuracy at least every 12 months or as required by the manufacturer.
5. Temperature excursions above or below the required limits are investigated and CSPs are discarded if available literature or analytical testing does not verify the affected CSP(s) are expected to retain integrity or quality.
6. CSP packaging materials protect CSPs from damage, leakage, contamination, degradation, and adsorption as well as prevent accidental exposure to transport personnel.
7. Tamper evident closures are used for all controlled substance CSPs and all other CSPs shipped outside of Watsonville Community Hospital.
8. Light-resistant packaging materials are used for light-sensitive CSPs.
9. Shipping and transportation methods and vendors are selected that reasonably and reliably deliver properly packaged CSPs in an undamaged, sterile, and stable condition.
10. CSPs delivered or shipped outside of Watsonville Community Hospital bear the appropriate visible and legible labeling on the outer packaging or container conveying in-transit storage requirements, special handling instructions (if applicable), and immediate storage requirements (if appropriate) upon receipt. Refer to the **Labeling of CSPs policy** for further information.

III. ROLES & RESPOSIBILITIES

1. The Designated Person(s) (DP):

- Provide appropriate training and competency evaluations for personnel performing CSP handling, storage, packaging, and transport
- Ensure CSP storage locations are appropriately monitored, and temperature is recorded daily or readily accessible
- Research CSP stability and integrity when drug storage temperature excursions occur and determine if CSPs have retained quality and can be dispensed or must be destroyed due to a lack of uncertainty in the available stability and sterility data in the event of an excursion
- Ensure packaging procedures and materials are appropriate to help retain the quality of the CSP

2. Internal Personnel Handling, Storing, Packaging, & Transporting CSPs:
   - Personnel successfully complete and remain current on training and competency assessments required to perform job functions. Refer to **Sterile Compounding Personnel Training & Evaluation policy** for further information.
3. Third Party Delivery and Shipping Vendors:
   - Maintain appropriate CSP storage conditions during transit per labeling and delivery or shipping instructions.

IV. DEFINITIONS

1. **Closure:** A material that seals an otherwise open space of a *Container* and provides protection for the contents. It also provides access to the contents of the *Container* (e.g., screw caps and stoppers).
2. **Container:** A receptacle that holds an intermediate compound, API, excipient, or dosage form, and is in direct contact with the article (e.g., ampules, vials, bottles, syringes, and pen injectors).
3. **Controlled room temperature:** The temperature maintained thermostatically that encompasses the usual and customary working environment of 20°–25° (68°–77° F).
4. **Freezer:** A place in which the temperature is controlled between −25° and −10° (−13° and 14° F)
5. **Room temperature** (also referred to as Ambient temperature)**:** The temperature prevailing in a working environment.
6. **Tamper-evident packaging:** A *Packaging system* that may not be accessed without obvious destruction of the seal or some portion of the *Packaging system*

V. PROCEDURE

A. CSP Handling and Storage

- After CSPs have been compounded and transferred to final dispensing containers, minimize jostling, shaking, or inverting CSPs unless labeling or literature promotes these actions to maintain or reestablish homogeneity of mixture.
- Transport CSPs to drug storage locations on carts or in sanitized bins to minimize the risk of jostling, dropping, or damaging packaging and container closure systems and, as result, potentially impacting CSP integrity.
- Move CSPs to the designated storage areas within controlled compounding areas corresponding with the labeled storage conditions upon pharmacist final verification, when delays in final verification exceed 30 minutes from completion of compounding of CSPs requiring refrigeration or pending release testing results.
- Move CSPs to designated storage areas within or outside of controlled areas when CSPs have been released for dispensing or administration, packaging, transport, or shipping.
- Store CSPs in the following storage locations:

Storage Condition	Within Controlled Area(s)	Outside of Controlled Area(s)
Prior to Final Verification *(including CSPs that have not undergone final verification or pending release testing results)*		
Controlled Room Temperature: 20°C - 25°C	Inpatient Pharmacy	N/A
Refrigerated: 2°C - 8°C	Inpatient Pharmacy	N/A
Frozen: -25°C to -10°C	N/A	N/A
After Final Verification *(CSPs released for dispensing, delivery, or shipping)*		
Controlled Room Temperature: 20°C - 25°C	Inpatient Pharmacy	Automated Dispensing Cabinet at Nursing Station
Refrigerated: 2°C - 8°C	Inpatient Pharmacy	Refrigerator associated with Automated Dispensing Cabinet at Nursing Station
Frozen: -25°C to -10°C	N/A	N/A

B. CSP Packaging

- Select CSP container closure systems and packaging that do not interact physically or chemically (e.g., adsorption) with the CSP and that protect the CSP's sterility, identity, potency, purity, and similar quality criteria (e.g., light sensitivity).
  - Refer to the USP-NF drug monograph, manufacturer's packaging data, or similar literature to determine appropriate container closure systems and packaging.
  - Record container closure system and packaging requirements and references on the Master Formulation Record (MFR), if applicable, for future reference.
- Use tamper evident CSP containers or closure systems for the following:
  - Controlled substance CSPs
  - Ophthalmic and Otic CSPs
  - CSPs for use via high-risk routes of administration (e.g., intrathecal, epidural)
  - CSPs delivered, transported, or shipped by a third party vendor

C. CSP Transport, Delivery, & Shipment

- Transport CSPs to drug storage locations within the immediate facility on well-organized carts to minimize the risk of jostling, dropping, or damaging packaging and container closure systems and potentially impacting CSP integrity.
  - If multiple CSP deliveries occur simultaneously, sort CSPs into sanitized and labeled bins or totes to reduce the risk of mix up or missed delivery of time-sensitive medications.
  - Transport medications in appropriate packaging and storage conditions (see table below).

Transport Scenario / Storage Conditions	Required Packaging Materials		
	Controlled Room Temp (20°C - 25°C)	**Refrigerated: 2°C - 8°C**	**Frozen: -25°C to - 10**
Transport within immediate facility via cart	• CSP(s) placed in sanitized bins	• CSP(s) placed in clear zippered bag • Transported in cooler with ice packs	N/A

- Watsonville Community Hospital does not transport or ship CSPs outside of the immediate facility.

D. Monitoring & Logging Storage Temperatures
- Monitor and log temperatures of all drug storage locations and devices daily on days of operation or via continuous monitoring device.
- Temperatures are recorded; e.g., manual temperature log or electronically via recording system [e.g., Simplifi].
- Temperature monitoring devices are maintained, and accuracy validated at least once every 12 months or per manufacturer instructions.
- Retain readily retrievable records of temperature logs and accuracy validations.

E. CSP Storage Location Temperature Excursions
- Report out of range temperatures or continuous temperature monitoring system alarms immediately to the Designated Person or Designee. Temperature deviations in drug storage locations are considered urgent maintenance events and are remediated as quickly as possible.
- When deviations exceed ±3ºC (±37.4ºF) of the required storage conditions for longer than 30 minutes, quarantine CSPs located in the affected drug storage areas(s) in appropriate comparable storage conditions. Refer to the **Release Inspections & Testing policy** for CSP quarantine procedures.
- As soon as possible, the DP or responsible party conducts necessary research to determine if the affected CSP quality and integrity has been compromised.
  - If CSPs are determined to have retained quality and integrity, move CSPs back to the appropriate storage location.
  - If CSP quality or integrity cannot be determined or has been compromised, log or remove CSPs from dispensable inventory and destroy and/or dispose of per facility drug disposal policy.
- Investigate the temperature excursion to determine root cause(s) and implement corrective actions if appropriate. Consider historical trends in the investigation. Refer to the **Quality Assurance and Quality Control policy** for procedures related to conducting investigations and corrective actions.

F. CSPs Exposed to Temperature Deviation during Transport or Shipping
- Provide delivery personnel and vendors transporting CSPs within and outside of the immediate facility with training and instructions regarding:
  - Monitoring CSP temperatures, packaging, and storage conditions before, during, and immediately after transit
  - Managing and reporting temperature deviations and excursions
- When temperature excursions are reported to the Pharmacy, log the issue per the Complaints, Adverse Drug Reactions, & CSP Recall policy.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.
- United States Pharmacopeial Convention, Inc. <659> Packaging and Storage Requirements. Current version.

VII. STAKEHOLDERS

N/A

Watsonville Community Hospital	**Workflow and Aseptic Technique for Sterile Compounding**
Policy Number/ Version:	797-2022 Version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1 This policy describes the procedures for Sterile Compounding Workflow and materials handling within a Segregated Compounding Area (SCA) to maintain the quality of the compounding environment and minimize the risk of contamination to Compounded Sterile Preparations (CSPs) prepared within Watsonville Community Hospital.

1.2 This policy describes the procedures for Aseptic Technique of CSPs within an SCA where CSPs are prepared within Watsonville Community Hospital.

- Aseptic technique is set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count as an irreducible medium.

1.3 Sterile compounding workflow includes all the movement of materials within the designated compounding area. It is critical to control transfer of materials between areas of lower quality air to higher quality air to minimize the influx of contaminants, especially activities such as:

- Entering and exiting SCA
- Entering and exiting Restricted-access Barrier System (RABS)
- Use of pass-through chambers
- Aseptic technique during compounding

1.4 This policy is not intended to describe the requirements and procedures for aseptic technique of CSPs for Immediate Use within Watsonville Community Hospital.

- Policies and procedures for immediate use CSPs can be found in the **Immediate Use Compounding policy**.

1.5 [Conditional] This policy outlines the steps for workflow and aseptic technique for compounding non-hazardous sterile preparations. While many of the aseptic technique steps are the same for hazardous and non-hazardous sterile compounding, additional workflow steps are required when working with hazardous drugs (HDs). Please refer to USP <800> when working with HD CSPs.

- Watsonville Community Hospital does not compound hazardous drug CSPs.

2. Policy

2.1 [USP 797] It is the policy that compounding personnel maintain sterility of CSPs prepared within Watsonville Community Hospital by ensuring aseptic technique is followed in the entirety of the compounding process.

2.2 [USP 797] All furniture, equipment and other materials necessary for performing sterile compounding activities that is moved into the SCA is low-shedding and easily cleaned and disinfected.

2.3 [USP 797] All furniture, equipment and other materials necessary for performing sterile compounding activities that is moved into the SCA is cleaned per this policy.

2.4 [USP 797] Cardboard and other outside shipping containers are not allowed into the SCA

2.5 [USP 797] Personnel who compound CSPs within Watsonville Community Hospital independently have successfully completed all required sterile compounding training and competency programs.

2.6 [USP 797] All aseptic manipulations and processes occur inside an ISO Class 5 Primary Engineering Control (PEC).

2.7 [USP 797] All personnel who compound CSPs within Watsonville Community Hospital follow all procedures in the Hand Hygiene and Garbing policy including personnel conduct in the sterile compounding area(s).[USP 797] All supplies, medications, fluids and equipment are cleaned upon entry/crossing the Line of Demarcation (LOD) with sIPA at a minimum

2.8 [Best Practice] Visibly dirty or soiled items/equipment are cleaned with sporicidal agent before introduction into the sterile compounding area and then cleaned per this policy when crossing the LOD (and if introduced into the Primary Engineering Control).

3. Roles & Responsibilities

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

- Ensure all furniture, equipment and materials necessary for sterile compounding is low shedding and easily cleaned and disinfected
- Ensure all personnel involved in sterile compounding move materials, medications, fluids, and supplies into sterile compounding locations and ISO classified areas per this policy in order to maintain the sterility of the CSPs
- Ensure all personnel who compound CSPs are following aseptic technique throughout the entirety of the sterile compounding
- Ensure technology supporting sterile compounding workflow is maintained and consistent with organizational policies and procedures
- Communicate changes in workflow, procedures and systems to compounding staff.

3.2 [USP 797] Compounding personnel:

- Follow all policies and procedures for moving materials, medications, fluids, and supplies into and out of the sterile compounding locations per this policy
- Follow aseptic technique throughout the entirety of sterile compounding

3.3 [USP 797] Pharmacist:

- Provide direct oversight of compounding personnel and procedures to ensure compliance.
- Perform in-process checks and final verification checks of CSPs per policy.
- Perform all CSP storage and/or dispensing processes per policy.

4. Procedures

Movement of Materials: Segregated Compounding Area (SCA):

4.1 [USP 797] Remove all materials moving into the SCA from outer shipping containers and cardboard. Move these containers and carboard away from the immediate vicinity of the SCA and/or before crossing the line of demarcation (LOD) or perimeter line.

4.2 [USP 797] Disinfect all materials that are introduced inside the perimeter of an SCA by wiping with a low-lint wipe saturated with EPA-registered disinfectant or sterile 70% isopropyl alcohol (sIPA) prior to moving into the perimeter of the SCA.

- Wear gloves when wiping down materials.
- Ensure the integrity of all materials is not affected by wiping.
- [Conditional] EPA-registered disinfectant remain on the materials for the proper contact time.
- [Conditional] sIPA remains on the materials until it dries.

4.3 Disinfect all carts moving into the perimeter line of the SCA by wiping with a low-lint wipe saturated with EPA-registered disinfectant or sterile 70% isopropyl alcohol (sIPA) prior to moving into the perimeter line of the SCA. Ensure castors are also wiped down thoroughly.

4.4 [USP 797] Only introduce materials needed for sterile compounding activities inside the perimeter of the SCA.

4.5 [USP 797] Move materials into their storage location within the SCA or use materials for compounding CSPs.

Sterile Compounding Procedure:

4.6 [USP 797] Personnel follow all policies and procedures outlined in **Hand Hygiene and Garbing for Sterile Compounding** policy prior to compounding CSPs and/or working in the SCA.

4.7 [USP 797] Gather all materials needed for compounding CSPs prior to initiating compounding.

4.8 [USP 797] Check expiration date on all vials, ampules, and fluids being used for sterile compounding.

4.9 [USP 797] Check each vial, ampule, bag for:

- Changes in color
- Particles floating in the fluid
- Cloudiness
- Leakage or packaging defects that could impact the integrity of the sterile component
  - If any of these present, do not use for compounding CSPs

4.10 [USP 797] All items necessary for compounding CSPs are wiped down with sIPA and a low-lint wiper and allowed to dry before moving materials into the Primary Engineering Control (PEC).

- The wiping procedure does not render the product label unreadable.
- Sterile supplies in sealed containers moving into the PEC may be removed from the outer covering as the supplies are introduced into the PEC without needing to be wiped with sIPA

4.11 [Conditional] Movement of Materials – RABS (CAI):

- Spray gloved hands with sIPA
- Transfer all materials that have been wiped down into the ante chamber of the compounding isolator.
- Place gloved hands inside isolator sleeves and disinfect the isolator gloves and PEC, including the deck, with sIPA.
- Move materials from the antechamber to the main chamber. Disinfect outer wrapping of gloves.
- Don the sterile gloves over the isolator gloves being careful not to touch the non-sterile surface of the glove wrapping.

4.12 [USP 797] Spray gloved hands with sIPA prior to beginning any CSP manipulations. Gloved hands remain in the ISO 5 PEC for the entire sterile compounding process. When hands removed from PEC, spray gloved hands with sIPA prior to putting them back into the PEC.

4.13 [USP 797] Items used for compounding are arranged inside the PEC so that all items are receiving first air. [Best Practice] All clean/unused items should be located to the left-hand side of the DCA. All used items/discarded items should be arranged on the right-hand side of the DCA. Clean and dirty items are not intermingled.

- Like items are arranged together to organize the direct compounding area (DCA) inside the PEC.

[Best Practice] **Aseptic Technique:**

4.14 Flip dust covers off vials, disinfect vial septum by wiping with an individual sIPA wipe three times firmly in a single direction and allow to dry.

- Critical sites always receive first air after disinfection with sIPA. If first air is interrupted, wipe the vial septum again with sIPA.

4.15 Wipe ampule necks with individual sIPA wipes and allow to dry prior to manipulation. The individual sIPA wipes are used only once.

- Ensure all liquid is in the body of the ampule; lightly tap the head of the ampule, causing liquid to drip down into the body of the ampule.
- Open ampule by wrapping a sIPA wipe around the neck of the ampule and snapping the neck at the scored line if available, away from hands and body, and towards the side of the PEC.
- The ampule is never opened toward the HEPA filter of the PEC.

4.16 Assemble needle and syringe:

- Remove appropriately sized syringe for volume being drawn up from outer packaging. Do not push syringe through paper backing, if present. Gently peel back the two sides of the packaging without touching any of the critical sites. Place packaging trash off to the side. Maintain first air across the luer lock of the syringe, as this is the critical site. Hold syringe in hand as needle is opened.
- Remove outer packaging of appropriately sized needle and twist needle onto the syringe. Do not push needle through paper backing, if present. Gently peel back the two sides of the packaging without touching critical sites. Care is taken to avoid twisting the needle cap off needle; instead pull straight back in a single movement to avoid finger sticks.

4.17 Withdraw required volume from a vial:

- Pull back on the syringe to fill the syringe with air equal to the volume of fluid being removed from the vial
- Hold syringe so that the needle shaft is at a 45^{o} angle to the middle of the vial septum and needle bevel is up. Pierce vial septum with tip of the needle, rotate the needle to 90^{o} the vial septum and push down through the vial septum in one fluid motion. To avoid vial septum coring, do not twist the needle into the vial septum.
- Push air into the air space of the vial, invert vial and hold vial so as to not block first air to the critical site. Ensure needle is now in the fluid space in the vial.
- Pulling back on the plunger flange, withdraw required volume from vial, taking care only to touch the plunger flange and not the plunger shaft.

- Ensure plunger seal is in-line with the correct volume markings on the barrel of the syringe to confirm correct volume withdrawn.
- Check for air bubbles in the syringe barrel. If bubbles are present, flick the barrel of the syringe with fingers to move air bubbles to the top of the syringe. Push air into the vial into the air space, move needle to the fluid space and withdraw to required volume markings on syringe.
- Withdraw needle from the vial and ensure required volume is still within the syringe.
    - If required volume not in the syringe, disinfect vial septum with sIPA wipe and follow all above steps. Do not enter the vial septum in the same location, always utilize an unpierced area on the vial septum to avoid coring.
- Follow all the above steps to reconstitute other vials or withdraw volumes from more than one syringe.
- Needles should not be used more than five (5) times, as this dulls the needle and contributes to coring.
- Remove needle and replace with an unused needle if further manipulations need to be performed with that syringe.

4.18 Withdraw required volume from ampule:

- Ensure needle used in only one direction is a filter needle. The filter needle can be used to withdraw contents from an ampule or push syringe contents into final dose. [Best Practice] Use filter needle or filter straw to withdraw contents from ampule.
- Insert filter needle or filter straw into the contents of the ampule
- Pulling back on the plunger flange, withdraw more than the required volume from the ampule, taking care only to touch the plunger flange and not the plunger shaft.
- Remove the filter straw or filter needle from ampule and turn the syringe upward.
- Check for air bubbles in the syringe barrel. If bubbles are present, flick the barrel of the syringe with fingers to move air bubbles to the top of the syringe.
- Remove filter straw or filter needle from the syringe and replace with a new appropriately sized needle.
- Push the plunger flange upward to expel air bubbles and extra volume. Ensure plunger seal is in-line with the correct volume markings on the barrel of the syringe to confirm correct volume withdrawn.

4.19 Withdrawing or adding required volume from or into IV bag:

- Disinfect drug additive port of IV bag by wiping three times firmly in a single direction with sIPA wipe and allow to dry
- With needle at a 90^{o} angle to the drug additive port, push needle into drug additive port through the center of the port. To avoid coring, do not twist the needle into the IV bag port.
- Pulling back on the plunger flange, withdraw required volume from IV bag, taking care only to touch the plunger flange and not the plunger shaft.
- Ensure plunger seal is in-line with the correct volume markings on the barrel of the syringe to confirm correct volume withdrawn.
- Check for air bubbles in the syringe barrel. If bubbles are present, flick the barrel of the syringe with fingers to move air bubbles to the top of the syringe. Push air into the bag then pull back to withdraw required volume to markings on syringe.
- Pull back on the syringe to remove needle from the IV bag.

4.20 Medication reconstitution:

- Withdraw the required amount of diluent from a bag or vial; following steps above for piercing bags and vials.
- Inject the required diluent into the medication vial; verifying with medication package insert for the instructions for reconstitution (into the powder cake or into the side of the vial).
- Withdraw air from the vial equal to the amount of diluent injected then withdraw needle.
- Follow medication package insert for instructions on the method for ensuring the medication goes into solution (can the medication be shaken or only swirled).

4.21 The following limits should be followed:
- The maximum number of times a needle is used is five (5) times
- The maximum needle gauge for a multiple dose vial is recommended to be 21 gauge
- The selection of syringe size to use is based on volume being measured

4.22 When recapping needle, always utilize the one-handed scoop technique to avoid finger sticks:
- With the syringe in dominant hand and needle cap laying on the DCA, scoop up the needle cap with the needle. Once cap resting over needle, press needle cap completely onto the needle.

4.23 [Conditional: Best Practice when not using an IV Workflow system] All ingredients and measured volumes are checked by a pharmacist prior to being injected or mixed into the final dose.

4.24 [USP 797] Continuously inspect gloves during sterile compounding for holes, punctures, or tears. Gloves are replaced immediately upon discovery of these defects.
- Do not don or doff gloves inside the PEC.
- To replace gloves:
  - Step away from PEC when in a SCA
  - Remove torn, punctured, or soiled gloves
  - Reapply hand sanitizer to hands/wrists and allow to dry
  - Don new pair of sterile gloves

4.25 Cover critical sites of completed CSPs with a tamper evident seal, cover, or cap.

4.26 [USP 797] Compounding personnel inspect completed CSPs for cores, visible particles, discoloration, or other defects and removed from the PEC.

4.27 Move completed CSPs from the PEC to a cart in the buffer room, accumulate all trash in the PEC and discard, and place sharps into a hard-sided sharps container.

4.28 [USP 797] Wipe the DCA of the PEC with sIPA and allow to dry prior to beginning the next CSP.

4.29 Move completed CSPs from the SCA through pass-throughs or doors.

[USP 797] **Conclusion of Compounding: Visual Inspection:**

4.30 Pharmacists check completed CSPs in person and on paperlogs. Items checked include:
- Correct ingredients: medication, diluents, and fluids are used
- Correct measured volumes are removed from vials and/or fluid bags
- Correct measured volumes are injected into vials and/or fluid bags
- Correct/required supplies were used (i.e., filter needle/filter straw, correct needle size, correct syringe size)
- All required steps are completed including lot number/expiration date recording and all required pictures are taken

4.31 Pharmacist visually checks final CSPs for inappropriate physical appearance including:
- Particles **[Best Practice]:** by holding CSP up to white light and black box, when available
- Foreign matter such as vial coring pieces
- Discoloration
- Cloudiness
- Other defects
- Ensure the container closure integrity:
  - Is free of leaks, cracks and improper seals

4.32 Pharmacist visually inspects the final CSP to ensure the label matches the medication order or prescription. Refer to **Release Inspections and Testing policy** for additional criteria.

4.33 Pharmacist ensures correct Beyond Use Date (BUD) is located on the label of the final CSP.
- BUD is determined by Category of CSP and facility conditions during compounding. Refer to **Establishing Beyond-use Dates policy** for additional criteria**.**

4.34 Pharmacist signs completed CSP dose to indicate all checks have been completed
- Signature is printed on the CSP label or hand written

4.35 Any CSP found to have unacceptable quality; the CSP is not signed and immediately rejected.
- The CSP is clearly denoted by the pharmacist as rejected
- The CSP is removed immediately and segregated, then appropriately destroyed

4.36 Move completed, verified, and checked CSPs to the proper storage location and storage conditions within the facility for future dispensation or dispense to the patient.

[USP 797] Visual Inspection Upon Release of CSP:

4.37 All CSPs that have been stored and not released on the day of compounding, are visually inspected before dispensing by a pharmacist.

4.38 Visual inspection includes checking for:
- Precipitation
- Cloudiness
- Leakage

4.39 Any CSP found to have unacceptable quality; the CSP is not signed and immediately rejected.
- The CSP is clearly denoted by the pharmacist as rejected
- The CSP is removed immediately and segregated, then appropriately destroyed

4.40 Any defects found upon visual inspection are investigated as they may indicate a failure in closure integrity, sterility and/or stability.
- The investigation is documented per the processes defined in the QA/QC policy.

5. Definitions

5.1 **Beyond-Use Date (BUD):** The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.

5.2 **Critical Site:** A location that includes and component or fluid pathway surfaces (e.g., vial septum, injection port, and beakers) or openings (e.g., opened ampules and needle hubs) that are exposed and at risk of direct contact whit air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.

5.3 **Designated Person(s) (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.

5.4 **Direct Compounding Area (DCA):** A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

5.5 **EPA:** Environmental Protection Agency

5.6 **First Air:** The air exiting the HEPA filter in a unidirectional air stream

5.7 **Hazardous Drug (HD):** Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, orang toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.

5.8 **High-efficiency particulate air (HEPA) filtration:** Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.

5.9 **Line of Demarcation (LOD):** A visible line on the floor that separates the clean and dirty side of the anteroom

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

5.11 **Pass-through:** An enclosure with sealed doors on both sides that should be interlocked. The pass-through is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.

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

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

6. Related Policies, Documents, References

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

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

7. Approval and Review Summary

Approved by/date:	PTIC, Date of approval (9/2023)
Next review:	Month/year

Initial version published by Wolters Kluwer 2022.

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

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Work and Aseptic Technique for Sterile Compounding	Policy #	PHARM2727
Responsible	Pharmacy Director	Revised/Reviewed	09/2023

I. PURPOSE

1. This policy describes the procedures for Sterile Compounding Workflow and materials handling within a Segregated Compounding Area (SCA) to maintain the quality of the compounding environment and minimize the risk of contamination to Compounded Sterile Preparations (CSPs) prepared within Watsonville Community Hospital.
2. This policy describes the procedures for Aseptic Technique of CSPs within an SCA where CSPs are prepared within Watsonville Community Hospital.
    - Aseptic technique is set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count as an irreducible medium.
3. Sterile compounding workflow includes all the movement of materials within the designated compounding area. It is critical to control transfer of materials between areas of lower quality air to higher quality air to minimize the influx of contaminants, especially activities such as:
    - Entering and exiting SCA
    - Entering and exiting Restricted-access Barrier System (RABS)
    - Use of pass-through chambers
    - Aseptic technique during compounding
4. This policy is not intended to describe the requirements and procedures for aseptic technique of CSPs for Immediate Use within Watsonville Community Hospital.
    - Policies and procedures for immediate use CSPs can be found in the **Immediate Use Compounding policy**.
5. This policy outlines the steps for workflow and aseptic technique for compounding non-hazardous sterile preparations. While many of the aseptic technique steps are the same for hazardous and non-hazardous sterile compounding, additional workflow steps are required when working with hazardous drugs (HDs). Please refer to USP <800> when working with HD CSPs.
    - Watsonville Community Hospital does not compound hazardous drug CSPs.

II. POLICY

A. It is the policy that compounding personnel maintain sterility of CSPs prepared within Watsonville Community Hospital by ensuring aseptic technique is followed in the entirety of the compounding process.
B. All furniture, equipment and other materials necessary for performing sterile compounding activities that is moved into the SCA is low-shedding and easily cleaned and disinfected.
C. All furniture, equipment and other materials necessary for performing sterile compounding activities that is moved into the SCA is cleaned per this policy.
D. Cardboard and other outside shipping containers are not allowed into the SCA
E. Personnel who compound CSPs within Watsonville Community Hospital independently have successfully completed all required sterile compounding training and competency programs.

F. All aseptic manipulations and processes occur inside an ISO Class 5 Primary Engineering Control (PEC).
G. All personnel who compound CSPs within Watsonville Community Hospital follow all procedures in the Hand Hygiene and Garbing policy including personnel conduct in the sterile compounding area(s).[USP 797] All supplies, medications, fluids and equipment are cleaned upon entry/crossing the Line of Demarcation (LOD) with sIPA at a minimum
H. Visibly dirty or soiled items/equipment are cleaned with sporicidal agent before introduction into the sterile compounding area and then cleaned per this policy when crossing the LOD (and if introduced into the Primary Engineering Control).

III. ROLES & RESPONSIBILITIES

1. The Designated Person(s) (DP):
   - Ensure all furniture, equipment and materials necessary for sterile compounding is low shedding and easily cleaned and disinfected
   - Ensure all personnel involved in sterile compounding move materials, medications, fluids, and supplies into sterile compounding locations and ISO classified areas per this policy in order to maintain the sterility of the CSPs
   - Ensure all personnel who compound CSPs are following aseptic technique throughout the entirety of the sterile compounding
   - Ensure technology supporting sterile compounding workflow is maintained and consistent with organizational policies and procedures
   - Communicate changes in workflow, procedures and systems to compounding staff.
2. Compounding personnel:
   - Follow all policies and procedures for moving materials, medications, fluids, and supplies into and out of the sterile compounding locations per this policy
   - Follow aseptic technique throughout the entirety of sterile compounding
3. Pharmacist:
   - Provide direct oversight of compounding personnel and procedures to ensure compliance.
   - Perform in-process checks and final verification checks of CSPs per policy.
   - Perform all CSP storage and/or dispensing processes per policy.

IV. DEFINITIONS

1. **Beyond-Use Date (BUD):** The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
2. **Critical Site:** A location that includes and component or fluid pathway surfaces (e.g., vial septum, injection port, and beakers) or openings (e.g., opened ampules and needle hubs) that are exposed and at risk of direct contact whit air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.
3. **Designated Person(s) (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.
4. **Direct Compounding Area (DCA):** A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
5. **EPA:** Environmental Protection Agency
6. **First Air:** The air exiting the HEPA filter in a unidirectional air stream
7. **Hazardous Drug (HD):** Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans,

orang toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.

8. **High-efficiency particulate air (HEPA) filtration:** Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.
9. **Line of Demarcation (LOD):** A visible line on the floor that separates the clean and dirty side of the anteroom
10. **Low-lint:** Material that exhibits few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from the material in a dry condition
11. **Pass-through:** An enclosure with sealed doors on both sides that should be interlocked. The pass-through is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
12. **Primary Engineering Control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
13. **Restricted-access Barrier System (RABS):** An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include Compounding Aseptic Isolators (CAIs) and Compounding Aseptic Containment Isolators (CACIs).

V. PROCEDURE

A. Movement of Materials: Segregated Compounding Area (SCA):

1. Remove all materials moving into the SCA from outer shipping containers and cardboard. Move these containers and carboard away from the immediate vicinity of the SCA and/or before crossing the line of demarcation (LOD) or perimeter line.
2. Disinfect all materials that are introduced inside the perimeter of an SCA by wiping with a low-lint wipe saturated with EPA-registered disinfectant or sterile 70% isopropyl alcohol (sIPA) prior to moving into the perimeter of the SCA.
   - Wear gloves when wiping down materials.
   - Ensure the integrity of all materials is not affected by wiping.
   - EPA-registered disinfectant remain on the materials for the proper contact time.
   - sIPA remains on the materials until it dries.
3. Disinfect all carts moving into the perimeter line of the SCA by wiping with a low-lint wipe saturated with EPA-registered disinfectant or sterile 70% isopropyl alcohol (sIPA) prior to moving into the perimeter line of the SCA. Ensure castors are also wiped down thoroughly.
4. Only introduce materials needed for sterile compounding activities inside the perimeter of the SCA.
5. Move materials into their storage location within the SCA or use materials for compounding CSPs.

B. Sterile Compounding Procedure:

1. Personnel follow all policies and procedures outlined in **Hand Hygiene and Garbing for Sterile Compounding** policy prior to compounding CSPs and/or working in the SCA.
2. Gather all materials needed for compounding CSPs prior to initiating compounding.
3. Check expiration date on all vials, ampules, and fluids being used for sterile compounding.
4. Check each vial, ampule, bag for:
   - Changes in color
   - Particles floating in the fluid

- Cloudiness
- Leakage or packaging defects that could impact the integrity of the sterile component
  - If any of these present, do not use for compounding CSPs

5. All items necessary for compounding CSPs are wiped down with sIPA and a low-lint wiper and allowed to dry before moving materials into the Primary Engineering Control (PEC).
   - The wiping procedure does not render the product label unreadable.
   - Sterile supplies in sealed containers moving into the PEC may be removed from the outer covering as the supplies are introduced into the PEC without needing to be wiped with sIPA
6. Movement of Materials – RABS (CAI):
   - Spray gloved hands with sIPA
   - Transfer all materials that have been wiped down into the ante chamber of the compounding isolator.
   - Place gloved hands inside isolator sleeves and disinfect the isolator gloves and PEC, including the deck, with sIPA.
   - Move materials from the antechamber to the main chamber. Disinfect outer wrapping of gloves.
   - Don the sterile gloves over the isolator gloves being careful not to touch the non-sterile surface of the glove wrapping.
7. Spray gloved hands with sIPA prior to beginning any CSP manipulations. Gloved hands remain in the ISO 5 PEC for the entire sterile compounding process. When hands removed from PEC, spray gloved hands with sIPA prior to putting them back into the PEC.
8. Items used for compounding are arranged inside the PEC so that all items are receiving first air. All clean/unused items should be located to the left-hand side of the DCA. All used items/discarded items should be arranged on the right-hand side of the DCA. Clean and dirty items are not intermingled.
   - Like items are arranged together to organize the direct compounding area (DCA) inside the PEC.

C. Aseptic Technique:

1. Flip dust covers off vials, disinfect vial septum by wiping with an individual sIPA wipe three times firmly in a single direction and allow to dry.
   - Critical sites always receive first air after disinfection with sIPA. If first air is interrupted, wipe the vial septum again with sIPA.
2. Wipe ampule necks with individual sIPA wipes and allow to dry prior to manipulation. The individual sIPA wipes are used only once.
   - Ensure all liquid is in the body of the ampule; lightly tap the head of the ampule, causing liquid to drip down into the body of the ampule.
   - Open ampule by wrapping a sIPA wipe around the neck of the ampule and snapping the neck at the scored line if available, away from hands and body, and towards the side of the PEC.
   - The ampule is never opened toward the HEPA filter of the PEC.
3. Assemble needle and syringe:
   - Remove appropriately sized syringe for volume being drawn up from outer packaging. Do not push syringe through paper backing, if present. Gently peel back the two sides of the packaging without touching any of the critical sites. Place packaging trash off to the side. Maintain first air across the luer lock of the syringe, as this is the critical site. Hold syringe in hand as needle is opened.
   - Remove outer packaging of appropriately sized needle and twist needle onto the syringe. Do not push needle through paper backing, if present. Gently peel back the two sides of the packaging without touching critical sites. Care is taken to avoid

twisting the needle cap off needle; instead pull straight back in a single movement to avoid finger sticks.

4. Withdraw required volume from a vial:
   - Pull back on the syringe to fill the syringe with air equal to the volume of fluid being removed from the vial
   - Hold syringe so that the needle shaft is at a 45^{o} angle to the middle of the vial septum and needle bevel is up. Pierce vial septum with tip of the needle, rotate the needle to 90^{o} the vial septum and push down through the vial septum in one fluid motion. To avoid vial septum coring, do not twist the needle into the vial septum.
   - Push air into the air space of the vial, invert vial and hold vial so as to not block first air to the critical site. Ensure needle is now in the fluid space in the vial.
   - Pulling back on the plunger flange, withdraw required volume from vial, taking care only to touch the plunger flange and not the plunger shaft.
   - Ensure plunger seal is in-line with the correct volume markings on the barrel of the syringe to confirm correct volume withdrawn.
   - Check for air bubbles in the syringe barrel. If bubbles are present, flick the barrel of the syringe with fingers to move air bubbles to the top of the syringe. Push air into the vial into the air space, move needle to the fluid space and withdraw to required volume markings on syringe.
   - Withdraw needle from the vial and ensure required volume is still within the syringe.
     - If required volume not in the syringe, disinfect vial septum with sIPA wipe and follow all above steps. Do not enter the vial septum in the same location, always utilize an unpierced area on the vial septum to avoid coring.
   - Follow all the above steps to reconstitute other vials or withdraw volumes from more than one syringe.
   - Needles should not be used more than five (5) times, as this dulls the needle and contributes to coring.
   - Remove needle and replace with an unused needle if further manipulations need to be performed with that syringe.
5. Withdraw required volume from ampule:
   - Ensure needle used in only one direction is a filter needle. The filter needle can be used to withdraw contents from an ampule or push syringe contents into final dose. Use filter needle or filter straw to withdraw contents from ampule.
   - Insert filter needle or filter straw into the contents of the ampule
   - Pulling back on the plunger flange, withdraw more than the required volume from the ampule, taking care only to touch the plunger flange and not the plunger shaft.
   - Remove the filter straw or filter needle from ampule and turn the syringe upward.
   - Check for air bubbles in the syringe barrel. If bubbles are present, flick the barrel of the syringe with fingers to move air bubbles to the top of the syringe.
   - Remove filter straw or filter needle from the syringe and replace with a new appropriately sized needle.
   - Push the plunger flange upward to expel air bubbles and extra volume. Ensure plunger seal is in-line with the correct volume markings on the barrel of the syringe to confirm correct volume withdrawn.
6. Withdrawing or adding required volume from or into IV bag:
   - Disinfect drug additive port of IV bag by wiping three times firmly in a single direction with sIPA wipe and allow to dry
   - With needle at a 90^{o} angle to the drug additive port, push needle into drug additive port through the center of the port. To avoid coring, do not twist the needle into the IV bag port.
   - Pulling back on the plunger flange, withdraw required volume from IV bag, taking care only to touch the plunger flange and not the plunger shaft.

- Ensure plunger seal is in-line with the correct volume markings on the barrel of the syringe to confirm correct volume withdrawn.
- Check for air bubbles in the syringe barrel. If bubbles are present, flick the barrel of the syringe with fingers to move air bubbles to the top of the syringe. Push air into the bag then pull back to withdraw required volume to markings on syringe.
- Pull back on the syringe to remove needle from the IV bag.

7. Medication reconstitution:
   - Withdraw the required amount of diluent from a bag or vial; following steps above for piercing bags and vials.
   - Inject the required diluent into the medication vial; verifying with medication package insert for the instructions for reconstitution (into the powder cake or into the side of the vial).
   - Withdraw air from the vial equal to the amount of diluent injected then withdraw needle.
   - Follow medication package insert for instructions on the method for ensuring the medication goes into solution (can the medication be shaken or only swirled).
8. The following limits should be followed:
   - The maximum number of times a needle is used is five (5) times
   - The maximum needle gauge for a multiple dose vial is recommended to be 21 gauge
   - The selection of syringe size to use is based on volume being measured
9. When recapping needle, always utilize the one-handed scoop technique to avoid finger sticks:
   - With the syringe in dominant hand and needle cap laying on the DCA, scoop up the needle cap with the needle. Once cap resting over needle, press needle cap completely onto the needle.
10. All ingredients and measured volumes are checked by a pharmacist prior to being injected or mixed into the final dose.
11. Continuously inspect gloves during sterile compounding for holes, punctures, or tears. Gloves are replaced immediately upon discovery of these defects.
    - Do not don or doff gloves inside the PEC.
    - To replace gloves:
      - Step away from PEC when in a SCA
      - Remove torn, punctured, or soiled gloves
      - Reapply hand sanitizer to hands/wrists and allow to dry
      - Don new pair of sterile gloves
12. Cover critical sites of completed CSPs with a tamper evident seal, cover, or cap.
13. Compounding personnel inspect completed CSPs for cores, visible particles, discoloration, or other defects and removed from the PEC.
14. Move completed CSPs from the PEC to a cart in the buffer room, accumulate all trash in the PEC and discard, and place sharps into a hard-sided sharps container.
15. Wipe the DCA of the PEC with sIPA and allow to dry prior to beginning the next CSP.
16. Move completed CSPs from the SCA through pass-throughs or doors.

D. Conclusion of Compounding: Visual Inspection:

1. Pharmacists check completed CSPs in person and on paper logs. Items checked include:
   - Correct ingredients: medication, diluents, and fluids are used
   - Correct measured volumes are removed from vials and/or fluid bags
   - Correct measured volumes are injected into vials and/or fluid bags
   - Correct/required supplies were used (i.e., filter needle/filter straw, correct needle size, correct syringe size)
   - All required steps are completed including lot number/expiration date recording and all required pictures are taken

2. Pharmacist visually checks final CSPs for inappropriate physical appearance including:
   - Particles: by holding CSP up to white light and black box, when available
   - Foreign matter such as vial coring pieces
   - Discoloration
   - Cloudiness
   - Other defects
   - Ensure the container closure integrity:
     - Is free of leaks, cracks and improper seals
3. Pharmacist visually inspects the final CSP to ensure the label matches the medication order or prescription. Refer to **Release Inspections and Testing policy** for additional criteria.
4. Pharmacist ensures correct Beyond Use Date (BUD) is located on the label of the final CSP.
   - BUD is determined by Category of CSP and facility conditions during compounding. Refer to **Establishing Beyond-use Dates policy** for additional criteria**.**
5. Pharmacist signs completed CSP dose to indicate all checks have been completed
   - Signature is printed on the CSP label or hand written
6. Any CSP found to have unacceptable quality; the CSP is not signed and immediately rejected.
   - The CSP is clearly denoted by the pharmacist as rejected
   - The CSP is removed immediately and segregated, then appropriately destroyed
7. Move completed, verified, and checked CSPs to the proper storage location and storage conditions within the facility for future dispensation or dispense to the patient.

E. Visual Inspection Upon Release of CSP:

1. All CSPs that have been stored and not released on the day of compounding, are visually inspected before dispensing by a pharmacist.
2. Visual inspection includes checking for:
   - Precipitation
   - Cloudiness
   - Leakage
3. Any CSP found to have unacceptable quality; the CSP is not signed and immediately rejected.
   - The CSP is clearly denoted by the pharmacist as rejected
   - The CSP is removed immediately and segregated, then appropriately destroyed
4. Any defects found upon visual inspection are investigated as they may indicate a failure in closure integrity, sterility and/or stability.
   - The investigation is documented per the processes defined in the QA/QC policy.

VI. REFERENCES

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

VII. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Compounded Sterile Products: Sterile Compounding Procedures and Aseptic Technique	Policy #	PHARM2727
Responsible	Pharmacy Director	Revised/Reviewed	05/2022

I. PURPOSE

- To ensure appropriate conduct of personnel in controlled areas, which include buffer areas (cleanrooms), ante-areas, Pharmacy preparation areas, and Pharmacy storage/warehouse areas.
- To insure utilization of general principles and techniques of aseptic technique in preparation of compounded sterile products (CSPs).
    - Aseptic technique refers to procedures performed under controlled conditions in an effort to minimize the risk of contamination which is the foundation of product integrity.

II. POLICY

A. All CSPs (compounded sterile products) will be prepared within an ISO Class 5 environment.
- ISO Class 5 environment is an environment in a:
    - Laminar Air Flow Hood or Workbench (LAFW);
    - Biological Safety Cabinet – Class 1 or 2, Type A or B (BSC);
    - Compounding Aseptic Containment Isolator (CACI); or
    - Compounding Aseptic Isolator (CAI).
- ISO Class 5 environment at WCH includes both a Compounding Aseptic Isolator (CAI) and a Compounding Aseptic Containment Isolator (CACI).

B. Strict adherence to aseptic technique will be maintained at all times throughout all critical component manipulations.

C. All compounding employees must conduct themselves in a professional manner which includes but is not limited to behavior that is consistent with:
- Defined policy and procedure;
- Attention to detail;
- Monitoring visitor behavior;
- Calling attention to personnel not adhering to policy and procedure;
- Minimizing waste;
- General attention to all aspects of compounding operations.

D. The preparation of CSPs may be performed by either a qualified pharmacist and/or pharmacy technician under the supervision of a registered pharmacist.

III. DEFINITIONS

A. Aseptic Break:
- An aseptic break is the result of an aseptic manipulation, whereby the manufacturer/ sterile container of medication or solution for injection is pierced, opened, entered, or exposed to an outside environment, which would allow for the introduction of microorganisms or particulate matter.
- This manipulation causes a break or opening in the sterile fluid pathway, in an otherwise closed or sealed system.

- It is of utmost importance to minimize the number of these breaks as well as the duration of such breaks thus reducing the potential for contamination.

B. Contact Surfaces:
   - All components are compounded and eventually placed into sterile containers that have sterile interior surfaces.
   - These interior surfaces have the potential to become exposed to an outside environment during aseptic manipulations.
   - To minimize this potential, only the non-solution or powder side or the non-solution contact surface may be handled.

C. First Air:
   - The air exiting the HEPA filter in a unidirectional air stream that is essentially particle-free.

D. Direct Compounding Area (DCA):
   - The critical area within the ISO Class 5 primary engineering control (PEC) where critical sites are exposed to first air.

E. Critical Area:
   - Essentially the ISO Class 5 environment in which compounding takes place.

F. Clean Cart:
   - A designated and appropriately labeled cart used solely to transport supplies and products to and from the compounding and labeling areas.
   - The clean cart is prohibited from leaving these areas.
   - NOTE: WCH does not utilize “Clean Carts.”

G. Dirty Cart:
   - A designated cart used solely to gather compounding supplies from the general Pharmacy storage area, loading dock, or Pharmacy areas for transport to and from the ante-area.
   - This designated cart is strictly prohibited from crossing the line of demarcation in the ante-area.

H. IV Additive Pooling:
   - his procedural method directs several small volume components be combined into a larger sterile container to obtain a resultant solution of specific concentration and or calculated aliquot.
   - This solution will then be dispensed to individual unit of use containers via a high speed automated compounder, peristaltic Pharmacy pump, or multi-additive syringe.
   - Due to the large number of aseptic breaks required to make a pool, all pooled solutions are required to be cold sterilized by means of a 0.22 micron filter into the final container, unless there is use of an additional injection cap off of the final container. (See section IV.F. Aseptic Breaks)
   - Example: parenteral nutrition.

I. Batch:
   - A batch is either a single or multiple component unit that is prepared by an individual during a limited period of time for a single product.

J. Primary Engineering Control (PEC):
   - A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs.

- Such devices include but may not be limited to laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), Compounding Aseptic Isolators (CAIs), and Compounding Aseptic Containment Isolators (CACIs).
    - PEC / ISO Class 5 environment at WCH includes a Compounding Aseptic Isolator (CAI) and a Compounding Aseptic Containment Isolator (CACI).

IV. PROCEDURE

A. Materials and Equipment
1. ISO Class 5 work station
2. Approved hand hygiene and garbing equipment and supplies
3. Approved cleaning and disinfecting agents and supplies such as lint-free towels, mops, buckets, etc.
4. Sterile alcohol pads or spray bottles containing sterile 70% IPA (isopropyl alcohol)
5. Sterile medications per prescription requirements
6. Sterile diluents and additives per prescription requirements
7. Sterile syringes, needles, and transfer devices
8. Sterile tubing, transfer sets, and appropriate empty containers
9. Automated compounders or other filling devices

B. Preparing to Compound: Material and Supply handling
1. All supplies introduced into the clean room environment, either for storage or for immediate compounding, are to be selected from the storage area.
    a. These supplies are brought into the general Pharmacy area by means of the dirty cart.
2. All products will be removed from their shipment cartons or non-plastic overwrap prior to leaving the Pharmacy storage area.
    a. Shipment cartons, secondary packaging and non-plastic overwrap generate considerable particulate matter and possibly harbor mold and microorganisms which can possibly contaminate products.
3. The cart will be brought into the general Pharmacy area where the products and or supplies will be inspected for excess particulate matter and container integrity.
4. Supplies required for immediate operations are wiped down with an appropriate disinfecting agent before being transferred into the buffer area/cleanroom.
    a. By wiping off all materials going into the ante-area and buffer area/cleanroom, particulates on the outer container are removed potential lessening the potential bioburden introduced into the controlled environments.
5. Supplies required frequently as back up to immediate operations may be stored on shelving in the buffer area/cleanroom on one or more movable carts after they are wiped down with the designated disinfecting agent.
6. Supplies that are required frequently or are otherwise needed close at hand but not necessarily needed for the scheduled operations of the shift can be decontaminated and stored on shelving in the ante-area.
7. Personnel gathering the individual supplies need to review the patient specific prescription order to ascertain that all supplies and drug products are obtained prior to initiating the compounding.
8. Personnel will document on the batch or compounding record the appropriate lot number and expiration dates of all products being used.
9. Placing the components in a plastic bin or tote will segregate them and prevent errors.

10. Each batch bin or tote is transported into the buffer area/cleanroom on a clean cart through the pass-through area or transferred from the dirty cart to the clean cart at the line of demarcation.
11. Only one batch should be placed at a workstation to avoid errors with the mix-up of components and labels for which the CSP is being prepared.

C. ISO Class 5 Areas
1. Primary Engineering Controls (PECs) should be operated continuously.
   a. If PECs are turned off, only one compounding employee may enter the buffer area/cleanroom to turn the blowers on.
   b. The PEC must be allowed to operate at least 30 minutes prior to initiating cleaning and compounding.
2. All work areas are to be cleaned and disinfected prior to the start of any compounding activity, and at the completion of each compounded batch.
3. All aseptic manipulations must be performed at least 6 inches inside the front edge of the LAFW.
4. For BSCs (including CAI), assure that the front return grate or air inlet grid located at the front edge of the work surface is not blocked with debris or supplies.
   a. The blockage of this vent will greatly reduce airflow and proper circulation and possible inhibit the proper ventilation and operations of this equipment.
5. Supplies used in the DCA (direct compounding area) must be decontaminated once again prior to placing them inside the PEC using sterile 70% IPA.
6. Drugs, supplies, and equipment in the DCA must be arranged to reduce clutter and provide maximum efficiency and order in work.
7. Identification of all items need to complete compounding of a particular batch or patient specific preparation should occur so the number of times the compounder has to remove their hands from the ISO Class 5 environment is minimized.
8. If a compounding employee's hands leave the ISO Class 5 environment, they must be re-sanitized with sterile 70% IPA.
9. Drugs, supplies, and equipment must be placed and used in a manner that does not disrupt the clear and uninterrupted path of HEPA-filtered first air that will bathe all critical sites during the planned procedures.
10. No objects should be placed between the first air and the exposed critical sites.

D. General Conduct
1. Entry into controlled areas shall be limited to trained employees who need access to complete assigned tasks.
2. Conduct of Approved Visitors:
   a. Occasionally, other persons, such as administrators, service vendors, and maintenance personnel, may require entry into controlled compounding area.
      1) These individuals must be accompanied at all times by Pharmacy personnel.
   b. Director of Pharmacy or designee must approve entry by non-compounding personnel.
   c. Approved visitors who desire to enter the ante-area or buffer area, must follow all parameters of the Hand Hygiene and Garbing procedures.
   d. The escorted visitors must keep their gloved, disinfected hands clasped in front of or behind their backs during their time in the buffer area/cleanroom and are not permitted to touch any surfaces unless performing necessary maintenance functions.
3. When possible, entry passages to controlled areas must remain closed and never left propped open.

4. Eating, drinking, gum chewing, tobacco, spitting, and smoking are prohibited in any controlled areas.
5. Conversations should be limited to reduce airborne particles in the ante-area and buffer/cleanroom.
6. Coughing, sneezing, and talking directly into the PEC is to be avoided.
7. The number of personnel in the ante-area/buffer area/cleanroom should be limited to those required for essential operations.
8. The number of units being prepared in each work area at one time should be consistent with the amount of work space in the critical area.
9. No food or drinks will be stored in any of the controlled areas' refrigerators, freezers, or storage area at any time.
    a. Food and drinks must be stored in the designated refrigerator in the employee lounge/breakroom.
    b. Consumption of food and drinks is limited to the lounge/breakroom or offices.
    c. Any drinks of food transported through the general Pharmacy area must be covered or be in an enclosed container.
10. All trash will be removed from the controlled areas on an as needed basis and at the end of the day.
11. All fluid, vial and ampule containers must be examined prior to use.
    a. Products that exhibit turbidity, cloudiness, or show signs of visual particulate will not be used.
12. All critical sites such as vial tops, injection port covers, ampules, and rubber stoppers must be cleaned with 70% sterile IPA and allowed to dry prior to entry with a needle.
13. Should any break in technique occur, the drug or additive must be discarded, and new drugs and compounding materials obtained and utilized.

E. Prior to the start of batch compounding, a pharmacist will perform the following:
1. Review calculations for accuracy.
2. Ensure the appropriate component products have been selected.
3. Review and document, if required, the lot numbers and expiration dates onto the batch record.
    a. This record must be maintained and readily available for review by legal and regulatory bodies as required by standard or law.
4. Assure that the product being compounded matches the device to be utilized for administration.
5. Record any additional instructions onto the batch record and communicate them to the personnel performing the compounding.
6. Assure that the product being compounded matches the device to be utilized for administration.
7. Record any additional instructions onto the batch record and communicate them to the personnel performing the compounding.
8. Verify the appropriate assembly and setup of components
9. Verify pump settings and calibration of equipment
10. Address any compounding questions or concerns.
11. If post-compounding errors are determined, all products must be discarded.

F. Aseptic Breaks
1. If the number of aseptic breaks exceeds fifteen per final container, then the CSP being compounded should be filtered utilizing a 0.22 micron filter downstream of the breaks or the use of an additional injection cap off of the final container.

2. The transfer of all components into a large sterile container followed by the filtration of the resultant product prior to entry into the final unit of use packaging provides a final (acceptable) the filtration method.
3. The additional injection cap method is accomplished by attaching an injection cap onto, for example, an 18-gauge needle.
    a. This unit is then placed into the injection cap of the final container.
    b. All aseptic breaks are made through the additional injection cap.

G. Sterile Compounding Manipulations
1. Needles and Syringes
    a. A needle may be used for a maximum of 10 entries into an injection port or vial before being discarded and replaced. New non-coring needles may be utilized up to 15 times.
    b. In order to assure that the final container is completely resealed after entry, the largest size needle utilized in final container preparation is an 18 gauge plain needle or a 18 gauge non-coring needle.
    c. Filter needles may be used only once and then discarded.
    d. Add-on filters may be used throughout the entire batch or until they become noticeably clogged.
    e. Removing a syringe from its packaging
        1) Note that the outer wrap is intact, dry, unsoiled, and/or undamaged. If not, then discard.
        2) Note that the syringe is the appropriate and desired size.
        3) Separate the two halves of the packaging by slowly peeling the paper half from the plastic outer wrap and then lay the syringe on the work surface.
        4) This procedure should be done without actually touching the syringe.
    f. Removing a needle from its package and attaching to a syringe.
        1) Inspect the outer wrap to ensure that it is intact, dry, unsoiled, and/or undamaged. If it is not, then discard.
        2) Insure that the appropriate and desired size is chosen.
        3) Holding the needle between your thumb and forefinger in the non-dominant hand, gently peel back the two halves of the packaging being careful not to touch the exposed end of the interlocking hub.
        4) Do not fully unwrap the needle.
        5) Hold the paper outer wrap aside by pinching the peeled back paper approximately ¾ of the way down and against the plastic barrel of the needle packaging,
        6) Hold the needle firmly.
        7) Pick up the syringe with the free dominant hand.
        8) Utilizing just the pinkie finger of the non-dominant hand, dislodge the syringe cap by wrapping the pinkie around the cap while twisting the syringe in a counterclockwise motion.
        9) Avoid touching the hub of the syringe.
        10) Once the plastic syringe cap has been removed, it may be dropped onto the work surface or held.
        11) Now that both the syringe hub and needle hub are exposed, carefully insert the male end of the syringe hub into the female distal end of the needle and connect the two by gently pushing the two together and twisting in a clockwise motion.

12) The needle should seat firmly and straight and should not continue to twist after one rotation.
13) To remove the needle guard, pull it straight without a twisting motion. It should separate easily from the syringe.
14) To remove a needle, carefully reinsert the needle into the needle guard and twist counterclockwise.

2. Transferring solution from a vial to a syringe
   a. Remove the vial closure cap and swab the diaphragm with an alcohol pad and allow to dry.
   b. Pull back on the syringe plunger to a volume equal to the volume to be withdrawn from the vial unless the volume to be withdrawn is very small or the vial is already pressurized.
   c. When pulling back on the plunger, hold the barrel of the syringe tightly between the thumb and first two fingers of the non-dominant hand.
   d. Grip only the very distal flat end of the plunger being careful not to touch the shaft of the plunger. Touching the shaft may introduce contaminants into the barrel of the syringe as the solution is expelled and might draw contaminants into the solution upon reuse of the syringe.
   e. Holding the syringe with the attached needle at roughly a 90-degree angle to the vial, rotate the syringe to locate the bevel side of the needle.
   f. The bevel should be aimed upward or away from the vial stopper and should be clearly visible.
   g. Holding the vial firmly against the work surface, penetrate the vial diaphragm. In most cases, a target area has been imprinted on the stopper in the center of the vial which should be the preferred entry point.
   h. With the needle still inserted into the vial, invert the vial by grasping the base of the vial and holding it between the thumb and forefingers of the non-dominant hand. The vial stopper should hold the syringe in place.
   i. Hold the vial about eye level and maintain the grip on the base of the vial using only the tips of the fingers of the non-dominant hand. This action will form an open grip that will allow maximum airflow to pass over the hand and the vial while the solution is being withdrawn.
   j. Using the dominant hand, pull back on the entire syringe to position the point of the needle so that it just barely protrudes through the vial stopper. This will allow for the maximum amount of medication contained in the vial to be withdrawn.
   k. Pull back on the syringe plunger until the required amount of solution is drawn into the barrel of the syringe.
   l. Check the graduations on the syringe to assure the appropriate amount of solution is being withdrawn.
3. Removing air bubbles
   a. Air bubbles may commonly be withdrawn from the vial in addition to the solution hindering the accurate measurement of solutions.
   b. To remove air bubbles, hold the syringe vertically so that the needle is pointing upward.
   c. Pull the syringe plunger back to allow a small amount of air to enter the syringe barrel.
   d. Gently tap the side of the syringe to dislodge any bubbles that are adhering to the sides.

e. If necessary, rotate or roll the barrel of the syringe to remove smaller bubbles.
f. Expel all of the air by slowly pushing the plunger until the solution starts to exit the needle.
g. Read the volume of the solution by aligning the rubber portion of the plunger with the graduated markings on the syringe barrel.
h. An alternative method for expelling the air may be accomplished while the needle is still inserted in the vial.
    1) Position the point of the needle into the air space beyond the solution being drawn up and tap the syringe to release air bubbles.
    2) Inject the air back into the vial as you adjust the volume in the syringe to the correct volume amount. This procedure maintains a closed system and allows for any excess drug to be retained in the vial for reuse.

4. Transfer of Medication from an Ampule
    a. Hold the ampule upright and either by tapping the neck of the ampule or by grasping the ampule by its top; quickly rotate it in a semicircle to work all the contents that may be in the top of the ampule into the body of the ampule.
    b. Swab the neck of the ampule with an alcohol pad paying particular attention to the juncture of the neck and body.
    c. Wrap an alcohol pad around the neck of the ampule and grasp the ampule firmly with the thumb of one hand and the forefinger of the other hand.
    d. Quickly snap the neck of the ampule by leveraging the forefinger against the neck of the ampule while using the alcohol pad to cushion and create pressure against the wall of the ampule.
    e. The ampule should break easily and evenly. If the ampule does not break easily, rotate it slightly so pressure may be exerted at a weaker point.
    f. Once the ampule is opened, hold the base between the thumb and fingers of one hand positioning the ampule so that it is approximately at a 60 degree angle with its opening facing down.
    g. Placing the syringe across the palm of the hand, place the needle bevel side down into the shoulder of the ampule, pull back the plunger by using the leverage created by pushing against the syringe barrel and the plunger.
    h. Once the appropriate amount of solution is drawn into the syringe, the needle must be changed to a 5 micron or less filter needle prior to injection into final containers.
    i. Without allowing the needle to touch any surface, the solution is now ready for transfer into an appropriate container.
5. Reconstitution of Powders
    a. If a drug is lyophilized or in a powdered form, it first must be converted to a solution.
    b. Determine the appropriate diluent and volume for reconstitution based on the manufacturer's recommendations.
    c. Remove the close cap from the vial and with 70% sterile IPA.
    d. Draw up the appropriate volume of diluent using previously described methods.
    e. After drawing up the appropriate diluent volume, change the needle by recapping, twisting counterclockwise, and replace it with an 18 gauge vented needle.
    f. The vented needle will allow the diluent to flow into the vial while allowing air to escape thus making room for the solution to easily enter the vial.
        1) This process should not be performed if compounding agents are designated as hazardous by NIOSH.

g. Remove the needle and agitate the vial until all powder is dissolved and the solution appears to be uniform.
h. Using a new syringe and needle, re-enter the vial and withdraw the appropriate amount of medication.
i. The needle may be replaced with a sterile syringe cap if the syringe is to be the final container.

6. Utilizing a Large Volume Parenteral Bag for Reconstitution
   a. All solution bags used by this method must be newly opened.
   b. All bags from the previous days compounding session should be removed and disposed.
   c. Remove the protective closure cover from the fluid spike port of the large volume parenteral bag. This section of exposed tubing is a sterile pathway and must be handled carefully.
   d. Aseptically insert the spike of a multiple additive syringe set into this fluid port after first clamping off the tubing that runs from the bag to the syringe setup.
   e. Attach the spring-loaded or other syringe device to the tubing set.
   f. Unclamp the tubing set and prime the device by expelling air and removing bubbles that may be clinging to the inside if the syringe barrel.
   g. For multiple additions of the same volume, the syringe volume is normally adjusted by means of a locking, threaded screw mechanism. Simply screw the mechanism so that the rubber portion of the plunger is set to the desired volume and lock the mechanism by pushing it forward.
   h. Attach an 18 gauge vented needle to the delivery set and leave the protective cap on.
   i. The vented needle may be used to reconstitute up to 10 vials of the same drug, then it is to be replaced.
      1) The vented needle must also be replaced whenever a different drug product is reconstituted or at the start of a new prescription batch.
      2) All diluent should be transferred consecutively into the multiple vials as part of a continuous process.
   j. During the process, a pharmacist should assure the following:
      1) The appropriate diluent and volumes are correct.
      2) All products contained in ampules are being filtered.
      3) Ensure correct drug dosages are being dispensed either by direct observation or by having compounding personnel leave syringes for checking by a pharmacist.
      4) Visually inspect for particulate matter. If particulate matter is visible, the solution should be filtered by means of 0.22 micron filter.
      5) Check container integrity for leaks or cracks.
      6) Check for signs of product deterioration or microbial contamination.
      7) The correct number of doses has been prepared per batch record specifications.
      8) Any external product or spills onto a compounded container should be cleaned away with a lint free cloth moistened with sterile water prior to labeling.
      9) A sample copy of the label should be attached to the batch record.
      10) All completed batch records should be filed and readily retrievable to verify compounding status and determination of delivery status, if required.

I. REFERENCES

Joint Commission Standards: EC.02.01.01 EP 3 IC.02.01.01 EP 2

MM.05.01.07 EP 1 – 2, 4 MM.05.01.09 EP 1 – 12

II. STAKEHOLDERS

N/A

Watsonville Community Hospital	**Beyond Use Dating and Stability Considerations**
Policy Number/ Version:	797-2022 Version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the procedures for the determination and assignment of beyond use dating (BUD) for Compounded Sterile Preparations (CSP) prepared within Watsonville Community Hospital.

1.2. [USP 797] BUD limits are intended to help prevent patient harm resulting from microbial proliferation and contamination of CSPs. BUDs are determined by evaluating the chemical stability of the CSP components or formulation, storage conditions, starting components (sterile vs. non-sterile), sterile processing approach, and type of sterile compounding area where the CSP is prepared.

1.3. [USP 797] Expiration dates and BUDs are not interchangeable terms or concepts and medication administration terms cause confusion around the definition and application of BUDs assigned to compounded sterile preparations.

- **Expiration date** is the time during which a manufactured product can be expected to meet the requirements of the USP–NF monograph, if one exists, or maintain expected quality provided it is kept under the specified storage conditions; applies to all conventionally manufactured products, active pharmaceutical ingredients (API), and added substances.
- **BUD** is the date, or hour and date, after which the administration of a CSP cannot begin. BUDs are not intended to limit administration time; applies to all CSPs and stock solutions made by Compounding Personnel.
- **Hang time or administration time** refers to the amount of time during which a CSP or conventionally manufactured product (e.g. pre-mix, large volume parenteral solution) may by be infused before which the tubing or medications needs to be changed due to stability considerations. Hang time is not determined by USP <797> and is considered out of scope for this policy.

1.4. This policy denotes the BUD assignment for all CSPs compounded at Watsonville Community Hospital.

- Refer to **policy** for the procedures pertaining further information about the requirements and definition of Immediate Use Compounding

2. Policy

2.1. [USP 797] Every CSP is labeled with a date, or date and hour, after which administration of the medication cannot occur (i.e., BUD). BUDs are:

- Based on anticipated storage conditions
- Determined from the time compounding begins
- Not allowed to exceed the shortest remaining expiration date of any of the commercially available or compounded components used in the preparation of the CSP.
- Consider one day equivalent to 24 hours

2.2. [USP 797] Maximum BUDs differ for Immediate Use and Category 1 CSPs and, at no times, are extended beyond those stated in USP <797>; adapted from Tables 12 and 13 of USP <797>.

- Watsonville Community Hospital has a Segregated Compounding Area (SCA), not a cleanroom suite.

	Controlled Room Temperature [20°C to 25°C]	Refrigerated Temperature [2°C to 8°C]	Frozen Temperature [-25°C to -10°C]
Immediate Use CSPs			
Aseptically processed CSPs from only sterile starting components	≤ 4 hours	≤ 4 hours	Not Applicable
Category 1 CSPs			
Aseptically processed CSPs from only sterile starting components	≤ 12 hours	≤ 24 hours	Not Applicable

2.3. [USP 797] BUDs are assigned by Compounding Personnel with consideration for factors that could impact the CSP quality or sterility including, but not limited to:

- Chemical and physical stability of the components and/or formulation
- Container closure system and compatibility with the final preparation and storage conditions
- Compounding environment in which the CSP is prepared
- Aseptic processing and sterilization method
- Sterility of starting components
- Whether or not sterility testing is performed (if applicable)
- Storage conditions

2.4. [USP 797] When the chemical or physical stability of the CSP is shorter than the maximum BUD, the most conservative dating becomes the BUD.

- Chemical stability is based on available manufacturer's data, published literature, and industry references.

2.5. [USP 797] Packaging is selected for the CSP to preserve sterility, chemical stability, and potency.

2.6. [USP 797] CSPs stored under or moved to different storage conditions before they are used assume the new shorter BUD of the storage condition(s) which does not to exceed the original BUD placed on the CSP at the time of preparation

- BUDs are not additive; administration is initiated before the BUD is exceeded or the CSP is promptly and appropriately discarded
- Once a CSP has been stored under a new storage condition requiring a shorter BUD, the CSP is used within the shortened timeframe

2.7. [USP 797] Storage conditions per **USP <659> Packaging and Storage Requirements**:

- Controlled Room Temperature: 20°C to 25°C
- Refrigerated: 2°C to 8°C
- Frozen: -25°C to -10°C

2.8. [USP 797] Conventionally manufactured sterile products or components used in the preparation of CSPs adhere to the following BUDs, use and storage requirements:

Conventionally Manufactured Products & Components		
	Expiration Date	Use and Storage Conditions
Single-dose containers	12 hours	• Punctured and entered within an ISO Class 5 PEC • Stored per labeled storage conditions
Ampule (or open plastic luer lock vials)	Discard immediately after use	• Punctured and entered within an ISO Class 5 PEC
Multi-dose containers	28 days (unless otherwise specified by manufacturer's labeling)	• Punctured and entered within an ISO Class 5 PEC • Stored per labeled storage conditions
Pharmacy bulk packages	Per manufacturers labeling	• Punctured and entered within an ISO Class 5 PEC • When manufacturer provides a shorter expiration time after puncture or entry, use the shorter dating and clearly label on packaging
Proprietary bag & vial systems	• Docking and activation for immediate use – is NOT considered compounding (no BUD assignment required) and can be performed in a non-classified area. • Docking for future activation and use – performed in an ISO Class 5 PEC and assigned a BUD that does not exceed the BUD specified in the manufacturer's labeling.	

2.9. [USP 797] CSPs compounded as components for use in other CSPs are initially assigned BUDs per USP <797> (see Section 2.2) and adhere to the following BUDs, use, and storage conditions once entered or punctured for use in a Final CSP; the BUD of the Final CSP is not impacted by the component CSP.

CSPs Compounded as a Component in a Final CSP			
	BUD of Component CSP Once Punctured	BUD of Final CSP Using Component	Use and Storage Conditions of Component
Preserved multi-dose Component CSP	No longer than 28 Days or the Component BUD (whichever is shorter)	Per USP <797> (not impacted by the Component BUD)	• Punctured and entered within an ISO Class 5 PEC • Stored per conditions intended for the initial BUD
Single-Dose & CSP Stock Solutions	≤ 12 Hours or the Component BUD (whichever is shorter)	Per USP <797> (not impacted by the Component BUD)	• Punctured and entered within an ISO Class 5 PEC • Stored per conditions intended for the initial BUD • Remainder is discarded

3. Roles & Responsibilities

3.1. The Designated Person(s):

- Ensures all CSPs compounded at Watsonville Community Hospital are assigned the correct and appropriate BUD by careful consideration and research pertaining to component and final CSP stability, sterility of components and sterilization method used (if appropriate), container closure system, and compounding conditions
- Ensures Master Formula Records (MFRs) have the correct BUD, CSP storage, and drug stability information and instructions
- Ensures Compounding Personnel are educated on how to accurately determine and document BUDs and storage conditions for CSPs and conventionally manufactured and compounded components used in compounding Final CSPs
- Ensures individuals (e.g., practitioners, patients, caregivers, other support staff) transporting, storing, or administering mediations understand how to interpret and/or adjust BUDs if conditions warrant

3.2. Compounding Personnel

- Determine and properly record the BUD on the immediate product label and affix all appropriate auxiliary labels confirming required storage conditions
- Conduct all aseptic manipulations in an ISO 5 and store CSPs and components appropriately

4. Procedures

4.1. [USP 797] **Immediate Use Compounds**

- See **Immediate-Use Compounding** policy for the conditions that must be met to utilize immediate use dating

4.2. [USP 797] **Category 1 Compounded Sterile Preparations**

- Determine the appropriate BUD for Category 1 CSPs (refer to Section 2.2 adapted from Table 12 of USP <797>). Category 1 CSPs meet the following criteria:
    - Compounded in a Segregated Compounding Area (SCA)
    - Compounded in a certified ISO Class 5 Primary Engineering Control (PEC)
    - Compounded aseptically by qualified Compounding Personnel
    - Compounded using only sterile starting components
    - Stored in conditions associated with the assigned BUD
- Sterility and endotoxin testing is not required for Category 1 CSPs

4.4. **Preserved Multi-dose CSPs**:

- If a multi-dose CSP meets the requirements of antimicrobial effectiveness testing per USP <51>, the maximum BUD does not exceed the assigned BUD or 28 days from initial puncture, whichever is shorter.

4.5. **CSPs Compounded as a Component or Stock Solution:**

- When the CSP component or stock solution is stored according to its originally assigned BUD and only punctured or entered in an ISO 5 PEC for use in a Final CSP:
    - Preserved, multi-dose component CSPs can be used for up to 28 days

- Single-dose (non-preserved) component CSPs or stock solution can be used for up to 12 hours or the originally assigned BUD, whichever is shorter. Any remaining CSP from the original component or stock solution is discarded.

- Final CSPs compounded from multi-dose, single-dose, or stock solution CSPs are assigned BUDs consistent with USP <797> (refer to Section 2.2); the BUD of the component CSP does not affect the determination of the BUD for the Final CSP.

4.6. **Proprietary bag and vial systems**:

- Docking of proprietary bag and systems for FUTURE activation and administration is considered compounding and is compounded in in an ISO Class 5 PEC. BUD assignment does not exceed the BUD stated in the manufacturer's labeling.
- Docking and activation of proprietary bag and vial systems for IMMEDIATE administration is not considered sterile compounding and is not assigned a BUD.

4.7. **Conventionally Manufactured Products, APIs, and Components used in CSPs**

- BUDs for entered or punctured commercially manufactured products used to compound a CSP do not exceed the values listed in Section 2.9.
- Inspect for damage or visible defects to the packaging or the product prior to use.
- Puncture or enter in an ISO Class 5 PEC.
- Commercially manufactured products are stored per the labeled instructions. When storage temperature and/or condition deviations are known or suspected, consult with the Designated Person(s) or the manufacturer's healthcare support line. Discard the product if data validating the safety and stability of the medication under the excursion conditions cannot be attained.

5. Definitions

5.1. **Administration:** The direct application of a sterile medication to a single patient by injecting, infusing, or otherwise providing a sterile medication in its final form.

5.2. **Beyond-Use Date (BUD):** The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.

5.3. **Category 1 CSP**: A CSP that is assigned a BUD of 12 h or less at controlled room temperature or 24 h or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.

5.4. **Category 2 CSP**: A CSP that may be assigned a BUD of greater than 12 h at controlled room temperature or greater than 24 h refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.

5.5. **Category 3 CSP**: A CSP that may be assigned a BUD exceeding the limits in Table 13 for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.

5.6. **Component:** Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.

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

5.8. **Conventionally manufactured product:** A pharmaceutical dosage form, usually the subject of an FDA approved application, and manufactured under current good manufacturing practice conditions.

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

5.10. **Stability:** The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.

6. Related Policies, Documents, References

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

6.2. United States Pharmacopeial Convention, Inc. <7> Labels and Labeling for Products in Other Categories, Expiration Date and Beyond Use Date. Current version.

6.3. United States Pharmacopeial Convention, Inc. <51> Antimicrobial Effectiveness Testing. Current version.

6.4. United States Pharmacopeial Convention, Inc. <71> Sterility Testing. Current version.

6.5. United States Pharmacopeial Convention, Inc. <85> Bacterial Endotoxin Testing. Current version.

6.6. United States Pharmacopeial Convention, Inc. <659> Packaging and Storage Requirements. Current version.

6.7. United States Pharmacopeial Convention, Inc. <788> Particulate Matter in Injections. Current version.

6.8. United States Pharmacopeial Convention, Inc. <789> Particulate Matter in Ophthalmic Solutions. Current version.

6.9. United States Pharmacopeial Convention, Inc. <1163> Quality Assurance in Pharmaceutical Compounding. Current version.

6.10. United States Pharmacopeial Convention, Inc. <1207> Package Integrity Evaluation – Sterile Products. Current version.

6.11. United States Pharmacopeial Convention, Inc. <1225> Validation of Compendial Procedures. Current version.

7. Approval and Review Summary

Approved by/date:	PTIC, Date of approval (9/2023)
Next review:	Month/year

7.1. Initial version published by Wolters Kluwer 2022.

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

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Beyond Use Dating and Stability Considerations	Policy #	PHARM2728
Responsible	Pharmacy Director	Revised/Reviewed	09/2023

I. PURPOSE

1. This policy describes the procedures for the determination and assignment of beyond use dating (BUD) for Compounded Sterile Preparations (CSP) prepared within Watsonville Community Hospital.
2. BUD limits are intended to help prevent patient harm resulting from microbial proliferation and contamination of CSPs. BUDs are determined by evaluating the chemical stability of the CSP components or formulation, storage conditions, starting components (sterile vs. non-sterile), sterile processing approach, and type of sterile compounding area where the CSP is prepared.
3. Expiration dates and BUDs are not interchangeable terms or concepts and medication administration terms cause confusion around the definition and application of BUDs assigned to compounded sterile preparations.
    - **Expiration date** is the time during which a manufactured product can be expected to meet the requirements of the USP–NF monograph, if one exists, or maintain expected quality provided it is kept under the specified storage conditions; applies to all conventionally manufactured products, active pharmaceutical ingredients (API), and added substances.
    - **BUD** is the date, or hour and date, after which the administration of a CSP cannot begin. BUDs are not intended to limit administration time; applies to all CSPs and stock solutions made by Compounding Personnel.
    - **Hang time or administration time** refers to the amount of time during which a CSP or conventionally manufactured product (e.g. pre-mix, large volume parenteral solution) may by be infused before which the tubing or medications needs to be changed due to stability considerations. Hang time is not determined by USP <797> and is considered out of scope for this policy.
4. This policy denotes the BUD assignment for all CSPs compounded at Watsonville Community Hospital.
    - Refer to **policy** for the procedures pertaining further information about the requirements and definition of Immediate Use Compounding

II. POLICY

1. Every CSP is labeled with a date, or date and hour, after which administration of the medication cannot occur (i.e., BUD). BUDs are:
    - Based on anticipated storage conditions
    - Determined from the time compounding begins
    - Not allowed to exceed the shortest remaining expiration date of any of the commercially available or compounded components used in the preparation of the CSP.
    - Consider one day equivalent to 24 hours

2. Maximum BUDs differ for Immediate Use and Category 1 CSPs and, at no times, are extended beyond those stated in USP <797>; adapted from Tables 12 and 13 of USP <797>.
    - Watsonville Community Hospital has a Segregated Compounding Area (SCA), not a cleanroom suite.

	Controlled Room Temperature [20°C to 25°C]	Refrigerated Temperature [2°C to 8°C]	Frozen Temperature [-25°C to -10°C]
Immediate Use CSPs			
Aseptically processed CSPs from only sterile starting components	≤ 4 hours	≤ 4 hours	Not Applicable
Category 1 CSPs			
Aseptically processed CSPs from only sterile starting components	≤ 12 hours	≤ 24 hours	Not Applicable

3. BUDs are assigned by Compounding Personnel with consideration for factors that could impact the CSP quality or sterility including, but not limited to:
    - Chemical and physical stability of the components and/or formulation
    - Container closure system and compatibility with the final preparation and storage conditions
    - Compounding environment in which the CSP is prepared
    - Aseptic processing and sterilization method
    - Sterility of starting components
    - Whether or not sterility testing is performed (if applicable)
    - Storage conditions

4. When the chemical or physical stability of the CSP is shorter than the maximum BUD, the most conservative dating becomes the BUD.
    - Chemical stability is based on available manufacturer's data, published literature, and industry references.

5. Packaging is selected for the CSP to preserve sterility, chemical stability, and potency.

6. CSPs stored under or moved to different storage conditions before they are used assume the new shorter BUD of the storage condition(s) which does not to exceed the original BUD placed on the CSP at the time of preparation
    - BUDs are not additive; administration is initiated before the BUD is exceeded or the CSP is promptly and appropriately discarded
    - Once a CSP has been stored under a new storage condition requiring a shorter BUD, the CSP is used within the shortened timeframe

7. Storage conditions per **USP <659> Packaging and Storage Requirements**:
    - Controlled Room Temperature: 20°C to 25°C
    - Refrigerated: 2°C to 8°C
    - Frozen: -25°C to -10°C

8. Conventionally manufactured sterile products or components used in the preparation of CSPs adhere to the following BUDs, use and storage requirements:

Conventionally Manufactured Products & Components		
	Expiration Date	Use and Storage Conditions
Single-dose containers	12 hours	• Punctured and entered within an ISO Class 5 PEC • Stored per labeled storage conditions
Ampule (or open plastic luer lock vials)	Discard immediately after use	• Punctured and entered within an ISO Class 5 PEC
Multi-dose containers	28 days (unless otherwise specified by manufacturer's labeling)	• Punctured and entered within an ISO Class 5 PEC • Stored per labeled storage conditions
Pharmacy bulk packages	Per manufacturers labeling	• Punctured and entered within an ISO Class 5 PEC • When manufacturer provides a shorter expiration time after puncture or entry, use the shorter dating and clearly label on packaging
Proprietary bag & vial systems	• Docking and activation for immediate use – is NOT considered compounding (no BUD assignment required) and can be performed in a non-classified area. • Docking for future activation and use – performed in an ISO Class 5 PEC and assigned a BUD that does not exceed the BUD specified in the manufacturer's labeling.	

9. CSPs compounded as components for use in other CSPs are initially assigned BUDs per USP <797> (see Section 2.2) and adhere to the following BUDs, use, and storage conditions once entered or punctured for use in a Final CSP; the BUD of the Final CSP is not impacted by the component CSP.

CSPs Compounded as a Component in a Final CSP			
	BUD of Component CSP Once Punctured	BUD of Final CSP Using Component	Use and Storage Conditions of Component
Preserved multi-dose Component CSP	No longer than 28 Days or the Component BUD (whichever is shorter)	Per USP <797> (not impacted by the Component BUD)	• Punctured and entered within an ISO Class 5 PEC • Stored per conditions intended for the initial BUD
Single-Dose & CSP Stock Solutions	≤ 12 Hours or the Component BUD (whichever is shorter)	Per USP <797> (not impacted by the Component BUD)	• Punctured and entered within an ISO Class 5 PEC • Stored per conditions intended for the initial BUD • Remainder is discarded

III. ROLES & RESPONSIBILITIES

1. The Designated Person(s):

   - Ensures all CSPs compounded at Watsonville Community Hospital are assigned the correct and appropriate BUD by careful consideration and research pertaining to component and final CSP stability, sterility of components and sterilization method used (if appropriate), container closure system, and compounding conditions
   - Ensures Master Formula Records (MFRs) have the correct BUD, CSP storage, and drug stability information and instructions

- Ensures Compounding Personnel are educated on how to accurately determine and document BUDs and storage conditions for CSPs and conventionally manufactured and compounded components used in compounding Final CSPs
- Ensures individuals (e.g., practitioners, patients, caregivers, other support staff) transporting, storing, or administering mediations understand how to interpret and/or adjust BUDs if conditions warrant

2. Compounding Personnel

- Determine and properly record the BUD on the immediate product label and affix all appropriate auxiliary labels confirming required storage conditions
- Conduct all aseptic manipulations in an ISO 5 and store CSPs and components appropriately

IV. DEFINITIONS

1. **Administration**: The direct application of a sterile medication to a single patient by injecting, infusing, or otherwise providing a sterile medication in its final form.
2. **Beyond-Use Date (BUD):** The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
3. **Category 1 CSP:** A CSP that is assigned a BUD of 12 h or less at controlled room temperature or 24 h or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.
4. **Category 2 CSP**: A CSP that may be assigned a BUD of greater than 12 h at controlled room temperature or greater than 24 h refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.
5. **Category 3 CSP:** A CSP that may be assigned a BUD exceeding the limits in Table 13 for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.
6. **Component:** Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
7. **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.
8. **Conventionally manufactured product:** A pharmaceutical dosage form, usually the subject of an FDA approved application, and manufactured under current good manufacturing practice conditions.
9. **Immediate Use CSP:** CSP aseptically compounded outside of ISO classified air for direct and immediate administration to a single patient with a maximum BUD of 4 hours from the initiation of compounding.
10. **Stability:** The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.

V. PROCEDURE

1. **Immediate Use Compounds**

- See **Immediate-Use Compounding** policy for the conditions that must be met to utilize immediate use dating

2. **Category 1 Compounded Sterile Preparations**

- Determine the appropriate BUD for Category 1 CSPs (refer to Section 2.2 adapted from Table 12 of USP <797>). Category 1 CSPs meet the following criteria:
    - Compounded in a Segregated Compounding Area (SCA)
    - Compounded in a certified ISO Class 5 Primary Engineering Control (PEC)
    - Compounded aseptically by qualified Compounding Personnel
    - Compounded using only sterile starting components
    - Stored in conditions associated with the assigned BUD
- Sterility and endotoxin testing is not required for Category 1 CSPs

3. **Preserved Multi-dose CSPs:**
    - If a multi-dose CSP meets the requirements of antimicrobial effectiveness testing per USP <51>, the maximum BUD does not exceed the assigned BUD or 28 days from initial puncture, whichever is shorter.

4. **CSPs Compounded as a Component or Stock Solution:**
    - When the CSP component or stock solution is stored according to its originally assigned BUD and only punctured or entered in an ISO 5 PEC for use in a Final CSP:
        - Preserved, multi-dose component CSPs can be used for up to 28 days
        - Single-dose (non-preserved) component CSPs or stock solution can be used for up to 12 hours or the originally assigned BUD, whichever is shorter. Any remaining CSP from the original component or stock solution is discarded.
    - Final CSPs compounded from multi-dose, single-dose, or stock solution CSPs are assigned BUDs consistent with USP <797> (refer to Section 2.2); the BUD of the component CSP does not affect the determination of the BUD for the Final CSP.

5. **Proprietary bag and vial systems**:
    - Docking of proprietary bag and systems for FUTURE activation and administration is considered compounding and is compounded in in an ISO Class 5 PEC. BUD assignment does not exceed the BUD stated in the manufacturer's labeling.
    - Docking and activation of proprietary bag and vial systems for IMMEDIATE administration is not considered sterile compounding and is not assigned a BUD.

6. **Conventionally Manufactured Products, APIs, and Components used in CSPs**
    - BUDs for entered or punctured commercially manufactured products used to compound a CSP do not exceed the values listed in Section 2.9.
    - Inspect for damage or visible defects to the packaging or the product prior to use.
    - Puncture or enter in an ISO Class 5 PEC.
    - Commercially manufactured products are stored per the labeled instructions. When storage temperature and/or condition deviations are known or suspected, consult with the Designated Person(s) or the manufacturer's healthcare support line. Discard the product if data validating the safety and stability of the medication under the excursion conditions cannot be attained.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <7> Labels and Labeling for Products in Other Categories, Expiration Date and Beyond Use Date. Current version.
- United States Pharmacopeial Convention, Inc. <51> Antimicrobial Effectiveness Testing. Current version.

- United States Pharmacopeial Convention, Inc. <71> Sterility Testing. Current version.
- United States Pharmacopeial Convention, Inc. <85> Bacterial Endotoxin Testing. Current version.
- United States Pharmacopeial Convention, Inc. <659> Packaging and Storage Requirements. Current version.
- United States Pharmacopeial Convention, Inc. <788> Particulate Matter in Injections. Current version.
- United States Pharmacopeial Convention, Inc. <789> Particulate Matter in Ophthalmic Solutions. Current version.
- United States Pharmacopeial Convention, Inc. <1163> Quality Assurance in Pharmaceutical Compounding. Current version.
- United States Pharmacopeial Convention, Inc. <1207> Package Integrity Evaluation – Sterile Products. Current version.
- United States Pharmacopeial Convention, Inc. <1225> Validation of Compendial Procedures. Current version.

VII. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Compounded Sterile Products: Stability and Assignment of Beyond Use Dating (BUD)	Policy #	PHARM2728
Responsible	Pharmacy Director	Revised/Reviewed	05/2022

I. PURPOSE

To provide an efficient, accurate and consistent process by which the chemical stability and beyond use dates for prepared compounded sterile preparations (CSPs) are determined and documented.

II. POLICY

A. Beyond use dating is assigned to compounded sterile preparations (CSPs) within the guidelines of USP Chapter <797> and based on both the chemical stability and microbial sterility of the components as well as the compounding risk level of a given CSP.

B. Since CSPs have been associated with microbiological contamination, USP Chapter <797> assigns risk levels to certain types of activity associated with compounding CSPs and assigns beyond-use dating (BUD) to CSPs prepared at each risk level. Refer to Table 2 of this policy.

C. BUDs may not exceed those based on the storage times published in USP Chapter <797> unless sterility testing is performed in accordance with USP Chapter <797>. Refer to Table 1 of this policy.

D. If a given CSP's chemical stability is a lesser time period than the maximum storage period published in USP Chapter <797>, then the CSPs BUD is assigned based on the shorter chemical stability of the formulation. When considering both the stability and sterility storage dates, the lesser time is always used to assign the BUD.

E. Maximum BUDs for CSPs according to risk level are valid as long as the temperature of the storage area is within limits and documented. Refer to Table 1 in this policy.

F. If sterility testing in accordance with USP Chapter <797> is performed, the BUD dating may not exceed the maximum chemical stability of the drug in solution based on valid references.

G. Valid references that may be used to determine appropriate BUD include:
   - Manufacturer's data.
   - Trissel, L.A. Handbook on Injectable Drugs; 15th Edition, 2008.
   - Trissel, L.A. Stability of Compounded Formulations; 3rd Edition.
   - King's Guide to Parenteral Admixtures, 2003.
   - Bing, C. Extended Stability of Parenteral Drugs, 3rd Edition.
   - Published literature in the form of stability studies and journal articles
   - Direct CSP testing performed by a certified laboratory using quantitative stability indication assays such as high-performance liquid chromatographic (HPLC) assays whenever possible. Refer to USP Chapter <1150> for appropriate stability parameters to be considered when initiating a preparation specific stability study.

H. Determinations of BUD must critically evaluate data and determine dating conservatively in keeping with patient safety.

I. The data sources used to determine stability and BUD assignment will be documented for each CSP type compounded.

J. The Director of Pharmacy will identify the risk level of CSPs to be prepared in the pharmacy.

K. The Director of Pharmacy or designee will gather information about CSPs that may be compounded outside of the pharmacy and identify opportunities to prepare the CSPs within the pharmacy-controlled environments.

L. The Director of Pharmacy or designee will verify that CSPs for immediate use or those that meet the 12 hour beyond use dating for low risk compounding in segregated compounding areas meet the criteria described in USP Chapter <797>.

M. CCR 1751.4(f)(1)-(3) states:
Unidirectional compounding aseptic isolators (CAI) or compounding aseptic containment isolators (CACI) may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

- Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations;
- Not more than 3520 particles (0.5um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer;
- Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

1. CAI that do not meet the requirements as outline above or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.
   a. CCR 1751.8(d): The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours …
2. CAI that meet the requirements in CCR 1751.4(f) (1)-(3) and meet the criteria for low risk preparations may use the maximum beyond use dating for CSPs as noted in Table 1 for low risk preparations.
3. CAI that meet the requirements in CCR 1751.4(f)(1)-(3) and meet the criteria for medium risk preparations may use the maximum beyond use dating for CSPs as noted in Table 1 for medium risk preparations.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Evaluation of current and new CSP types prepared by pharmacy
   1. The Director of Pharmacy or designee is responsible to review CSPs prepared in the Pharmacy.
   2. The Director of Pharmacy or designee is responsible to ascertain that each specific CSP formula record describes the general methods used to assign BUD and storage conditions. Documentation should be performed on the CSP Stability and Beyond Use Dating Documentation Form. The form needs to be completed only once for each specific CSP type and signed by the Director of Pharmacy.
   3. The completed CSP Stability and Beyond Use Dating Documentation Form must be retained in the Pharmacy records for a minimum of three years.
   4. Should available data change the BUD requirement, a new form can be completed for the CSP type.

5. The Director of Pharmacy is responsible to develop a system by which evaluation of formula stability, risk level, and storage conditions are verified and tracked.

B. Multiple Dose Vials (MDVs)
   1. The BUD for MDVs once punctured that are kept at their proper storage temperature is 28 days subsequent to initial use or less based on the expiration date on the packaging or other manufacturer instructions.
   2. MDVs must be dated with the specific beyond use date and time based on the time and date of initial use.
   3. Contents remaining past the established BUD must be properly discarded.

C. Single Dose Containers
   1. Single use vials, bags, bottles that are sterile but have been opened or punctured must be used for compounding within 1 hour if exposed to air quality less than ISO Class 5.
   2. Single use containers that have been punctured may be used for up to 6 hours if exposed to air that is ISO Class 5.
   3. Single use containers of this type must be dated with the specific BUD and time based on the time and date of initial use.
   4. Contents remaining past the established BUD must be properly discarded.

D. Removal of Outer Wrappers
   1. Outer plastic wrappers of IV bags shall not be removed until immediately prior to use or preparation.
      a. This wrapper must be removed in the anteroom.
   2. After outer wrappers are removed, the following retention requirements apply:
      - Abbott (any volume) -- No longer than 30 days
      - Baxter (100 ml or less) -- No longer than 15 days
      - Baxter (More than 100 ml) -- No longer than 30 days
      - B. Braun – No longer than 30 days
   3. If the outer wrapper is removed prior to use and the IV bag is not labeled immediately for patient use, the date shall be affixed to the container using a supplemental adhesive label attached to the bag.

E. Re-dispensed CSPs
   1. CSPs may only be re-dispensed if all of the following conditions are met:
      a. The CSP was continually stored under required conditions and
      b. There is no evidence of tampering and
      c. The CSP will be administered before the original BUD assigned.
   2. BUDs will not be reassigned beyond the original assignment date unless there is supporting evidence from sterility testing and quantitative assay of ingredients.
   3. Reusable products delivered by the manufacturer in a frozen form may be reused until the BUD assigned by the pharmacy after being thawed. Thawed products may not be re-frozen.

F. Documentation
   1. The CSP Stability and Beyond Use Dating Documentation Form is to be completed for each CSP type.

2. Single dose containers and multiple dose vials that are retained for subsequent use within the parameters outlined will be labeled with the following information at the time they are initially punctured:
   a. Date initially punctured
   b. Time initially entered
   c. Name of the person initially puncturing the container.
3. Re-dispensed CSPs must be documented on an appropriate form that provides assurance that the CSP and its components can be tracked to the original lot number and compounding personnel should recalls or quality assurance issues arise requiring follow-up.

V. REFERENCES

- Joint Commission Standards: MM.03.01.01 EP 1 – 8 MM.05.01.07 EP 2 – 4 MM.05.01.09 EP 1 - 12
- ASHP, Principles of Sterile Product Preparation, Revised 1st Edition, 2002. p.134.
- California Board of Pharmacy, CCR 1735.5(a), 1751.8(f)(1)-(3) [2017]

VI. STAKEHOLDERS

N/A

Stability and Assignment of Beyond Use Dating

Table 1: Maximum Storage Periods according to Risk Level in the absence of sterility testing

Storage Temperatures	Immediate Use*	Segregated Compounding Area	Low Risk Preparations	Medium Risk Preparations	High Risk Preparations
Controlled Room Temperatures 20° to 25° C (68° to 77° F)	**1 hour**	**12 hours**	**48 hours**	**30 hours**	**24 hours**
Controlled Cold Temperatures 2° to 8° C (36° to 46° F)	**N/A**	**12 hours**	**14 days**	**9 days**	**3 days**
Controlled Frozen Temperatures -30° to -10° C (-13° to 14° F)	**N/A**	**N/A**	**45 days**	**45 days**	**45 days**

****Refer to USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations for detail on Immediate Use CSPs intended for emergency use only and not intended for storage.**

Table 2: Abbreviated Description of CSP Characteristics by Risk Level *

CSPs for Immediate Use	Low Risk Level CSPs with ≤ 12 hour BUD	Low Risk Level CSPs	Medium Risk Level CSPs	High Risk Level CSPs
• Simple transfer of ≤ 3 sterile non-hazardous products from the manufacturer's • Compounding is a continuous process • Aseptic technique used • CSP under continuous supervision to prevent contamination • Labeled unless completely administered by person preparing • Properly discarded if not used within 1 hour	• Certified PEC located in area that meets USP <797> criteria for segregated compounding area • No sinks in room with PEC • Other requirements such as hand hygiene, garbing, cleaning, and disinfecting, viable and non-viable environmental sampling and personnel training and competency are followed.	• At least ISO Class 5 air • ≤ 3 sterile products • ≤ 3 entries into any container	• > 3 sterile products • > 3 entries into container • Pooling ingredients from multiple sterile products	• Nonsterile ingredients or sterile ingredients exposed to air quality < ISO Class 5 > 1 hour • Compounding personnel improperly garbed • Nonsterile CSPs stored greater than 6 hours before being sterilized

CSP Stability and Beyond Use Dating Documentation Form

1. Enter CSP Formula/Prescription below:

2. Circle the stability reference source(s) and data below. Attach references or data as needed.
   a. Manufacturer's data: _____
   b. Trissel, Lawrence A., handbook on Injectable Drugs, 14th Edition, 2007
   c. Trissel's 2 Clinical Pharmaceutics Database
   d. Trissel, Lawrence A. Stability of Compounded Formulations, 3rd Edition
   e. King's Guide to Parenteral Admixtures. 2003
   f. Bing, C. Extended Stability of Parenteral Drugs, 3rd Edition
   g. Published literature in the form of stability studies and journal articles (note below)
   h. Direct CSP testing performed by a certified laboratory (attach).

   Comments: _____

The CSP in #1 above is chemically stable for _____ hours/days based on the information from the source indicated above.

3. Circle the Risk Category Below:

Storage Temperatures	Immediate Use*	Segregated Compounding Area	Low Risk Preparations	Medium Risk Preparations	High Risk Preparations
Controlled Room Temperatures 20° to 25° C (68° to 77° F)	**1 hour**	**12 hours**	**48 hours**	**30 hours**	**24 hours**
Controlled Cold Temperatures 2° to 8° C (36° to 46° F)	**N/A**	**12 hours**	**14 days**	**9 days**	**3 days**
Controlled Frozen Temperatures -30° to -10° C (-13° to 14° F)	**N/A**	**N/A**	**45 days**	**45 days**	**45 days**

*Refer to USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations for detail on Immediate Use CSPs intended for emergency use only and not intended for storage.

Standardized Storage and Handling based on Stability and Sterility Considerations is as follows:
Store at Controlled Cold Temperature _____ days
Store at Controlled Frozen Temperature _____ Days
Special requirements: Do Not Refrigerate Do Not Freeze Protect From Light
Other Special Requirements: _____

_____ _____
Signature of Primary Reviewer Date

_____ _____
Signature of Pharmacy Director Date

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: September 27, 2023

Report Type: Discussion

Title: Medical Committees Reports September 2023

Recommendation: Receive Quality report and pass a **Motion** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of September 2023; 2) Addition of Fluoroscopy and Sedation Privilege to Gastroenterology Privilege Delineation List.

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- Addition of Fluoroscopy and Sedation Privilege to Gastroenterology Privilege Delineation List

WATSONVILLE COMMUNITY HOSPITAL

Medical Executive Committee Summary – September 27, 2023
ITEMS FOR BOARD APPROVAL

Credentials Committee

INITIAL APPOINTMENTS: (3)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Bennet, Justin MD	Gastroenterology / Provisional	Medicine	Gastroenterology, Sedation	09/28/2023 - 08/31/2025
Campbell, Steffani, MD	Emergency Medicine / Provisional	Emergency Medicine	Emergency Medicine; Sedation	09/28/2023 - 08/31/2025
Castellanos, Angela, MD	Pediatric Hospitalist / Provisional	Pediatrics	Pediatrics	09/28/2023 - 08/31/2025

REAPPOINTMENTS: (6)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Bretan, Peter, MD	Urology / Active	Surgery	Urology; Fluoroscopy	10/01/2023 - 09/30/2025
De, Ajanta, MD	Cardiovascular Disease / Active	Medicine	Cardiovascular Disease, Sedation, Fluoroscopy; Wound Care	10/01/2023 - 09/30/2025
Guez, Ghislaine, MD	Internal Medicine Hospitalist / Active	Medicine	Critical Care, Non-Intensivist & Medicine	09/30/2023 - 08/31/2025
Mensch, Kenneth, MD	Orthopedics / Active	Surgery	Orthopedics; Fluoroscopy	09/30/2023 - 08/31/2025
Salahuddin, Farah, MD	Internal Medicine Hospitalist / Active	Medicine	Critical Care, Non-Intensivist; Medicine	09/30/2023 - 08/31/2025
Thompson, Gregory, MD	Anesthesiology / Active	Surgery	Anesthesia	09/30/2023 - 08/31/2025

MODIFICATION / ADDITION OF PRIVILEGES: (1)

NAME	SPECIALTY / STATUS	Privileges
Joye, James, DO	Cardiovascular Disease / Active	Wound Care

STAFF STATUS MODIFICATIONS: (4)

NAME	SPECIALTY / DEPARTMENT	RECOMMENDATION
Alexander, Charlotte, MD	OBGYN / OBGYN	Release from C-Section and OB Delivery Proctoring Continue vacuum assisted vaginal delivery and GYN proctoring
Guez, Ghislaine, MD	Internal Medicine Hospitalist / Medicine	Release from Proctoring and Advance from Provisional to Active Staff

NAME	SPECIALTY / DEPARTMENT	RECOMMENDATION
Mensch, Kenneth, MD	Orthopedics / Surgery	Release from Proctoring and Advance from Provisional to Active Staff
Salahuddin, Farah, MD	Internal Medicine Hospitalist / Medicine	Advance from Provisional to Active Staff
Borte, Bernadette, MD	Teleneurology / Medicine	Voluntary Resignation, 05/01/2023

TEMPORARY PRIVILEGES: (1)

NAME	SPECIALTY / DEPARTMENT	DATES
Castellanos, Angela, MD	Pediatric Hospitalist / Pediatrics	09/19/2023 – 09/28/2023

INTERDISCIPLINARY PRACTICE CREDENTIALS REPORT

Initial Appointment: (0)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
None				

REAPPOINTMENT: (1)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Rasmussen, Cara, CNM	Certified Nurse Midwife / Allied Health Professional	OBGYN	Certified Nurse Midwife	10/01/2023 - 09/30/2025

Temporary Privileges: (0)

NAME	SPECIALTY / DEPARTMENT	DATES
None		

STAFF STATUS MODIFICATIONS: (0)

NAME	SPECIALTY / DEPARTMENT	RECOMMENDATION
None		

GASTROENTEROLOGY PRIVILEGE DELINEATION LIST
PROPOSED ADDITION

SPECIAL PRIVILEGES

FLUOROSCOPY PRIVILEGES _____**Requested** _____**Approved**

- **Criteria: Documentation of California State Fluoroscopy X-Ray Supervisor and Operator Permit**

PROCEDURAL SEDATION PRIVILEGES _____**Requested** _____**Approved**

- **Criteria: See Hospital Policy for Procedural Sedation**

- **Approved by Credentials Committee, 09/08/2023**
- **Forwarded to MEC, 09/19/2023**

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

BOARD REPORT

Meeting Date: September 27, 2023

Report Type: Discussion

Title: Chief Executive Officer (CEO) Employment Agreement with Stephen Gray and Related Actions

Recommendation: Pass a **Resolution**:1) approving the CEO Employment Agreement to appoint Stephen Gray as the CEO of Pajaro Valley Health Care District Hospital Corporation dba Watsonville Community Hospital (Hospital); 2) authorizing the Board Chair to executive the agreement and 3) approving the market study findings and confirming the reasonableness of Mr. Gray's compensation package.

Contact: Ad Hoc CEO Selection Committee (Board Chair John Friel and Director Pimentel); Staff Contact, Allyson Hauck, Chief Human Resources Officer.

Analysis: On March 22, 2023, following the resignation of CEO Steven Salyer, the Board of Directors appointed an Interim CEO and established an Ad Hoc CEO Selection Committee (Committee). The Committee met weekly with staff to establish selection criteria and process. On May 1, 2023, the Hospital posted a CEO job announcement and commenced recruitment for a new CEO. Staff screened over twenty qualified candidates and presented a summary to the Committee. The Committee selected eight (8) candidates for a first-round interview. Of those candidates, four (4) were selected as finalists. The four (4) finalists each completed a full day interview in the last week of July, meeting with a panel of hospital managers, a panel of key community stakeholders, members of the executive team, and the Board of Directors. The final two (2) candidates returned for a final interview with the Board of Directors. Based on this selection process, the Committee is recommending that the Board approve Stephen Gray as the CEO of the Hospital.

Stephen Gray is currently the chief adminstrative officer and operations executive for Sutter Bay Medical Foundation – Santa Cruz Division, a multi-specialty medical group, and Sutter Maternity & Surgery Center of Santa Cruz. From September 2017 to September 2019 he was CEO at Sutter Eden Medical Center, a 130-bed full-service acute care hospital with 1,200 staff and 300 medical staff members. An 11-year resident

of Capitola, he has a master's degree in business administration as well as in public health. Stephen has a breadth of leadership experience from multiple hospitals, where he has held administrative and management roles.

In accordance with the IRS requirements for 501(c)(3) tax exempt organizations as well as the California Nonprofit Integrity Act, Wipfli Inc. (Wipfli) was engaged to provide a review of the reasonableness of CEO compensation. Wipfli is a healthcare industry leader that provides a suite of services including human capital management and talent development in support of recruitment efforts. Wipfli ensured that any proposed compensation is within the range of reasonableness based on comparable organizations with regard to budget, number of employees, revenues and geography. In July of 2022 Wipfli provided a CEO Salary Survey (CEO Salary Survey). The CEO Salary Survey relied on over 100 private, on-profit, and public hospitals with comparable revenue and bed sizes. Wipfli recommended, based on the survey results, the maximum compensation the Hospital should consider in 2022 for a CEO base a base salary was $540,000 and total compensation of $810,000. The low-end recommendation was a base salary of $360,000 and total compensation of $468,000. Within the survey results, some available local compensation information was obtained for Natividad Hospital (operated by the County of Monterey) and Salinas Valley Memorial Hospital (operated by a healthcare district). Their base CEO compensation was similar to or far exceeded the Committee proposed base compensation. Natividad provided a base compensation of $448,000 and Salinas Valley Memorial Hospital, a base compensation of $835,000. However, Natividad provides a strong defined benefit retirement plan through the CalPERS retirement system and Salinas Valley Memorial Hospital provides its own considerable defined benefit retirement plan, whereas the proposed compensation package for Mr. Gray does not.

Based on Mr. Gray's experience and expertise, and the desire to engage a successful CEO to provide long term leadership, and in recognition of the highly competitive market for healthcare leadership, the Committee recommends a four-year at will agreement with Mr. Gray at a base compensation of $475,000, and a total compensation of up to $641,250, if Mr. Gray meets specific contractual incentives as defined annually by the Hospital Board. In addition to his base salary and incentive pay, the terms of the agreement include, but are not limited to (1) a Board expectation that Mr. Gray will engage in community development, (2) Board support of Mr. Gray's professional development, (3) a $35,000 signing incentive bonus, with $15,000 due no later than 90 days from first day of employment, and $20,000 paid no later than 90 days following November 1, 2024; (5) PTO based on an adjusted rate of 11 years seniority; (6) transition leave in the amount of 120 hours, which transition leave has no cash value and is not paid out at separation; and (7) a severance in the amount of 12 months of base salary, or the number of months remaining on the agreement, whichever is less, in the event Mr. Gray is separated from service as the CEO of the Hospital without cause during the term of the agreement.

Mr. Gray would also serve as the CEO of the Pajaro Valley Health Care District (District), at no additional cost and under the existing terms of the Hospital agreement, if so requested by the District.

Financial Impact: The cost of the agreement is in excess of budgeted compensation for the prior CEO agreement that is included in the operational forecast and transition plan by the following amounts, (1)$25,000 base salary, (2) $15,000 for incentive signing bonus paid in 2024, and (3) $20,000 for incentive singing bonus paid in 2025.

Attachments:

A. Resolution Approving Findings Conforming to Reasonableness of Compensation Package
   Exhibit A Employment Agreement

BEFORE THE BOARD OF DIRECTORS OF THE PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL

RESOLUTION NO.

RESOLUTION APPROVING THE CHIEF EXECUTIVE OFFICER EMPLOYMENT AGREEMENT TO APPOINT STEPHEN GRAY AS THE CEO OF PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION DBA WATSONVILLE COMMUNITY HOSPITAL (HOSPITAL); 2) AUTHORIZING THE BOARD CHAIR TO EXECUTIVE THE AGREEMENT AND 3) APPROVING THE MARKET STUDY FINDINGS AND CONFIRMING THE REASONABLENESS OF MR. GRAY'S COMPENSATION PACKAGE.

The Board of Directors ("Board") of the Pajaro Valley Health Care District Hospital Corporation ("PVHCDHC"), a tax-exempt California nonprofit public benefit corporation, doing business as Watsonville Community Hospital ("WCH"), does hereby adopt the following resolution pursuant to the California Nonprofit Integrity Act, and as also guided by the Internal Revenue Service requirements for organizations exempt from taxation under section 501(c)(3) of the Internal Revenue Code:

WHEREAS, upon the recommendation of the Board's Ad Hoc CEO Selection Committee, on September 27, 2023, the Board voted to approve the employment of Stephen Gray as the CEO of WCH under the terms and conditions as set forth in the CEO Employment Agreement, attached hereto as Exhibit A; and

WHEREAS, the Board must ensure that the proposed compensation to be paid to Mr. Gray, including all monetary or non-monetary benefits to be provided, is reasonable; and

WHEREAS, the Board must assign the compensation of the Chief Executive Officer of WCH within the confines of legal requirements and best practices for tax-exempt, nonprofit corporations; and

WHEREAS, the Board must ensure the Chief Executive Officer's compensation is within the range of organizations comparable with regard to budget, number of employees, and geography, also taking into account other factors the Board believes pertinent to the setting of its Chief Executive Officer compensation; and

WHEREAS, the Board has been presented with and reviewed the CEO Competitive Pay Analysis Report provided by Wipfli, LLP in July of 2022 (the "CEO Salary Survey") to support the finding that the compensation offered to Mr. Gray is

reasonable and well within the range of comparable compensation paid to similarly situated healthcare CEOs in WCH's region;

WHEREAS, the Board relied on the CEO Salary Survey in making its offer to Mr. Gray; and

WHEREAS, no member of the Board of Directors has a financial conflict of interest in the approval of the engagement of Mr. Gray as Chief Executive Officer of WCH;

NOW, THEREFORE, the Board of Directors of the Pajaro Valley Health Care District Hospital hereby RESOLVES and ORDERS as follows:

Section 1. The foregoing recitals are adopted as findings of the Board of Directors as set forth within the body of this Resolution.

Section 2. The Board approves the hiring and employment of Stephen Gray as the Chief Executive Officer of the Pajaro Valley Health Care District Hospital Corporation and authorizes the Chair of the Board to execute the CEO Employment Agreement attached hereto as Exhibit A; and

Section 3. The Board finds that the total compensation set forth in the CEO Employment Agreement is fair and reasonable based on the opinion and studies rendered in the CEO Salary Survey, and as determined by the Board to be in the best interests of WCH and its mission.

PASSED AND ADOPTED by the Board of Directors of the Pajaro Valley Health Care District Hospital, this _____day of _____, 20__, by the following vote:

AYES:
NOES:
ABSENT:
ABSTAIN:

_____
Chair, Board of Directors

ATTEST: _____
Clerk of the Board

Approved as to Form:

_____
Attorney for the Hospital Board

EMPLOYMENT AGREEMENT

This Employment Agreement (this "**Agreement**") is entered into and effective as of November 1, 2023, by and between the Pajaro Valley Health Care District Hospital Corporation dba Watsonville Community Hospital (the "Employer"), and Stephen Gray (the "**Employee**") (collectively, the "**Parties**" and individually, a "**Party**"). In consideration of the mutual covenants and agreements included in this Agreement and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

1. TERM OF EMPLOYMENT.

The Employee's term of employment pursuant to the terms of this Agreement (the "**Term**") shall be four (4) years, starting on November 1, 2023, (the "**Effective Date**") and ending on October 31, 2027. Notwithstanding the foregoing, employment with Employer is voluntarily entered into and shall be considered "at-will". Employee is free to resign at any time, with or without notice, and with or without cause. Similarly, Employer may terminate the employment relationship at any time, with or without notice, and with or without or cause, so long as there is no violation of applicable federal or state law. Nothing in this Agreement or in any document or statement shall limit the right of Employer to terminate the employment relationship "at-will" at any time, with or without cause. Only the Board of Directors of Employer has the authority to make any such agreement altering the "at-will" nature of this Agreement, and then only in writing.

2. TITLE AND DUTIES; EXCLUSIVE SERVICES.

(a) Title and Duties. The Employee agrees to be employed by Employer as the Chief Executive Officer of Watsonville Community Hospital (the "**Hospital**"), which is operated by Employer. The Employee's principal place of business will be 75 Nielson Street in Watsonville, California. The Employee will perform such job duties as are usual and customary for this position and will perform such additional services and duties as the Employer may from time to time designate and which are consistent with this position, including, but not limited to, participating in and being a member of local community organizations that support the Hospital and that serve a similar population as that of the Hospital and serving as Chief Executive Officer of the Pajaro Valley Health Care District (the "**District**") which is the owner of the Hospital if so requested by the District (collectively, the "**Services**"). The Employee will report directly to the Chair of the Board of Employer and, if placed in the roll as Chief Executive Officer of the District, Employee shall report to the Chair of the District. The Employee agrees to abide by the rules, regulations, policies and practices as adopted or modified from time to time by the Employer.

(b) Exclusive Services. Employee will devote the Employee's full working time and efforts to the business and affairs of the Employer. During employment with the Employer, the Employee shall not: (A) accept any other employment or consultancy, (B) serve on the board of directors or similar body of any other entity that is directly or indirectly competitive with the Employer, or (C) engage, directly or indirectly, in any other business activity (whether or not pursued for pecuniary advantage) that is or may be competitive with, or that might place the Employee in a competing position to, that of the Employer

3. COMPENSATION AND BENEFITS.

(a) Base Salary. During the Term, the Employer will pay the Employee an annual gross base salary of **Four Hundred and Seventy Five Thousand Dollars ($475,000.00)** (the "Annual Base Salary"), less appropriate payroll deductions and all required withholdings. All payments of the Annual Base Salary are payable in regular installments in accordance with the Employer's normal payroll practices, as in effect from time to time and prorated monthly or weekly or for any partial pay period of employment. Annual Base Salary will be eligible for an increase at such a time and at the equivalent rate as provided to Employer's other administrative executive and/or management staff.

(b) Signing Bonus. Employer shall pay to Employee a signing bonus in the amount of **Thirty Five Thousand Dollars ($35,000)** (the "Signing Bonus") in consideration of Employee agreeing to accept employment with Employer. The Signing Bonus shall be paid in two (2) installments, with the first installment of **Fifteen Thousand Dollars ($15,000)** to be paid no later than the payroll which occurs 90 days after the first day of employment and the second installment of **Twenty Thousand Dollars ($20,000)** to be paid no later than the payroll which occurs 90 days after November 1, 2024, provided Employee remains employed as the Chief Executive Officer as of November 1, 2024.

(c) Incentive Pay. During the Term of the Agreement, Employee is eligible to participate in the Employer's CEO discretionary incentive plan at an annual rate up to and not to exceed **Thirty-Five Percent (35%)** of the then base salary (the "**Incentive Pay**"). For the first year of this Agreement, the Incentive Pay, if any, shall be based on Employee's performance and achievement of certain metrics approved by Employer's Board of Directors no later than December 31, 2023, and shall be payable not later than 90 days following the completion of the first-year incentive period and in accordance with Employer's current payroll and bonus practices. During the second, third, and fourth year of the Term of this Agreement, the Board will define the metrics for the Incentive Pay no later than the 60 days before the start of the next contract year, for the succeeding 12-month period. Such Incentive Pay, if any, shall be based on Employee's performance and achievement of certain goals and objectives approved by Employer's Board of Directors and payable not later than 90 days following the completion of the incentive period and in accordance with Employer's current payroll and bonus practices. The determination of eligibility or the amount for any Incentive Pay is at the discretion of the Board of Directors, and as such is not part of Employee's regular salary.

(d) Employee Benefits. During the Term, the Employee will be eligible to participate in such group health, leave, sick, disability and other insurance plans, programs and policies as are maintained or sponsored by or for the benefit of the Employer from time to time and in which any other employees of the Employer may participate, subject to the terms and conditions of the applicable plans, programs or policies, as may be amended from time to time in the Board of Directors' sole and absolute discretion. Employee's medical benefits shall be effective on the first of the month following the Effective Date of this agreement i.e. anticipated to be December 1, 2023 based on a November 1, 2023 Effective Date. In addition, Employee shall accrue Paid Time Off ("PTO") under Employer's policy based on an adjusted rate applicable for those employees with eleven (11) years of Seniority. Employer will also grant **One Hundred and Twenty (120) hours** of "transition leave" on November 1, 2023, which can be used for personal time off (the "**Transition Leave**"). The Transition Leave is being granted to accommodate Employee and shall have no cash value, shall not be considered part of the PTO accrual program, and any balance remaining at the time of separation shall not be paid out. The Employer agrees to consider expansion of the number and/or type of voluntary retirement plans available to staff and the CEO during the term of this Agreement. The Employer agrees to review, in year two of this Agreement, the extension of retirement plans and contributions to all excluded staff, including but not limited to the CEO, executive team, and management.

(f) Professional Development. Employer will support Employee's membership in applicable associations that support non-profit hospitals and hospital management, and Employee is encouraged to seek roles in those associations that support or bring positive attention to the Hospital. Employer will support Employee's professional development and community engagement through professional resources and in programs that support mitigating social determinants of health, including dismantling systematic racism

4. COVENANTS.

(a) Confidential Information. During the course of the Employee's employment, the Employer will provide the Employee with access to certain confidential information, trade secrets and other matters which are of a confidential or proprietary nature, including, without limitation, the Employer's customer lists, pricing information, production and cost data, compensation and fee information, strategic business plans, budgets, financial statements, data and other information the Employer treats as confidential or proprietary (collectively, "**Confidential Information**") as the Employer deems necessary or desirable to aid the Employee in the performance of the Employee's duties. The Employee understands and acknowledges that such Confidential Information is confidential and proprietary, and agrees not to disclose such Confidential Information to anyone outside the Hospital except to the extent that: (i) the Employee deems such disclosure or use reasonably necessary or appropriate in connection with performing the Employee's duties on behalf of the Employer; (ii) the Employee is required by order of a court of competent jurisdiction (by subpoena or similar process) to disclose or discuss any Confidential Information, provided that in such case, the Employee will promptly inform the Employer of such event, will cooperate with the Employer in attempting to obtain a protective order or to otherwise restrict such disclosure and will only disclose Confidential Information to the minimum extent necessary to comply with any such court order; or (iii) such Confidential Information becomes generally known to and available for use in the industries in which the Employer does business, other than as a result of any breach by the Employee of this Section 4(a). The Employee further agrees that the Employee will not, during the Term and/or at any time thereafter use such Confidential Information for any purpose other than legitimate purposes in the performance of the Employee's duties, including, without limitation, competing, directly or indirectly, with the Employer. At such time as the Employee ceases to be employed by the Employer or earlier upon the Employer's request, the Employee will promptly turn over to the Employer all Confidential Information, including papers, documents, writings, electronically stored information, other property and all copies of them, provided to or created by the Employee during the course of the Employee's employment with the Employer.

(b) Third-Party Confidential Information. The Employee agrees that any confidential or proprietary information and materials that the Employee receives from third parties in connection with or relating to the Employee's employment with the Employer shall also be deemed "Confidential Information" for all purposes of this Agreement and will be subject to all limitations on use and disclosure set forth in this Agreement. The Employee will not use or disclose any such information and materials in any manner inconsistent with any of the Employer's obligations towards such third party. Additionally, the Employee acknowledges the Employee's obligation to preserve the trade secrets and confidential and proprietary information of the Employee's prior employers. As such, the Employee must not retain copies of any trade secret or confidential and proprietary information of any prior employer, and may not bring such materials to the Employer or otherwise utilize or disclose the contents of such materials as part of the Employee's work for the Employer.

(c) Non-Disparagement. During and after the Term, including following termination of the Employee's employment with the Employer for any reason, the Employee agrees that the Employee shall not publicly or privately disparage or defame the Employer or its officers, directors,

employees or representatives. The Employer agrees that it shall not, and shall take any and all commercially reasonable efforts to cause its executives not to, publicly or privately disparage or defame the Employee. Notwithstanding the foregoing, no affidavit, testimony, deposition or other statement that states factually the decisions and/or actions taken by prior management shall be deemed to violate this Section. Nothing in this Agreement prevents Employee from discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that Employee has reason to believe is unlawful.

(d) Written, Printed or Electronic Material. All written, printed and electronic material, notebooks and records including, without limitation, computer disks used by the Employee in performing duties for the Employer, including any Confidential Information and all copies thereof in any medium contained, are and shall remain the sole property of Employer. Upon termination of the Employee's employment or any earlier request by the Employer, the Employee shall promptly return all such materials (including all copies, extracts and summaries thereof) to the Employer.

(e) Reasonableness of Covenants. The Employer and the Employee agree that the restrictions contained in this Section 4 are reasonable in scope and duration and are necessary to protect the Employer's legitimate business interests and Confidential Information.

(f) Breach of Covenants. The Parties acknowledge and agree that any breach of this Section 4 by the Employee will cause irreparable damage to the Employer, and upon any such breach of any provision of these covenants, the Employer shall be entitled to injunctive relief, specific performance or other equitable relief without the need to post bond or other security therefor; provided, however, that this Section 4(f) shall in no way limit any other remedies which Employer may have (including, without limitation, the right to seek monetary damages). Should the Employee violate any provision of this Section 4, then, in addition to all other rights and remedies available to Employer at law or in equity, the duration of this covenant shall automatically be extended for the period of time from which the Employee began such violation until the Employee permanently ceases such violation.

5. SEVERANCE.

(a) If, during the Term of this Agreement, the Employer terminates the Employee's employment without Cause (as defined below), such a separation from employment shall be deemed a "Separation from Service" for the purposes of this Agreement. In the event of such Separation from Service, Employer shall promptly, as such obligations become due, pay or provide to the Employee: (i) the Employee's earned but unpaid Annual Base Salary accrued through the date of such Separation from Service (the "**Termination Date**"), (ii) reimbursement of any business expenses incurred by the Employee prior to the Termination Date that are reimbursable under Section 3(d) above, and (iii) any vested benefits and other amounts due to the Employee under any plan, program or policy of Employer (together, the "**Accrued Obligations**"). In addition, subject to the Employee's execution and non-revocation of a binding release in accordance with Section 5(d) below, the Employer shall pay to the Employee an amount equal to an amount of the lesser of (1) **twelve (12) months' base salary**, or (2) an amount equal to the remaining term on this agreement, subject to the limitations set forth in paragraph 5(f) below, commencing on the date that Employee separates from service at Employee's then current base rate of pay, less all applicable payroll tax and withholdings and authorized or required deductions (the "**Severance**"). Notwithstanding the foregoing, in no event may the amount of Severance exceed the number of months remaining on the term of the Agreement at the time of separation. Payment of such Severance shall be in regular payday intervals or as otherwise designated by the Employer and shall be paid in accordance with Employer's normal payroll practices. The Employer shall have the sole discretion to accelerate all or any portion of the

installment payments of the Severance. No installments shall be payable prior to the date the binding release described in Section 5(d) becomes effective. No interest shall be paid on the Severance.

(b) Death or Disability. If the Employee dies during the Term or the Employee's employment is terminated due to Employee's inability to perform the essential functions of Employee's position due to a mental or physical disability (as determined in good faith by Employer), the Employee or the Employee's estate, as applicable, shall be entitled to receive the Accrued Obligations promptly or, in the case of benefits described in Section 5(a)(iii) above, as such obligations become due. Termination of Employee's employment due to Employee's death or disability shall not be considered a termination without Cause for purposes of severance. No Severance shall be due.

(c) Termination for Cause. If the Employer terminates the Employee's employment for Cause, the Employee shall be entitled to receive the Accrued Obligations promptly or, in the case of benefits described in Section 5(a)(iii) above, as such obligations become due. No Severance shall be due.

(d) Release. The Employee's right to receive the Severance set forth in this Section 5(a) is conditioned on and subject to, within thirty (30) days of the Employee's Termination Date, the Employee executing and not revoking a binding general release and waiver of claims against the Employer in a form provided by the Employer. If the Employee does not execute such release within thirty (30) days following the Termination Date, no Severance shall be payable under this Section 5. The Parties warrant and represent that they shall fully cooperate in good faith regarding the execution and delivery of the release.

(e) Exclusivity of Benefits. Except as expressly provided in this Section 5 or as required by law, the Employee acknowledges that the Employer shall have no further obligations to the Employee following the Termination Date, whether under this Agreement, in connection with the Employee's employment, the termination thereof or otherwise.

(f) Limitation on Severance. This section is intended to comply with the provisions of Government Code Section 53260 and 53261, et seq, and in no event shall Employee be entitled to severance benefits greater than provided for therein. This Agreement in no way affects Employee's rights to continue health insurance coverage as required under COBRA for Employee and Employee's eligible dependents. In addition, pursuant to Government Code section 53243, et. seq. if Employee is convicted of a crime involving an abuse of his office or position, all of the following shall apply: (1) if Employee is provided with administrative leave pay pending an investigation, Employee shall be required to fully reimburse such amounts paid; (2) if the Employer pays for the criminal legal defense of Employee (which would be in its sole discretion, as it is generally not obligated to pay for a criminal defense), Employee shall be required to fully reimburse such amounts paid; and (3) if the Agreement is terminated, any cash settlement related to the termination that Employee may receive from the Employer shall be fully reimbursed to the Employer. For this Section, abuse of office or position means either: (1) an abuse of public authority, including waste, fraud, and violation of the laws under color of authority; or (2) a crime against public justice, including a crime described in Title 7 commencing with section 92 of the Penal Code.

(g) Definitions. For purposes of this Agreement:

"Cause" shall mean:

(A) Continued or repeated non-performance by the Employee of the Employee's duties hereunder (other than by reason of the Employee's physical or mental illness, incapacity or disability);

(B) The Employee's refusal or failure to follow lawful directives from the Employer;

(C) The criminal conviction of the Employee for, or a plea of nolo contendere by the Employee to any felony or other crime involving moral turpitude, including, without limitation, commission of a theft, fraud or embezzlement;

(D) A material breach by the Employee of any provision of this Agreement;

(E) An act or omission by the Employee constituting a material act of misconduct in connection with the performance of the Employee's duties hereunder, including, without limitation, any violation of the Employer's policy on sexual harassment or discrimination, or any misappropriation of funds or property of the Employer other than the occasional, customary and de minimis use of the Employer property for personal purposes;

(F) Any other act of misconduct that has resulted in, or could reasonably be expected to result in, material injury to the reputation or financial condition of the Employer; or

(G) A material violation by the Employee of the Employer's employment policies.

Notwithstanding the foregoing, Employee shall not be terminated for "Cause" for any occurrence described under sub-clauses (A), (B), (D), (F) or (G) until the Employee receives written notice from the Employer specifying the applicable occurrence and, if reasonably susceptible to correction, such occurrence thereafter continues uncured for more than thirty (30) days following the Employer's delivery of such written notice.

6. NOTICES.

Any notice or other communication required or permitted under this Agreement shall be effective only if it is in writing and delivered as follows (or if it is sent through any other method or to any other person, as agreed upon by the Parties):

If to the Employer, such notice or other communication must be sent to Chairperson of the Board of Directors, as follows:

Watsonville Community Hospital
Attn: Chairperson of the Board of Directors
75 Nielson Street
Watsonville, CA 95076

If to the Employee, by FedEx Overnight Delivery to the Employee's most current home address on file with the Employer's Human Resources Department, or to such other address as any

Party hereto may designate by notice to the other in accordance with this Section 6, and any such notice shall be deemed to have been given upon receipt.

7. PARTIES BENEFITTED; ASSIGNMENT.

This Agreement shall be binding upon the Employee, the Employee's heirs and the Employee's personal representative or representatives. Neither this Agreement nor any rights or obligations hereunder may be assigned by the Employee, other than by will or by the laws of descent and distribution.

8. GOVERNING LAW; VENUE.

This Agreement shall be governed by and construed in accordance with the laws of the State of California without giving effect to any choice of law or conflict provisions or rule (whether of the State of California or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of California. Subject to Section 10 below, the Employee hereby expressly consents to the personal jurisdiction of the state and federal courts located in Santa Cruz County, California for any lawsuit arising from or relating to this Agreement.

9. LITIGATION AND REGULATORY MATTERS.

During and after the Term, the Employee will reasonably cooperate with the Employer in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Employer which relate to events or occurrences that transpired while the Employee was employed by the Employer. The Employee's cooperation in connection with such claims or actions shall include, without limitation, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Employer at mutually convenient times. During and after the Employee's employment, the Employee also shall cooperate fully with the Employer in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Employee was employed by the Employer. If any such cooperation occurs after the Employee's termination of employment with the Employer, then the Employer shall reimburse the Employee for all reasonable costs and expenses incurred in connection with the Employee's performance under this Section 9. To the extent such cooperation occurs following Employee's termination of employment with the Employer, the Employer shall pay Employee an hourly rate for performance of such duties equal to Employee's salary on the last day of Employee's employment with Employer divided by 2080.

10. ARBITRATION

The Parties agree that any dispute, controversy or claim, whether based on contract, tort, statute, discrimination, retaliation or otherwise, relating to, arising from or connected in any manner to this Agreement, or to any alleged breach of this Agreement, or arising out of or relating to the Employee's employment or termination of employment, shall, upon the timely written request of either Party be submitted to and resolved by final and binding arbitration. The Employee may only bring claims under this Agreement in Employee's individual capacity and not as a plaintiff or class member in any purported class, collective or representative proceeding. Further, the arbitrator may not consolidate more than one person's claims and may not otherwise preside over any form of a representative or class, collective or representative proceeding. The arbitration shall be conducted in Santa Cruz County, California. Any arbitration proceeding shall be conducted in accordance with the Federal Arbitration Act ("FAA"), 9 U.S.C. Section I, *et seq.*, California state laws, and the Judicial Arbitration and Mediation Services Employment Arbitration Rules and Procedures (the "JAMS

Rules"), which can be found at http://www.jamsadr.com, a copy of which will be provided to the Employee upon the Employee's request. Unless otherwise agreed to by the Parties in writing, the arbitration shall be conducted by one arbitrator who is a member of JAMS and who is selected pursuant to the methods set out in the Employment Arbitration Rules and Procedures of JAMS. Any claims received after the applicable/relevant statute of limitations period has passed shall be deemed null and void. The award of the arbitrator shall be a reasoned award with findings of fact and conclusions of law. Either Party may bring an action in any court of competent jurisdiction to compel arbitration under this Agreement, to enforce an arbitration award and to vacate an arbitration award. The Employer will pay all fees unique to arbitration of arbitration, including the fees and costs of the Arbitrator; provided, however, that if the Employee is the party initiating the claim, the Employee will contribute an amount equal to the appearance fee to defend against such a claim in the applicable court of general jurisdiction. Each Party shall have the right to be represented by an attorney and must pay for its own attorneys' fees subject to the authority of the arbitrator, as permitted by law, to award a Party reimbursement for such attorneys' fees. Each Party shall have the right to present evidence at the arbitration, through testimony and documents, and to cross-examine witnesses called by another party. Each Party will be responsible for paying the fees of any witnesses testifying at the Party's request, just as would be required during a litigation in court. The cost of any stenographic record of the arbitration hearing should be covered by the requesting Party, just as would be required during a litigation in court. The Parties understand and agree that this Agreement constitutes a waiver of their right to a trial by jury of any claims or controversies covered by this Agreement or to participate in a class, collective or representative action. The Parties agree that, to the fullest extent allowed by law, none of those claims or controversies shall be resolved by a jury trial or in a class, collective or representative action.

This agreement to arbitrate does not cover claims for workers' compensation, state or federal disability benefits, or unemployment compensation benefits; administrative charges of discrimination brought before the EEOC, or administrative claims falling under the jurisdiction of the NLRB; claims under an employee benefit or pension plan that either (1) specifies that its claims procedure shall culminate in an arbitration procedure different from this one; or (2) is underwritten by a commercial insurer which decides claims; and claims for public injunctive relief.

The Arbitrator shall have exclusive authority to resolve any dispute relating to the interpretation, applicability, enforceability, or formation of this Agreement, Section 10 and the agreement to arbitrate, including but not limited to any claim that all or any part of this Section 10 is void or voidable.

11. REPRESENTATIONS AND WARRANTIES OF THE EMPLOYEE.

The Employee represents and warrants to the Employer that: (i) the Employee is under no contractual or other restriction which is inconsistent with the execution of this Agreement, the performance of the Employee's duties hereunder or the other rights of the Employer hereunder; (ii) the Employee has no physical or mental disability that prevent Employee from performing Employee's duties under this Agreement with or without accommodation; and (iii) the Employee's execution of this Agreement and performance of the Services under this Agreement will not violate any obligations that the Employee may have to any other or former employer, person or entity, including any obligations to keep in confidence proprietary information, knowledge or data acquired by the Employee in confidence or in trust prior to becoming an employee of the Employer. The Employee further represents, warrants and covenants that the Employee will not disclose to the Employer, or use in connection with the Employee's activities as an employee of the Employer, or induce the Employer to use, any proprietary or confidential information or trade secrets of the Employee or any third party at any time, including, without limitation, any proprietary, confidential information or trade secrets of any former employer.

12. OTHER AGREEMENTS.

(a) Employee understands agrees that any and all other rights Employee may have to severance, compensation, benefits, or rights to continued employment (whether written, verbal, implied, or otherwise) are extinguished through this Agreement.

(b) Employee understands and agrees that this Agreement supersedes the Employer's policies with respect to the subject matter of the Agreement.

13. MISCELLANEOUS.

(a) Amendment. The terms of this Agreement may not be amended or modified other than by a written instrument executed by the Parties hereto or their respective successors.

(b) Withholding. The Employer shall withhold from any amounts payable under this Agreement all federal, state, local and/or foreign taxes, as the Employer determines to be legally required pursuant to any applicable laws or regulations.

(c) No Waiver. Failure by either Party hereto to insist upon strict compliance with any provision of this Agreement or to assert any right such Party may have hereunder shall not be deemed to be a waiver of such provision or right or any other provision or right of this Agreement. A waiver of the breach of any term or condition of this Agreement shall not be deemed to constitute a waiver of any subsequent breach of the same or any other term or condition.

(d) Severability. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement. If any provision of this Agreement, or the application thereof to any person or circumstance, shall, for any reason and to any extent, be held invalid or unenforceable, such invalidity and unenforceability shall not affect the remaining provisions hereof or the application of such provisions to other persons or circumstances, all of which shall be enforced to the greatest extent permitted by law.

(e) Construction. The Parties hereto acknowledge and agree that each Party has reviewed and negotiated the terms and provisions of this Agreement and has had the opportunity to contribute to its revision. Accordingly, any rule of construction to the effect that ambiguities are resolved against the drafting party shall not be employed in the interpretation of this Agreement. Rather, the terms of this Agreement shall be construed fairly as to all Parties hereto and not in favor or against any Party by the rule of construction abovementioned.

(f) Entire Agreement. As of the Effective Date, this Agreement constitutes the final, complete and exclusive agreement and understanding between the Employer and the Employee with respect to the subject matter hereof and replaces and supersedes any and all other agreements, offers or promises, whether oral or written, made to the Employee by the Employer or any representative thereof regarding the terms or conditions of the Employee's employment with the Employer. The Parties note that notwithstanding this Section, any Confidentiality Agreement or confidentiality obligation shall remain in full force and effect if not conflicting with this Agreement.

(g) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

(h) Captions. The captions of this Agreement are not part of the provisions hereof, rather they are included for convenience only and shall have no force or effect.

THE EMPLOYEE ACKNOWLEDGES THAT THE EMPLOYEE (I) HAS BEEN ADVISED BY EMPLOYER TO CONSULT WITH LEGAL COUNSEL CONCERNING THIS AGREEMENT AND HAS HAD THE OPPORTUNITY TO DO SO, (II) HAS READ AND UNDERSTANDS THIS AGREEMENT, (III) IS FULLY AWARE OF THE LEGAL EFFECT OF THIS AGREEMENT AND (IV) HAS ENTERED INTO IT FREELY BASED ON THE EMPLOYEE'S OWN JUDGMENT AND NOT ON ANY REPRESENTATIONS OR PROMISES OTHER THAN THOSE CONTAINED IN THIS AGREEMENT.

IN WITNESS WHEREOF, the Parties have duly executed and delivered this Agreement effective as of the date first written above.

Date:_____ _____

Stephen Gray, Employee

Date:_____ _____

John Friel, Chair
Pajaro Valley Health Care District Hospital Corporation
Employer

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: September 27, 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: September 27, 2023

Report Type: Discussion

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

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

Contact: Julie Peterson, Chief Financial Officer

Analysis

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

Financial Impact: See attached report.

Attachments

A: Financial Performance Report

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

CURRENT PERIOD					YTD			
Aug-23	BUDGET	VARIANCE	% VARIANCE		ACTUAL	BUDGET	VARIANCE	% VARIANCE
				Operating Revenues				
31,529,787	36,403,131	(4,873,344)	-13.4%	Inpatient Revenue	240,058,365	279,746,274	(39,687,909)	-14.2%
56,741,107	58,016,319	(1,275,212)	-2.2%	Outpatient Revenue	427,390,689	401,758,494	25,632,195	6.4%
88,270,894	**94,419,450**	**(6,148,556)**	**-6.5%**	**Total gross patient revenue**	**667,449,054**	**681,504,768**	**(14,055,714)**	**-2.1%**
				Deductions From Revenue:				
77,243,855	82,323,515	(5,079,660)	-6.2%	Contractual Allowances	575,010,489	591,531,646	(16,521,157)	-2.8%
(1,599,179)	(1,599,179)		0.0%	QAF	(12,793,434)	(12,793,434)		0.0%
(128,059)	(128,059)		0.0%	Disproportionate Share DSH	(1,024,468)	(1,024,468)		0.0%
75,516,617	**80,596,277**	**(5,079,660)**	**-6.3%**	**Total Deductions From Rev**	**561,192,587**	**577,713,744**	**(16,521,157)**	**-2.9%**
12,754,277	**13,823,172**	**(1,068,895)**	**-7.7%**	**Net Revenue**	**106,256,467**	**103,791,024**	**2,465,443**	**2.4%**
1,024,816	117,889	906,927	769.3%	Provision for Bad Dbt	14,715,895	885,091	13,830,804	1562.6%
11,729,461	**13,705,284**	**(1,975,823)**	**-14.4%**	**Collectible Patient Revenue**	**91,540,572**	**102,905,934**	**(11,365,362)**	**-11.0%**
85,451	136,542	(51,091)	-37.4%	Other Revenue	3,644,006	1,070,316	2,573,690	240.5%
11,814,912	**13,841,826**	**(2,026,914)**	**-14.6%**	**Total Net Operational Revenue**	**95,184,578**	**103,976,250**	**(8,791,672)**	**-8.5%**
				Operating Expenses				
5,593,534	6,148,710	(555,176)	-9.0%	Salaries & Wages	46,700,449	46,687,806	12,643	0.0%
1,854,083	2,090,473	(236,390)	-11.3%	Benefits	13,645,228	16,460,164	(2,814,936)	-17.1%
619,269	490,000	129,269	26.4%	Contract Labor	4,821,494	4,346,000	475,494	10.9%
8,066,886	**8,729,183**	**(662,297)**	**-7.6%**	**Subtotal Salaries Wages & Benefits**	**65,167,171**	**67,493,970**	**(2,326,799)**	**-3.4%**
582,553	857,167	(274,614)	-32.0%	Medical Spec Fees	5,264,095	6,736,883	(1,472,788)	-21.9%
794,358	971,530	(177,172)	-18.2%	Supplies	7,094,596	7,333,489	(238,893)	-3.3%
104,695	104,310	385	0.4%	Repairs & Maintenance	851,556	817,657	33,899	4.1%
172,929	167,121	5,808	3.5%	Utilities	1,725,209	1,308,505	416,704	31.8%
1,056,203	999,719	56,484	5.6%	Purchased Services	9,317,819	10,884,170	(1,566,351)	-14.4%
153,745	217,305	(63,560)	-29.2%	Lease Cost and Rent	1,250,562	1,689,032	(438,470)	-26.0%
325,422	281,049	44,373	15.8%	Prop Taxes & Ins	1,650,924	2,221,098	(570,174)	-25.7%
1,096	4,167			Marketing	4,115	33,333	(29,218)	-87.7%
771,760	878,031	(106,271)	-12.1%	Other Operating Exp	5,342,842	7,798,257	(2,455,415)	-31.5%
12,029,647	**13,209,582**	**(1,179,935)**	**-8.9%**	**Total Operating Exp**	**97,668,889**	**106,316,394**	**(8,647,505)**	**-8.1%**
(214,735)	**632,244**	**(846,979)**	**-134.0%**	**EBITDA**	**(2,484,311)**	**(2,340,144)**	**(144,167)**	**6.2%**
81,867	97,419	(15,552)	-16.0%	Depreciation and Amortization	698,956	772,700	(73,744)	-9.5%
346,947	402,467	(55,520)	-13.8%	Interest	2,993,646	3,216,271	(222,625)	-6.9%
428,814	**499,886**	**(71,072)**	-14.2%	**Total Other Expenses**	**3,692,602**	**3,988,971**	**(296,369)**	-7.4%
(643,549)	**132,359**	**(775,908)**	-586.2%	**Net Income/Loss from Operations**	**(6,176,913)**	**(6,329,115)**	**152,202**	-2.4%

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

CURRENT PERIOD					YTD			
Aug-23	BUDGET	VARIANCE	% VARIANCE		ACTUAL	BUDGET	VARIANCE	% VARIANCE
				Operating Revenues				
31,529,787	36,403,131	(4,873,344)	-13.4%	Inpatient Revenue	240,058,365	279,746,274	(39,687,909)	-14.2%
56,185,192	57,511,216	(1,326,024)	-2.3%	Outpatient Revenue	423,223,301	397,900,129	25,323,172	6.4%
87,714,979	**93,914,347**	**(6,199,368)**	**-6.6%**	**Total gross patient revenue**	**663,281,666**	**677,646,403**	**(14,364,737)**	**-2.1%**
				Deductions From Revenue:				
76,913,283	82,051,331	(5,138,048)	-6.3%	Contractual Allowances	572,463,101	589,395,617	(16,932,516)	-2.9%
(1,599,179)	(1,599,179)		0.0%	QAF	(12,793,434)	(12,793,434)		0.0%
(128,059)	(128,059)		0.0%	Disproportionate Share DSH	(1,024,468)	(1,024,468)		0.0%
75,186,045	**80,324,093**	**(5,138,048)**	**-6.4%**	**Total Deductions From Rev**	**558,645,199**	**575,577,715**	**(16,932,516)**	**-2.9%**
12,528,934	**13,590,254**	**(1,061,320)**	**-7.8%**	**Net Revenue**	**104,636,467**	**102,068,688**	**2,567,779**	**2.5%**
1,016,033	115,254	900,779	781.6%	Provision for Bad Dbt	14,699,574	865,611	13,833,963	1598.2%
11,512,901	**13,474,999**	**(1,962,098)**	**-14.6%**	**Collectible Patient Revenue**	**89,936,893**	**101,203,077**	**(11,266,184)**	**-11.1%**
18,074	116,792	(98,718)	-84.5%	Other Revenue	3,094,831	915,495	2,179,336	238.1%
11,530,975	**13,591,791**	**(2,060,816)**	**-15.2%**	**Total Net Operational Revenue**	**93,031,724**	**102,118,571**	**(9,086,847)**	**-8.9%**
				Operating Expenses				
5,394,564	5,868,341	(473,777)	-8.1%	Salaries & Wages	44,746,504	44,477,204	269,300	0.6%
1,816,835	2,037,256	(220,421)	-10.8%	Benefits	13,290,573	15,969,457	(2,678,884)	-16.8%
619,269	490,000	129,269	26.4%	Contract Labor	4,821,494	4,346,000	475,494	10.9%
7,830,668	**8,395,597**	**(564,929)**	**-6.7%**	**Subtotal Salaries Wages & Benefits**	**62,858,571**	**64,792,661**	**(1,934,090)**	**-3.0%**
578,353	843,983	(265,630)	-31.5%	Medical Spec Fees	5,176,281	6,615,738	(1,439,457)	-21.8%
784,948	959,844	(174,896)	-18.2%	Supplies	7,038,942	7,274,831	(235,889)	-3.2%
104,603	104,189	414	0.4%	Repairs & Maintenance	851,322	816,710	34,612	4.2%
171,824	165,741	6,083	3.7%	Utilities	1,715,601	1,299,195	416,406	32.1%
1,052,488	965,384	87,104	9.0%	Purchased Services	9,248,449	10,613,414	(1,364,965)	-12.9%
129,638	196,296	(66,658)	-34.0%	Lease Cost and Rent	1,057,637	1,538,707	(481,070)	-31.3%
318,388	272,329	46,059	16.9%	Prop Taxes & Ins	1,582,221	2,134,708	(552,487)	-25.9%
1,096	-	1,096		Marketing	4,115	-	4,115	
-	-			Management Fees	-	150,000	(150,000)	-100.0%
766,345	863,644	(97,299)	-11.3%	Other Operating Exp	5,317,956	7,613,035	(2,295,079)	-30.1%
11,738,351	**12,767,007**	**(1,028,656)**	**-8.1%**	**Total Operating Exp**	**94,851,095**	**102,848,999**	**(7,997,904)**	**-7.8%**
(207,376)	**824,783**	**(1,032,159)**	**-125.1%**	**EBITDA**	**(1,819,371)**	**(730,427)**	**(1,088,944)**	**149.1%**
-	-			Depreciation and Amortization	-	-		
16,084	16,008	76	0.5%	Interest	45,539	124,603	(79,064)	-63.5%
16,084	**16,008**	**76**	0.5%	**Total Other Expenses**	**45,539**	**124,603**	**(79,064)**	-63.5%
(223,460)	**808,775**	**(1,032,235)**	-127.6%	**Net Income/Loss from Operations**	**(1,864,910)**	**(855,030)**	**(1,009,880)**	118.1%

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

	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23
Assets								
Cash	$ 5,982	$ 6,078	$ 1,916	$ 3,958	$ 3,576	$ 2,081	$ 2,852	$ 3,296
A/R	43,166	43,452	42,474	39,084	39,504	41,108	57,266	57,769
Less: Allowance for BD	(8,134)	(7,325)	(6,587)	(6,365)	(7,298)	(7,420)	(21,342)	(22,157)
Supplies	2,079	2,073	2,118	2,069	2,058	2,056	2,024	2,027
Prepaid Expenses	1,185	1,209	1,104	1,096	1,028	831	951	775
Other Current Assets	722	1,195	2,551	2,271	2,217	2,757	2,347	2,260
Total Current Assets	$ 45,000	$ 46,682	$ 43,576	$ 42,113	$ 41,085	$ 41,413	$ 44,098	$ 43,970
Net PP&E	35,245	35,168	35,150	35,074	34,999	34,933	34,863	34,849
Operating Lease ROU, Net	1,676	1,634	1,491	1,449	1,408	1,367	1,326	1,284
Notes Receivable								
Deposits	5	5	5	5	5	5	5	5
Unamortized Loan Costs	50	50	50	50	50	50	50	50
Physician Recruitment Costs	-	-	-	-	-	-	-	
Deferred MIS Charges	698	631	562	496	431	367	349	340
Goodwill (Placeholder)	(20,666)	(20,551)	(20,963)	(20,963)	(20,963)	(20,963)	(19,771)	(19,771)
Total Other Assets	$ (18,237)	$ (18,231)	$ (18,855)	$ (18,963)	$ (19,069)	$ (19,174)	$ (18,041)	$ (18,092)
Total Assets	$ 62,008	$ 63,619	$ 59,871	$ 58,224	$ 57,015	$ 57,172	$ 60,920	$ 60,727
Liabilities and Equity								
Current maturities of LTD	$ (47)	$ (57)	$ (68)	$ (79)	$ (90)	$ (105)	$ (113)	$ (117)
Accounts Payable	6,622	7,194	7,009	7,361	6,855	7,478	9,746	9,607
Accrued Emp. Comp.	9,401	10,052	7,793	8,535	8,112	8,160	9,171	7,124
Operating Lease - Current	30	20	319	324	307	448	433	428
Other Accrued Liabilities	5,844	7,716	7,006	5,955	6,073	6,350	7,223	10,351
Total Current Liabilities	$ 21,850	$ 24,925	$ 22,059	$ 22,096	$ 21,257	$ 22,331	$ 26,460	$ 27,393
Deferred Credits and Other Long-term Liabilities	6,935	6,880	6,405	6,318	6,133	6,116	6,131	5,755
Operating Lease Liabilities	1,693	1,655	1,194	1,159	1,124	940	904	868
Long Term Debt	39,836	39,847	40,358	40,369	40,379	40,388	41,686	41,618
Total Liabilities	$ 70,314	$ 73,307	$ 70,016	$ 69,942	$ 68,893	$ 69,775	$ 75,181	$ 75,634
Stockholders' Equity	(8,306)	(9,688)	(10,145)	(11,718)	(11,878)	(12,603)	(14,261)	(14,907)
Total Liabilities and Equity	$ 62,008	$ 63,619	$ 59,871	$ 58,224	$ 57,015	$ 57,172	$ 60,920	$ 60,727

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: September 27, 2023

Report Type: Discussion

Title: Santa Cruz County Bank Business Loan Agreement

Recommendation: Pass a **Resolution** 1) authorizing the execution and delivery of a business loan agreement with Santa Cruz County Bank and approving related documents and actions;
2) authorizing the interim Chief Executive Officer, Matko Vranjes and Chief Financial Officer, Julie Peterson (or any interim) or either of their designees (each, an "Authorized Officer") and directing them to execute and deliver the Loan Agreement, the related Security Agreement, and all other related documents on behalf of the Pajaro Valley Health Care District Hospital Corporation.

Contact: Julie Peterson, Chief Financial Officer

Authorized Officers can designate staff to transact payments and disbursements on loan with approval by one officer. Designated staff will also have on-line and statement access to loan accounts for the purposes of record keeping and reconciliation.

Contact: Julie Peterson, Chief Financial Officer

Analysis

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. Terms and conditions have been negotiated with Santa Cruz County Bank and Community partners who will guarantee the loan. The District and the Pajaro Valley Health Care District Hospital Corporation will be co-borrowers. The Line of Credit will be guaranteed by Salud Para la Gente, a California nonprofit public benefit corporation, Community Foundation Santa Cruz County, a California nonprofit public benefit corporation, and the County of Santa Cruz.

Financial Impact: The Line of Credit is expected to be $5,000,000 in year one, $4,000,000 in year two and $3,000,000 in year three. The Line of Credit is expected to mature three years 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.), currently at $14,000.

Attachments:

A: Resolution

- Business Loan Agreement
- Promissory Note
- Security Agreement
- Commercial Guaranty for each Guarantor

RESOLUTION NO. _____

RESOLUTION OF THE BOARD OF DIRECTORS OF THE PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION AUTHORIZING EXECUTION AND DELIVERY OF A BUSINESS LOAN AGREEMENT WITH SANTA CRUZ COUNTY BANK AND APPROVING RELATED DOCUMENTS AND ACTIONS

WHEREAS, the Pajaro Valley Health Care District Hospital Corporation (the "Corporation") desires to obtain a revolving line of credit with Santa Cruz County Bank (the "Bank") with an initial maximum credit amount of $5,000,000; and

WHEREAS, in order to obtain the line of credit with the Bank, the Corporation has proposed to enter into that certain Business Loan Agreement and promissory note (together, the "Loan Agreement") with the Bank, whereby the Corporation and the Pajaro Valley Health Care District (the "District") will act as co-borrowers on the line of credit; and

WHEREAS, Salud Para la Gente, a California nonprofit public benefit corporation, Community Foundation Santa Cruz County, a California nonprofit public benefit corporation, and the County of Santa Cruz have all agreed to act as guarantor for the line of credit; and

WHEREAS, pursuant to Section 11.1 of the Corporation's Bylaws, the prior consent of the District is required for the Corporation to enter into and consummate the financing under the Loan Agreement, and such consent has been provided by the District; and

WHEREAS, it is consistent with the purposes of, and in the best interests of, the Corporation for the District and the Corporation to enter into the Loan Agreement for the purposes described therein; and

WHEREAS, the Board wishes at this time to authorize all proceedings relating to the financing as described herein and the execution and delivery of all agreements and documents relating thereto, including the Loan Agreement.

NOW, THEREFORE, it is hereby resolved by the Board of Directors of the Pajaro Valley Health Care District Hospital Corporation as follows:

Section 1. Recitals. The foregoing recitals are true and correct and the Board so finds and determines.

Section 2. Authorized Officer. The Chief Executive Officer and Chief Financial Officer (or any interim) or either of their designee (each, an "Authorized Officer") are hereby each, acting alone, authorized and directed to execute and deliver the Loan Agreement, the related Security Agreement, and all other related documents on behalf of the Corporation (subject to making such changes to the Loan Agreement or any related documents as they deem necessary or appropriate). The Authorized Officers are further authorized and directed to consummate the transaction described herein, execute any documents or supplementary agreements necessary to secure the

line of credit, and to approve any amendments necessary to carry out the provisions of this authorizing Resolution.

Section 3. Approval of Financing Plan and Documents. The Board hereby approves the financing plan outlined herein. To that end, the Board hereby approves each of the following financing documents in substantially the respective forms as presented to the Board at this meeting, together with any changes therein or additions thereto deemed advisable by an Authorized Officer, whose execution thereof shall be conclusive evidence of such approval.

- **Business Loan Agreement** between the Corporation, District, and the Bank, whereby the terms and provisions of the line of credit are prescribed.

- **Promissory Note** for the line of credit evidencing the Corporation and District's promise to pay.

- **Security Agreement** between the Bank and the Corporation whereby the Corporation grants to the Bank a security interest in certain assets of the Corporation to secure repayment of the line of credit.

An Authorized Officer is authorized and directed for and in the name and on behalf of the Corporation to execute and attest the final form of each of the foregoing documents. The documents are hereby approved, subject to the adjustment by an Authorized Officer, but not excess of the initial maximum credit amount of $5,000,000.

Section 4. Official Actions. The Authorized Officers are each, acting alone, authorized and directed in the name and on behalf of the Corporation to do any and all things and take any and all actions, including to make, execute, and deliver any and all amendments to the Loan Agreement and Security Agreement, assignments, certificates, requisitions, agreements, notices, consents, escrow agreements, and other instruments of conveyance, warrants, and other documents, which they might deem necessary or appropriate in order to consummate any of the transactions contemplated by the agreements and documents approved under this Resolution.

Section 5. Effective Date. This Resolution shall take effect from and immediately after the date of its passage and adoption.

PASSED AND ADOPTED by the Board of Directors of the Pajaro Valley Health Care District Hospital Corporation this ___ day of _____, 2023, by the following vote:

AYES: _____

NOES: _____

ABSENT: _____

ABSTAIN: _____

_____
John Friel
Chair of the Board

ATTEST:

_____
Dawn Bullwinkel
Consultant Clerk of the Board

BUSINESS LOAN AGREEMENT

THIS BUSINESS LOAN AGREEMENT ("Agreement") is dated for reference purposes and entered into as of November 1, 2023 ("Effective Date"), between **SANTA CRUZ COUNTY BANK**, a California state-chartered bank ("Lender"), with an address at P.O. Box 8426, Santa Cruz, CA 95061 and **PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION**, a California nonprofit public benefit corporation ("PVHDHC"), with a chief executive office located at 75 Nielson Street, Watsonville, CA 95076, and **PAJARO VALLEY HEALTHCARE DISTRICT,** a California nonprofit public benefit corporation ("PVHD"), with a chief executive office located at 75 Nielson Street, Watsonville, CA 95076 (PVHDHC and PVHD are together referred to herein as "Borrower"), and with reference to the below recitals.

ARTICLE I: RECITALS

1.1 PVHDHC is primarily in the business of owning and operating a community hospital by the name of Watsonville Community Hospital ("Hospital"), and PVHD is primarily in the business of providing public oversight of the Hospital and to advocate for community led healthcare services.

1.2 Borrower has requested that Lender extend credit to Borrower in the form of a revolving line of credit with an initial maximum credit limit of Five Million Dollars ($5,000,000.00), to decrease to Four Million Dollars ($4,000,000.00) beginning one (1) year after the date of the Note, and then to decrease to Three Million Dollars ($3,000,000.00) beginning two (2) years after the date of this Note, for the purpose of operating the Hospital.

1.3 Lender has agreed to extend credit to Borrower subject to and in accordance with the terms and conditions of this Agreement and the other "Loan Documents" (as that term is defined below).

NOW THEREFORE, IN CONSIDERATION OF THE MUTUAL BENEFITS ACCRUING TO THE PARTIES HERETO AND OTHER VALUABLE CONSIDERATION, THE RECEIPT AND SUFFICIENCY OF WHICH IS HEREBY ACKNOWLEDGED, AND IN ORDER TO INDUCE LENDER TO MAKE THE LOANS REFERRED TO ABOVE, THE PARTIES HERETO DECLARE, UNDERSTAND AND AGREE TO THE FOLLOWING TERMS:

ARTICLE II: DEFINITIONS AND CONSTRUCTION

2.1 Definitions. Capitalized terms in this Agreement that are not defined when first used shall have the meanings set forth below:

(a) Advances. The term "Advances" shall mean all funds advanced to the Borrower under the terms of this Agreement, including without limitation all funds advanced as Lender Expenses.

(b) Agreement. The term "Agreement" shall mean this Business Loan Agreement, any schedules hereto, any promissory notes, assignments and security agreements required hereunder (whether executed concurrently with or prior or subsequent to the date hereof), and any concurrent or subsequent amendments, modifications, supplements, chattel paper, extensions, or schedules to any of the foregoing.

(c) Authorized Officer. The term "Authorized Officer" shall mean any officer of Borrower set forth on Exhibit A attached hereto, as the same may be amended from time to time upon written notice to Lender.

(d) Borrower's Books. The term "Borrower's Books" shall mean: (a) all of Borrower's books and records including ledgers, records indicating, summarizing, or evidencing Borrower's assets or liabilities, or the Collateral; (b) all information relating to Borrower's business operations or financial condition; and (c) all computer programs, disk or tape files, printouts, runs, or other computer prepared information, and the equipment containing such information.

(e) Borrower's Performance Plan. The term "Borrower's Performance Plan" shall mean Borrower's financial performance plan and operating budget provided to Lender (in a form acceptable to Lender) before the Effective Date covering each calendar year from 2023 to 2027, and which includes the following with regard to Borrower for each quarter of each calendar year (with totals provided for each calendar year): (i) forecasted Net Worth; (ii) forecasted Net Profits; (iii) forecasted revenue and income; (iv) forecasted expenses; and (v) any other items Lender in its sole discretion requires Borrower to include in the performance plan.

(f) Business Day. The term "Business Day" shall mean any day which is not a Saturday, Sunday, or other day on which banks in the State of California are authorized or required to close.

(g) Collateral. The term "Collateral" shall mean certain assets of Borrower in which Borrower has granted to Lender a security interest, which assets are more particularly described in the "Security Agreement(s)."

(h) Event of Default. The term "Event of Default" shall mean the occurrence of an event described in Section 7.1 below.

(i) Financial Statement(s). The term "Financial Statement(s)" shall mean all income statements, balance sheets, agings of collection accounts, statements of retained earnings or other related statements which reflect the financial worth of Borrower.

(j) Guarantor(s). The term "Guarantor(s)" shall mean the following parties: (i) Salud Para La Gente, a California nonprofit public benefit corporation; (ii) Community Foundation Santa Cruz County, a California nonprofit public benefit corporation; and (iii) County of Santa Cruz.

(k) Lender Expenses. The term "Lender Expenses" shall mean each and all of the following: (a) all costs or expenses (including taxes and insurance premiums) required to be paid by Borrower under any of the Loan Documents which are paid or advanced by Lender, including without limitation, filing, recording, publication, and search fees paid or incurred by Lender in connection with Lender's transactions with Borrower; (b) all costs and expenses incurred by Lender to correct any default or enforce any provision of the Loan Documents, or in gaining possession of, maintaining, handling, preserving, storing, shipping, selling, preparing for sale, or advertising to sell the "Collateral," or any portion thereof irrespective of whether a sale is consummated; (c) all costs and expenses of suit incurred by Lender in enforcing or defending the Loan Documents; and (d) all Lender's reasonable attorneys' fees and expenses incurred in advising, structuring, drafting, reviewing, administering, amending, terminating, enforcing, defending, or concerning the Loan Documents, irrespective of whether suit is brought.

(l) Loan. The term "Loan" shall mean the aggregate of all Advances made by Lender to Borrower hereunder.

(m) Loan Documents. The term "Loan Documents" shall mean, collectively, this Agreement, the Note, the Security Agreement(s), any other note or notes executed by Borrower to the order of Lender, and any other document, instrument and agreement executed by Borrower in connection with this Agreement.

(n) Maximum Credit Limit. The term "Maximum Credit Limit" has the meaning provided in Section 3.1 below.

(o) Net Profit. The term "Net Profits" shall mean Borrower's consolidated net profit before payment of taxes.

(p) Net Worth. The term "Net Worth" shall mean an amount equal to Borrower's net worth as shown on Borrower's most recent consolidated balance sheet plus Borrower's debt that is specifically subordinated to Lender less the aggregate book value of the following: Borrower's patents, licenses, leasehold improvements, goodwill, subscription lists, organization expenses, monies due from affiliates (including officers, directors and shareholders), security deposits, and prepaid costs and expenses.

(q) Note. The term "Note" shall mean that certain promissory note of even date herewith in the original initial principal amount of Five Million Dollars ($5,000,000.00), to decrease to Four Million Dollars ($4,000,000.00) beginning one (1) year after the date of the Note, and then to decrease to Three Million Dollars ($3,000,000.00) beginning two (2) years after the date of the Note, executed by Borrower to the order of Lender, which will evidence Advances made to Borrower hereunder.

(r) Obligations. The term "Obligations" shall mean all Advances together with interest thereon, Lender Expenses, and all other amounts payable by Borrower under the Loan Documents, whether direct or indirect, absolute or contingent, due or to become due, now existing or hereafter arising, and including any debt, liability, or obligation owing from Borrower to others which Lender may have obtained by assignment or otherwise, and further including all interest not paid when due and all Lender Expenses which Borrower is required to pay or reimburse by the Loan Documents, by law or otherwise.

(s) Security Agreement(s). The term "Security Agreement(s)" shall mean that certain security agreement(s) of even date herewith, executed by: (i) Borrower in favor of Lender, pursuant to which Borrower has granted to Lender a security interest in the Collateral to secure the Obligations; and (ii) Pajaro Valley Healthcare District, a California nonprofit public benefit corporation ("PVHD") and Pajaro Valley Health Care District Hospital Corporation, a California nonprofit public benefit corporation ("PVHDHC"), in favor of Lender, pursuant to which PVHD and PVHDHC has granted to Lender a security interest in the Collateral to secure the Obligations.

(t) UCC. The term "UCC" shall mean the California Uniform Commercial Code.

2.2 Construction. Unless the context of this Agreement clearly requires otherwise, references to the plural include the singular, to the singular include the plural, to the part include the whole, and "including" is not limiting, and "or" has the inclusive meaning represented by the phrase "and/or." The words "hereof," "herein," "hereby," "hereunder" and similar terms in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement. Section, subsection, clause, and exhibit references are to this Agreement unless otherwise specified.

2.3 Accounting Terms. All accounting terms not specifically defined herein shall be construed in accordance with generally accepted accounting principles ("GAAP") as in effect from time to time. When used herein, the term "financial statements" shall include the notes and schedules thereto.

2.4 UCC Terms. Any terms used in this Agreement which are defined in the UCC shall be construed and defined as set forth in the UCC unless otherwise defined herein.

ARTICLE III: ADVANCES AND TERMS OF PAYMENT.

3.1 Extension of Credit. Subject to the full satisfaction of each and all of the conditions set forth in this Article III, and subject to the all other terms and conditions of this Agreement, Lender shall, upon the request of Borrower made from time to time during the term hereof, and so long as no Event of Default has occurred and is continuing, or so long as this Agreement has not been terminated, and subject to the full satisfaction of each and all of the conditions set forth in Section 3.4, make Advances to Borrower in an aggregate amount not to exceed, at any one time, the sum of the following (the "Maximum Credit Limit"): (i) Five Million Dollars ($5,000,000.00) during the first year after the date of the Note; (ii) Four Million Dollars ($4,000,000.00) beginning one (1) year after the date of the Note; and (iii) Three Million Dollars ($3,000,000.00) beginning two (2) years after the date of the Note.

3.2 Request for Advance. The Loan extended hereunder is a revolving line of credit, which means Borrower may borrow, repay and re-borrow amounts hereunder. Advances, as well as directions for payment from Borrower's deposit accounts maintained with Lender, may be requested orally or in writing on behalf of Borrower by any Authorized Officer as listed in Exhibit A. Lender may, but need not, require that all oral requests be confirmed in writing. Borrower agrees to be liable for all sums either: (A) advanced in accordance with Borrower's or Borrower's authorized representative's instructions, or (B) credited to any of Borrower's accounts with Lender. The unpaid Advances owing hereunder, at any time, will be evidenced by Lender's internal records, including daily computer printouts. All requests for Advances shall be received by Lender before 4:00 p.m. Pacific Time on the Business Day prior to the proposed date the requested Advance is to be made (referred to as the "cutoff" for purposes of this Section 3.2). If a request for an Advance is received after the cutoff, then the date the Advance will be made by Lender will be the Business Day immediately following the requested day of the Advance. Each request made to Lender for an Advance shall contain the following: (a) the aggregate principal amount of the Advance; and (b) the Business Day the Borrower is requesting Lender to make the Advance.

3.3 Authorization to Make Advances. Lender is hereby authorized to make Advances based on an oral or written request to Lender made by anyone purporting to be an Authorized Officer. Borrower hereby holds Lender harmless against any loss, claim, liability, cause of action, and damages arising out of Lender's reliance on such request in making an Advance hereunder.

3.4 Conditions to Each Advance. Lender shall not be obligated to disburse all or any portion of the first Advance and each subsequent Advance, unless and until Borrower has fully satisfied each and all of the following conditions:

(a) The outstanding principal balance owed on the Loan as evidenced by the Note does not at any time exceed the Maximum Credit Limit;

(b) Borrower shall have executed and delivered to Lender an original counterpart of this Agreement;

(c) Borrower shall have executed and delivered to Lender an original Note;

(d) If repayment of the Loan is secured by a security interest in personal property collateral, then Borrower shall have executed and delivered to Lender an original Security Agreement(s);

(e) If repayment of the Loan is secured by a security interest in personal property collateral, then Lender shall have received a certificate of (or, if no such certificate is available, the best evidence normally provided by) the Secretary of State of each state where a financing statement has been or is to be filed pursuant to this section showing all outstanding UCC filings against Borrower, together with copies of all filings referred to in any such certificate. If Lender so requests, Borrower shall have obtained and delivered to Lender any subordination agreements, termination statements and/or releases of interest from each secured party identified in any such filing who, in Lender's opinion, may have a security interest in any Collateral which does or potentially could conflict with the security interest granted to Lender hereunder;

(f) A duly executed corporate resolution to borrow authorizing the loan transactions contemplated hereby and the grant of the security interest provided for herein, and authorizing specific officers to act on behalf of the corporation in connection with this Agreement;

(g) A certificate of good standing showing that Borrower is in good standing under the laws of the state of its incorporation and certificates indicating that Borrower is qualified to transact business and is in good standing in

any other state in which the conduct of its business or its ownership of property requires that it be so qualified, and a copy of Borrower's articles or certificates of incorporation and its bylaws;

(h) Borrower shall have delivered to Lender any guaranties of the Obligations required by Lender, duly executed by the Guarantors and in a form that is acceptable to Lender in its sole discretion;

(i) If repayment of the Loan is secured by a security interest in Collateral, then Borrower shall have provided Lender with evidence satisfactory to Lender that Borrower has obtained insurance policies or binders, with such insurers and in such amounts as may be acceptable to Lender, covering the property comprising the Collateral and naming Lender as a loss payee on a lender's loss payable endorsement or co-insured on all applicable general liability and casualty policies;

(j) Borrower shall maintain a deposit account relationship with Lender held in a deposit account(s) maintained at lender;

(k) Lender shall have received any and all additional documents, instruments and certificates required pursuant to this Agreement, or otherwise deemed necessary and requested by Lender; and

(l) If required by Lender, Borrower shall have paid or reimbursed Lender for all attorneys' fees, filing fees, recording fees, insurance premiums and other costs associated with the preparation of the final Loan Documents, closing of the Loan and perfecting any liens granted to Lender to secure the Loan.

3.5 Repayment of Advances and not Exceeding the Maximum Credit Limit. Borrower shall repay all Advances together with interest thereon in accordance with the terms of the Note. Borrower agrees that at no time shall the outstanding principal balance owed on the Loan, as evidenced by the Note, exceed the Maximum Credit Limit, and before the Maximum Credit Limit decreases as provided in Section 3.1 above Borrower shall pay down the outstanding principal balance owed on the Loan as needed to ensure the outstanding principal balance owed on the Loan is equal to or less than the decreased Maximum Credit Limit.

3.6 Co-Borrowers. All references in this Agreement to "Borrower" include all co-borrowers executing this Agreement (*e.g.*, PVHDHC and PVHD), and each such Borrower is jointly and severally liable for: the repayment of the Loan, the Obligations, and the performance of all other obligations and responsibilities of Borrower under this Agreement and the Loan Documents.

ARTICLE IV: CONTINUING REPRESENTATIONS AND WARRANTIES.

Borrower represents and warrants to Lender as follows, each such representation and warranty to continue so long as any Obligations remain unpaid:

4.1 Corporate Warranties.

(a) Borrower is a duly organized, validly existing corporation and in good standing under the laws of the State of California;

(b) Borrower is duly qualified and in good standing as a foreign corporation in each state where any of the Collateral is located, or the failure to so qualify will not have a material adverse effect upon the business or financial condition of Borrower, its rights or duties hereunder, or its ability to comply with or enforce any lease or finance contract; and

(c) Borrower has the corporate power and authority to execute and deliver this Agreement to Lender and to perform its Obligations in connection with this Agreement and such of the Loan Documents under which Borrower has Obligations.

4.2 General Warranties.

(a) Authority to Borrower. The execution, delivery and performance of this Agreement by Borrower does not violate any agreement to which Borrower is a party or by which Borrower or Borrower's property is or may be bound, and no consent of, notice to, approval of or withholding of objection by any person or organization, including any governmental agency, is required in connection with such execution, delivery and performance.

(b) Enforceability. This Agreement constitutes a legally valid and binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as limited by applicable bankruptcy, insolvency, or reorganization or similar laws affecting the enforcement of creditors' rights generally.

(c) Relocation of Chief Executive Office. The chief executive office of Borrower is at the address indicated in the first paragraph of this Agreement and Borrower covenants and agrees that it will not, without thirty (30) days prior written notification to Lender, relocate such chief executive office.

(d) Due Authorization. Borrower has the right and power and is duly authorized to enter into each of the Loan Documents to which it is a party.

(e) Compliance with Governance Documents. The execution by Borrower of each of the Loan Documents to which it is a party shall not constitute a breach of any provision contained in Borrower's articles of incorporation, bylaws, operating agreement, partnership agreement, and/or certificate filed with the California Secretary of State (as applicable), nor does it constitute an Event of Default under any material agreement to which Borrower is now or may hereafter become a party.

(f) Litigation. There are no actions or proceedings pending by or against Borrower or any Guarantor before any court or administrative agency and Borrower has no knowledge or belief of any pending, threatened, or imminent litigation, governmental investigations, or claims, complaints, actions, or prosecutions involving Borrower, except for ongoing collection matters in which Borrower is the plaintiff. If any of the foregoing arise during the term of this Agreement, Borrower shall promptly notify Lender in writing.

(g) No Material Adverse Change in Financial Statements. All Financial Statements which have been or may hereafter be delivered by Borrower to Lender are, in all material respects, accurate and correct, and have been prepared in accordance with GAAP and fairly present Borrower's financial condition as of the date thereof. There has been no material adverse change in the financial condition of Borrower since the date of the most recent Financial Statements submitted to Lender. No liabilities of Borrower, contingent or otherwise, exist which are not shown on the Financial Statements.

(h) Solvency. Borrower is now and shall be at all times hereafter solvent and able to pay its debts (including trade debts) as they mature.

(i) Environmental Condition. None of Borrower's properties or assets have ever been used by Borrower or, to the best of Borrower's knowledge, by previous owners or operators in the disposal of, or to produce, store, handle, treat, release, or transport any hazardous waste or hazardous substance or toxic substance as defined and regulated by federal and state laws. None of Borrower's properties or assets have ever been designated or identified in any manner pursuant to any environmental protection statute as a hazardous waste or hazardous substance disposal site, or a candidate for closure pursuant to any environmental protection statute. No lien arising under any environmental protection statute has attached to any revenues or to any real or personal property owned by Borrower. Borrower has not received a summons, citation, notice, or directive from the Environmental Protection Agency or any other federal or state governmental agency concerning any action or omission by Borrower resulting in the releasing, or otherwise disposing of, hazardous waste or hazardous substances into the environment.

(j) Compliance with Business Laws. If Borrower conducts business under a fictitious name or trade style, Borrower has complied with all applicable laws regulating the conduct of business affairs under a fictitious name or trade style, including, without limitation, any law requiring the filing of fictitious name statements.

(k) Taxes. Borrower is not delinquent (to the extent applicable) in the payment of any federal, state, or local taxes, including, without limitation, any sales, use or personal property taxes.

(l) Securities. None of the proceeds of any Advance will be used directly or indirectly for the purpose of purchasing or carrying, within the meaning of Regulation U of the Board of Governors of the Federal Reserve System, as amended from time to time, any "Margin Stock" as defined in said Regulation.

4.3 Reliance by Lender; Cumulative. Each warranty, representation, and agreement contained in this Agreement shall be automatically deemed repeated with each Advance and shall be conclusively presumed to have been relied on by Lender regardless of any investigation made or information possessed by Lender. The warranties, representations, and agreements set forth in this Agreement shall be cumulative and in addition to any and all other warranties, representations, and agreements which Borrower shall now or hereafter give, or cause to be given, to Lender.

ARTICLE V: AFFIRMATIVE COVENANTS.

Borrower covenants and agrees that, so long as any credit hereunder shall be available and until payment in full of the Obligations, and unless Lender shall otherwise consent in writing, Borrower shall do all of the following:

5.1 Preservation of Existence and Assets. Borrower shall maintain and preserve its existence and assets and all rights, franchises and other authority necessary for the conduct of its business. Borrower shall not change its name, identity or business organization without prior written notice to Lender. Borrower shall maintain and preserve its properties, equipment and facilities in good order, condition and repair. Lender may, at reasonable times, visit and inspect any of the properties of Borrower.

5.2 Taxes, Assessments and Other Charges. Borrower shall duly and promptly pay and discharge, as the same become due and payable, all of the following (as applicable): taxes, assessments, and governmental and other charges, levies or claims levied or imposed, or which if unpaid might become a lien or charge, upon the properties, assets, earnings or business of Borrower, except such as are being diligently contested in good faith and by appropriate provisions approved by Lender have been established by Borrower to pay and discharge same upon resolution of any dispute. If Borrower fails to pay any such tax, assessment, charge, levy or claim, Lender may, in its sole and absolute discretion and without notice to Borrower, make payment of the same or any part thereof as Lender deems necessary to satisfy the liability therefor in which case Borrower agrees to immediately reimburse Lender in full for same. Lender may conclusively rely on the usual statements of the amount owing or other official statements issued by the appropriate governmental agency.

5.3 Payment of Obligations. Borrower shall pay all of its liabilities and obligations when due and prior to the date on which penalties attach thereto and will keep all existing debts current.

5.4 Deposit Account Relationship. Borrower shall maintain a deposit account relationship with Lender held in a deposit account(s) maintained at lender;

5.5 Compliance With Laws. Borrower shall comply with all federal and state laws, statutes and regulations affecting the ownership of its property and the conduct of its business.

5.6 Accounting System. Borrower at all times hereafter shall maintain a standard and modern system of accounting in accordance with GAAP, with ledger and account cards or computer tapes, disks, printouts, and records pertaining to the Collateral which contain information as may from time to time be requested by Lender.

5.7 Records. Borrower shall keep full and accurate accounts and records of its operations according to GAAP.

5.8 Audit. Borrower shall permit Lender, its employees or agents upon request to inspect and test Borrower's books and records for the purpose of verifying the accuracy of all information required under the terms of this Agreement or submitted pursuant to this Agreement. Pursuant to this Section, Borrower shall grant Lender complete access (including computer access) to all records in whatever form, including accounts, bank statements, agings, delinquency reports, collection reports and litigation reports, whether in hard form or on software.

5.9 Insurance. Borrower shall keep all its insurable property, including all Collateral, real, personal or mixed, insured against fire and such other risks as are customarily insured against with respect to like properties by companies conducting similar businesses, and Borrower shall maintain adequate workers' compensation insurance and adequate insurance against liability for damage to persons or property that shall not be materially modified or canceled without at least five days prior notice to Lender from the insurance carrier. All such insurance policies shall be in amounts and with carriers acceptable to Lender, and shall (except those of workers' compensation, public liability and property damage) name Lender as loss payee and additional insured, as appropriate. Borrower shall provide Lender with copies of all insurance policies obtained by Borrower.

5.10 Notice of Certain Events. Borrower shall give prompt written notice to Lender of the following: (i) all events of default under any of the terms or provisions of this Agreement or any other agreement entered into by Borrower; (ii) material changes in management of Borrower; (iii) litigation, arbitration, or filing of any judgment or lien with Borrower as a party; (iv) initiation of any bankruptcy proceeding with regard to Borrower; and (v) any other matter which has resulted in, or might reasonably be expected to result in, a material adverse change in Borrower's financial condition or operations.

5.11 Execution of Other Documents. Borrower shall promptly execute and deliver all supplements and amendments hereto, and all financing statements, fixture filings, continuation statements and such additional agreements, instruments and assurances in connection with this Agreement as Lender reasonably requests to effectuate the provisions hereof.

5.12 Borrowings and Prepayments. Borrower shall obtain Lender's prior written consent, which consent shall not be unreasonably withheld, to sell or discount any chattel paper, receivable or evidence of indebtedness, or to incur, whether directly or indirectly, any liability for borrowed money, or to prepay any indebtedness owed to any third party, including its executives, directors or officers. Nothing herein shall prohibit Borrower from being obligated to its vendors and suppliers under ordinary credit terms. If, at any time, Lender determines that it is necessary or advisable to obtain an intercreditor agreement from one or more third party creditors of Borrower, Borrower shall cooperate with Lender and use its best efforts to assist Lender in procuring such intercreditor agreement.

5.13 Asset Forfeiture. Borrower covenants and agrees that it has not committed and shall not commit any act or engage in any conduct which shall cause the Collateral or any assets of Borrower to be subject to any claim by the federal, state or local government, now or in the future, under the asset forfeiture laws or regulations promulgated thereunder and as may be amended from time to time.

5.14 Environmental Due Diligence. Borrower shall maintain all of its assets, including, without limitation, the Collateral in good operable condition free of any form of contamination by hazardous substances as defined by 42 USC 9601 et seq., the California Health and Safety Code, and other federal, state and municipal laws and regulations. Borrower shall maintain all real and personal property in its possession in compliance with federal and state law and the rules and regulations promulgated thereunder by federal, state and municipal regulatory agencies, and shall obtain all the required permits and audits required by any government agency which governs Borrower or Borrower's assets or business activities.

5.15 Environmental Audit. In the event that Borrower pledges personal property collateral or Borrower's business is engaged in the manufacture, transportation or storage of a hazardous substance as defined in federal, state or municipal regulation, Borrower shall provide Lender, at Borrower's expense, with a complete environmental audit by an environmental consulting company acceptable to Lender, based on criteria acceptable to Lender, which audit provides an unqualified opinion that the personal property or business which is subject to the audit is in compliance with all pertinent federal, state and municipal regulations.

5.16 Financial Statement(s), Reports, Certificates.

(a) Within one hundred twenty (120) days after the close of each fiscal year of Borrower, a copy of Borrower's audited consolidated financial statements prepared by a Certified Public Accountant and consisting of, at a minimum, a balance sheet, statement of income and expenses, and a cash flow statement;

(b) Within forty five (45) days after each quarter of each fiscal year of Borrower, Borrower shall deliver to Lender the following as prepared by Borrower and in a form acceptable to Lender in its sole discretion: (i) balance sheet; (ii) profit and loss statement; and (iii) comparison of Borrower's Perormance Plan to actual performance during the quarter in question.

(c) If Borrower or PVHD file a federal income tax return with the Internal Revenue Service (if applicable), then within one hundred twenty (120) days after the filing Borrower shall provide Lender with a copy of the signed tax return filed with the Internal Revenue Service as filed by Borrower or PVHD (as applicable).

(d) As soon as available, but in any event no later than thirty (30) days after the end of each fiscal year of Borrower, a copy of Borrower's board-approved annual budget;

(e) Borrower shall deliver to Lender other reports reasonably requested by Lender relating to the Collateral and the financial condition of Borrower.

(f) Borrower shall deliver to Lender a certificate signed by the chief financial officer of Borrower or PVHD (as applicable) to the effect that all reports, statements, or computer-prepared information of any kind or nature delivered or caused to be delivered to Lender under this Agreement are accurate, true and fairly present the financial condition of Borrower or PVHD (as applicable) and that there exists, on the date of delivery of such certificate to Lender, no condition or event which constitutes an Event of Default.

5.17 Guarantor Reports. Borrower agrees to cause any Guarantor of any of Borrower's obligations hereunder to deliver its annual financial statements and copies of all federal income tax returns as soon as the same are available.

5.18 Taxes. All assessments and taxes (if applicable), whether real, personal, or otherwise, due or payable by, or imposed, levied, or assessed against Borrower or any of its property, shall be paid in full before delinquency or before the expiration of any extension period.

5.19 Financial Covenants. Borrower shall maintain a Net Income for each year that is no more than twenty percent (20%) less than the forecasted Net Income for the same year provided in Borrower's Performance Plan. The calculations for the foregoing shall be based on a rolling four (4) quarters beginning January 1, 2023, and Borrower shall satisfy this convenant each quarter of each calendar year.

5.20 Lender Expense. Borrower shall immediately and without demand reimburse Lender for all sums expended by Lender which constitute Lender Expenses, and Borrower hereby authorizes and approves all Advances and payments by Lender for items constituting Lender Expenses.

5.21 Other Agreements. Borrower agrees to comply with all terms and conditions of all other agreements in effect during the term of this Agreement and between Borrower and any other party, and to immediately notify Lender in writing of any default in connection with any other such agreements.

5.22 Loan Proceeds. Unless Lender consents in writing, Borrower agrees to use all Loan proceeds solely for Borrower's business operations.

5.23 Operations. Borrower agrees to: (i) maintain management personnel with substantially the same qualifications and experience as the management personnel of Borrower as of the date of this Agreement; (ii) upon any change in

management personnel immediately provide written notice to Lender identifying the management personnel and certifying that the new management personnel have the same qualifications and experience as desceribed in clause (i) above; and (iii) conduct the business affairs in a reasonable and prudent manner.

ARTICLE VI: NEGATIVE COVENANTS.

Borrower covenants and agrees that, so long as any credit hereunder shall be available and until payment in full of the Obligations, Borrower will not do any of the following without Lender's prior consent:

6.1 Encumbrances and Liens. Sell, lease, transfer, exchange or otherwise dispose of any of the Collateral, nor create, assume or suffer to exist any mortgage, pledge, security interest, charge, encumbrance or lien (other than for taxes not delinquent and for taxes and other items being contested in good faith) on any of the Collateral other than the sale of inventory in the ordinary and usual course of Borrower's business as presently conducted.

6.2 Liquidation and Reorganization. Liquidate, dissolve or enter into any consolidation, merger or other combination in which its separate identity shall cease, nor convey, sell, lease, transfer or assign to any party all or any part of its assets or business, including, without limitation, any of its operating rights, licenses or franchises, except in the ordinary course of its business.

6.3 Dispose of Assets. Sell, lease, or otherwise dispose of, move, relocate, or transfer, whether by sale or otherwise, any of Borrower's assets other than sales of inventory in the ordinary and usual course of Borrower's business as presently conducted.

6.4 Merge, Acquire. Acquire, merge, or consolidate with or into any other business organization or change Borrower's business structure name or identity.

6.5 Extraordinary Transactions. Make any guaranty or loans, borrow any money, transfer assets, incur any debts or enter into any transaction, except in the ordinary course of business.

6.6 Guaranty. Guaranty or otherwise become in any way liable with respect to the obligations of any third party, except by endorsement of instruments or items of payment for deposit to the account of Borrower or which are transmitted or turned over to Lender.

6.7 Restructure. Make any change in Borrower's financial structure or in any of its business operations.

6.8 Prepayments. Prepay any existing indebtedness owing to any third party.

6.9 Change of Ownership. Cause, permit, or suffer any change, direct or indirect, in Borrower's capital ownership in excess of ten percent (10%).

6.10 Capital Expenditures. Make any plant or fixed capital expenditure, or any commitment therefor, or purchase or lease any real or personal property or replacement equipment subject to a purchase money security interest, deed of trust or lease, in any fiscal year, in excess of Borrower's annual allocation to depreciation reserves computed in accordance with GAAP.

6.11 Distributions. Make any distribution or declare or pay any dividends (in cash or in stock) on, or purchase, acquire, redeem, or retire any of Borrower's capital stock, of any class, whether now or hereafter outstanding.

6.12 Accounting Methods. Modify or change its method of accounting, storage and distribution of records. Borrower hereby waives the right to assert a confidential relationship, if any, it may have with any accounting firm or service bureau in connection with any information requested by Lender pursuant to or in accordance with this agreement, and agrees that Lender may contact directly any such accounting firm or service bureau in order to obtain such information.

6.13 Suspension. Suspend or go out of business.

6.14 Marijuana-related Business and Other Illegal Activites. Have ownership in, receive any funds from, be involved in the management of, be used for, and/or participate in: (i) any marijuana-related business or marijuana-related activities; or (ii) any other business or activities that are deemed illegal under federal or state laws or regulations.

6.15 Continuity of Operations. (i) Engage in any business activities that differ substantially from those in which Borrower is engaged as of the date of this Agreement; (ii) cease operations, transfer, merge, liquidate, acquire or consolidate with any other entity; (iii) change its name; or (iv) dissolve, transfer or sell Collateral, unless in the ordinary course of Borrower's business.

ARTICLE VII: DEFAULT AND REMEDIES

7.1 Events of Default. Any one or more of the following events shall constitute an "Event of Default" by Borrower under this Agreement:

(a) Borrower fails to pay when due and payable, or when declared due and payable, any amounts payable under the Note (whether of principal, interest, late payment charge, prepayment premium, or otherwise) or other Loan Documents and such amount is not paid within ten (10) days after such amount is due and payable;

(b) Borrower fails or neglects to perform, or observe when due, any term, provision, condition, covenant, warranty or representation contained in this Agreement or in any Loan Documents, or in any other present or future agreement or arrangement between Borrower and Lender, and such default shall not have been cured within fifteen (15) business days after notice thereof is given to Borrower by Lender;

(c) There is a material impairment of the prospective of repayment of any portion of the amounts owing to Lender under the Loan Documents or a material impairment of the value or priority of Lender's security interests in any Collateral;

(d) Any material portion of Borrower's assets are attached, seized, subjected to a writ or distress warrant, or are levied upon, or come into the possession of any judicial officer, or any lien is filed or recorded against the assets of the Borrower by a governmental agency, or any judgment against the Borrower becomes a lien against any of the Borrower's assets;

(e) A voluntary or involuntary petition in bankruptcy or for reorganization or for an arrangement or any composition, readjustment, liquidation, dissolution or similar relief pursuant to the federal bankruptcy law or under similar present or future federal or state bankruptcy or insolvency law, is filed by or against Borrower, and such petition is not dismissed within sixty (60) days thereafter;

(f) A receiver, trustee or liquidator (or other similar official) is appointed for Borrower or for all or any substantial part of its assets, or of the Collateral or any portion thereof, and is not discharged within sixty (60) days thereafter;

(g) Borrower makes an assignment of all or any portion of its assets for the benefit of creditors;

(h) Borrower is enjoined, restrained, or in any way prevented by court order from continuing to conduct all or any material part of its business affairs;

(i) There is a default in any material agreement to which Borrower is a party with third parties resulting in a right by such third parties to accelerate the maturity of Borrower's indebtedness;

(j) Any Guarantor of Borrower's obligations under the Loan Documents dies, terminates its guaranty, or becomes the subject of any insolvency proceeding;

(k) Any government agency files a lien or commences an action or any third party files a claim or lawsuit against Borrower in connection with a violation of state or federal environmental statutes, which claim may result in a substantial fine or penalty or the payment of damages;

(l) Any agency of the federal, state or local government commences any proceedings against Borrower or any Guarantor, or the assets of either, for the purpose of enforcing forfeiture rights as provided by federal or state law, or Borrower or any Guarantor is the subject of any investigation or any complaint or bill of indictment has been brought against any Borrower or any Guarantor in connection with conduct the penalty for which is forfeiture of all or any portion of Borrower's or Guarantor's assets;

(m) Borrower suspends its business or ceases doing business as a going concern; and

(n) Any of the foregoing events occur with respect to any Guarantor of Borrower's obligations under the Loan Documents.

7.2 Lender's Rights And Remedies. Upon the occurrence of an Event of Default (or any Guarantor's default under the terms of the Guarantor's guaranty), Lender may, at its election, without notice of its election and without demand, do any one or more of the following, all of which are authorized by Borrower:

(a) Terminate Lender's obligation to make Advances to Borrower hereunder;

(b) Declare all of Borrower's obligations to Lender immediately due and payable, whether evidenced by the Note, by any of the other (collectively "Loan Documents") or otherwise; and

(c) Exercise all other rights and remedies available to Lender under the Loan Documents, at law or in equity.

7.3 Remedies Cumulative. Lender's rights and remedies under this Note, the Loan Documents, and all other agreements shall be cumulative. Lender shall have all other rights and remedies not inconsistent herewith as provided under the UCC, by law, or in equity. No exercise by Lender of one right or remedy shall be deemed an election, and no waiver by Lender of any Event of Default on Borrower's part shall be deemed a continuing waiver. No delay by Lender shall constitute a waiver, election, or acquiescence by it.

ARTICLE VIII: GENERAL PROVISIONS

8.1 Time of the Essence. Time is hereby declared to be of the essence of this Agreement and of every part hereof.

8.2 Notices. Except as otherwise provided herein, any notice or other communication required to be given in writing shall be personally served by messenger, or sent by a commercial overnight delivery service (such as Federal Express), or by certified mail, return receipt requested, and shall be deemed given on the date actually received if served by messenger, or on the next business day after deposit with an overnight delivery service, or on the date of receipt as shown on the return receipt if sent by certified mail. The addresses of the parties to which notices and other communications shall be sent (until notice of a change thereof is served as provided herein) are set forth on the first page of this Agreement. Any party to this Agreement may change its address for giving notices or demands hereunder by written notice of such change to the other party in accordance with the provisions hereof. Borrower shall promptly notify Lender of any change of its principal place of business or mailing address in the manner prescribed by this paragraph.

8.3 Entire Agreement; Amendment. This Agreement and any agreements, instruments or documents referred to herein constitute the entire agreement among the parties hereto regarding the subject matter hereof, and all prior and/or contemporaneous communications, verbal or written, between or among the parties hereto regarding the subject matter hereof shall be of no further effect or evidentiary value. This Agreement can be amended only by a written agreement executed by duly authorized representatives of the parties hereto.

8.4 Construction of Agreement. Neither this Agreement nor any uncertainty or ambiguity herein shall be construed or resolved against any party hereto, whether under any rule of construction or otherwise. On the contrary, this Agreement has been reviewed by all parties and shall be construed and interpreted according to the ordinary meaning of the words used so as to fairly accomplish the purposes and intentions of the parties hereto.

8.5 Waivers.

(a) Demand; Protest, etc. Borrower waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension or renewal of any commercial paper, accounts, documents, instruments, chattel paper, and guarantees at any time held by Lender on which Borrower may in any way be liable.

(b) Jury Trial. Unless prohibited under the laws that govern an action or proceeding relating to this Agreement or related agreements entered into in connection herewith, Borrower and Lender each waive any right to trial by jury in any action or proceeding relating to this Agreement or any of the agreements entered into in connection herewith.

8.6 Choice of Law and Venue. The validity of this Agreement, its construction, interpretation, and enforcement, and the rights of the parties hereunder and concerning the Collateral, shall be determined under, governed by, and construed in accordance with the laws of the State of California. The parties agree that all actions or proceedings arising in connection with this Agreement shall be tried and litigated only in the state and federal courts located in Santa Cruz County, State of California. Borrower waives any right it may have to assert the doctrine of *forum non conveniens* or to object to such venue and hereby consents to any court ordered relief.

8.7 Destruction of Borrower's Documents. Any documents, schedules, invoices, aging, or other papers delivered to Lender may be destroyed or otherwise disposed of by Lender four (4) months after they are delivered to or received by Lender, unless Borrower does request, in writing, the return of the said documents, schedules, invoices or other papers and makes arrangements, at Borrower's expense, for their return.

8.8 Rights and Remedies Cumulative. Lender's rights, powers and remedies under this Agreement, and all other related agreements and instruments, shall be cumulative and not alternative, and shall be in addition to all rights, powers and remedies given to Lender under the UCC, other applicable law and in equity.

8.9 No Third Party Beneficiaries. Neither this Agreement nor any agreement or instrument required in connection herewith is intended, or shall be deemed, to create or grant any rights in favor of any third party. Nor may such third party claim any benefit of or from any warranty, representation, covenant, agreement, right, power or remedy made or granted hereunder, which benefits are reserved solely for the parties hereto.

8.10 Non-Waiver. Any forbearance or failure or delay by Lender in exercising any right, power or remedy hereunder shall not be deemed a waiver thereof, and any single or partial exercise of any right, power or remedy shall not preclude the further exercise thereof. No exercise by Lender of one right, power or remedy shall be deemed an election, and no waiver by Lender of any default on Borrower's part shall be deemed a continuing waiver.

8.11 Exhibits. All of the exhibits attached to this Agreement shall be deemed incorporated herein by reference.

8.12 Severability. Each provision of this Agreement shall be severable from every other provision of this Agreement for the purpose of determining the legal enforceability of any specific provision.

8.13 Headings. All section headings and section numbers have been set forth herein for convenience of reference only, and shall not limit or affect the meaning or interpretation of any section hereof.

8.14 Successors and Assigns. This Agreement shall bind and inure to the benefit of the respective successors and assigns of each of the parties.

8.15 Counterpart Execution. This Agreement may be executed in several counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same Agreement.

8.16 Attorneys' Fees. In the event any party to this Agreement shall be required to commence any action or proceeding against any other party by reason of any breach or claimed breach of any provision of this Agreement, to commence any action in any way connected with this Agreement, or to seek a judicial declaration of rights under this Agreement, the party prevailing in such action or proceeding shall be entitled to recover from the other party, or parties, the prevailing party's reasonable attorneys' fees and costs including, without limitation, all witness fees and associated expenses, including matters on appeal whether or not the proceeding or action proceeds to judgment.

8.17 Consent to Loan Participations. Borrower agrees and consents to, with or without notice from Lender, Lender selling or transfering (at any time) the whole Loan or one or more participation interests in the Loan to one or more other party, whether such party is related or unrelated to Lender ("Purchaser"). Borrower agrees that Lender may provide, without any limitation, any Purchaser and those considering whether to become a Purchaser any information or documents Lender may have with regard to Borrower, Borrower's business, the Collateral and the Loan (including, without limitation, information about Borrower's performance of obligations under the Loan Documents). Additionally, Borrower agrees that Purchasers shall have absolute ownership interest in the participation interests aquired by Purchaser. Borrower waives all rights of offset or counterclaim that it may now or later enforce against Lender or any Purchaser and agrees unconditionally that either Lender or Purchaser (as applicable) may enforce Borrower's obligation under the Loan irrespective of the failure or insolvency of any interest in the Loan and that the Purchaser may enforce its interest irrespective of any personal claims or defenses that Borrower may have against Lender.

[*Remainder of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, this Agreement is executed on behalf of each party by its duly authorized representative(s) on the date(s) indicated below and effective as of the date set forth above.

DATE: November 1, 2023	**DATE: November 1, 2023**
BORROWER: **PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION**, a California nonprofit public benefit corporation By_____ Name_____ Title_____ **PAJARO VALLEY HEALTHCARE DISTRICT**, a California nonprofit public benefit corporation By_____ Name_____ Title_____	**LENDER:** **SANTA CRUZ COUNTY BANK**, a California state-chartered Bank By_____ Name_____ Title_____

EXHIBIT A

LIST OF AUTHORIZED OFFICERS

Santa Cruz County Bank
PO Box 8426
Santa Cruz, CA 95061
Attn: Note Department

Re: Loan No. 900550560

To Santa Cruz County Bank:

Any _____ (_____) of the following persons are hereby authorized by PAJARO VALLEY HEALTHCARE DISTRICT HOSPITAL CORPORATION, a California corporation ("Borrower") to execute requests for disbursements of funds (*i.e.*, Advances as described in the Business Loan Agreement) under the above-described loan:

AUTHORIZED OFFICER:

Signature _____
Print Name _____
Title _____

AUTHORIZED OFFICER:

Signature _____
Print Name _____
Title _____

AUTHORIZED OFFICER:

Signature _____
Print Name _____
Title _____

AUTHORIZED OFFICER:

Signature _____
Print Name _____
Title _____

Date: November 1, 2023

BORROWER:

PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION, a California nonprofit public benefit corporation

By _____
Name _____
Title _____

PAJARO VALLEY HEALTHCARE DISTRICT, a California nonprofit public benefit corporation

By _____
Name _____
Title _____

PROMISSORY NOTE
(Revolving Line of Credit)

U.S. $5,000,000.00 November 1, 2023
Loan No.: 900550560

1. **BORROWER'S PROMISE TO PAY**. For value received, the undersigned **PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION**, a California nonprofit public benefit corporation ("PVHDHC"), with a chief executive office located at 75 Nielson Street, Watsonville, CA 95076, and **PAJARO VALLEY HEALTHCARE DISTRICT**, a California nonprofit public benefit corporation ("PVHD"), with a chief executive office located at 75 Nielson Street, Watsonville, CA 95076 (PVHDHC and PVHD are together referred to herein as "Borrower"), promises to pay to the order of **SANTA CRUZ COUNTY BANK**, a California state-chartered bank ("Lender") with an address at P.O. Box 8426, Santa Cruz, CA 95061, or such other place as Lender from time to time may designate, in accordance with the terms of this Note the initial maximum principal sum of **FIVE MILLION DOLLARS** (**$5,000,000.00**) (which shall decrease over time as provided below) or so much thereof as may be borrowed or re-borrowed from time to time, together with interest on unpaid principal from the disbursement date at the "Interest Rate" (as defined below), with principal and interest payable as provided below in lawful money of the United States.

2. **MAXIMUM CREDIT LIMIT**. The maximum credit limit (*i.e.*, the maximum principal balance that may be outstanding at any time) for the loan evidence by this Note shall be as follows (the "Maximum Credit Limit"): (i) Five Million Dollars ($5,000,000.00) during the first year after the date of this Note; (ii) Four Million Dollars ($4,000,000.00) beginning one (1) year after the date of this Note; and (iii) Three Million Dollars ($3,000,000.00) beginning two (2) years after the date of this Note. At no time shall the outstanding principal balance owed on the loan evidenced by this Note exceed the Maximum Credit Limit, and before the Maximum Credit Limit decreases as provided above Borrower shall pay down the outstanding principal balance owed on the loan as needed to ensure the outstanding principal balance owed on the loan is equal to or less than the decreased Maximum Credit Limit.

3. **CO-BORROWERS**. All references in this Note to "Borrower" include all co-borrowers executing this Note (*e.g.*, PVHDHC and PVHD), and each such Borrower is jointly and severally liable for: the repayment of the loan evidenced by this Note, all amounts owed under this Note and all other related loan documents, and the performance of all other obligations and responsibilities of Borrower under this Note and the other related loan documents.

4. **PAYMENT OF PRINCIPAL AND INTEREST.** Principal and interest shall be payable in accordance with the following provisions:

4.1 **Monthly Payment of Interest**. Beginning on December 5, 2023, and on the fifth day of each calendar month thereafter during the term of the loan evidenced by this Note, Borrower shall pay to Lender all accrued but unpaid interest on the outstanding principal balance due under this Note with the interest calculated at the Interest Rate.

4.2 **Calculation of Interest**. The interest rate used to calculate interest payable hereunder ("Interest Rate") shall equal one percent (1%) (the "Margin") plus the rate from time to time published in the "Money Rates" section of the Wall Street Journal and referred to therein as the "Prime Rate" ("Index"). In no event shall the Interest Rate exceed the maximum lawful rate enforceable in the jurisdiction where the loan evidenced by this Note is consummated. In the event collection from Borrower of interest at the Interest Rate would be contrary to applicable law, then the Interest Rate in effect on any day shall be the highest rate which may be collected from Borrower under applicable law. In

the event that changes in the Index are announced, from time to time hereafter, adjustment in the Interest Rate shall be made as of the date of any such change in the Index, provided that changes in the Interest Rate shall not occur more often than once each calendar day. Interest on this Note is computed on a 365/360 basis; that is, by applying the ratio of the interest rate over a year of 360 days, multiplied by the outstanding principal balance, multiplied by the actual number of days the principal balance is outstanding. All interest payable under this Note is computed using this method. If Lender at any time determines in its sole discretion that for any reason the applicable index (including, without limitation, the "Prime Rate" referenced above) cannot be adequately ascertained or is otherwise unavailable or unreliable, or if Lender can no longer offer the Index for legal reasons, then Lender may replace such index with another index or benchmark selected by Lender in its sole discretion ("Replacement Index"), and the Lender may also adjust the Margin to an amount selected by Lender in its sole discretion ("Adjusted Margin") so that the Replacement Index when added to the Adjusted Margin will perform more similarly to the corresponding index being replaced when added to the original Margin provided in this Section.

4.3 **Payment at Maturity**. Any unpaid principal payable under this Note, together with all accrued but unpaid interest under this Note shall be due and payable on the earliest of (i) the acceleration of the principal amount of this Loan pursuant to the terms of this Note, that certain Business Loan Agreement of even date herewith and executed by Borrower and Lender ("Loan Agreement"); or (ii) November 5, 2026 (the earlier of such dates being the "Maturity Date"). BORROWER ACKNOWLEDGES THAT LENDER IS UNDER NO OBLIGATION TO REFINANCE THE LOAN EVIDENCED BY THIS NOTE AT MATURITY.

4.4 **Application of Payments**. Unless applicable law provides otherwise, all payments received by Lender from Borrower under this Note, whether by wire transfer of funds, check, or other item of payment shall be applied in such manner and order of priority as Lender shall determine in Lender's sole discretion. Until otherwise agreed, or if required by applicable law, payments received by Lender under this Note will be applied and credited first to pay any accrued but unpaid interest due under this Note, second to reduce any outstanding principal balance due under this Note, and third to any late payment charges or fees due under the this Note.

4.5 **Prepayment**. This Note may be prepaid in whole or in part at any time. Early payments will not, unless agreed to by Lender in writing, relieve Borrower of Borrower's obligation to continue to make payments of accrued unpaid interest. Rather, early payments will reduce the principal balance due. Borrower agrees not to send Lender payments marked "paid in full", "without recourse", or similar language. If Borrower sends such a payment, Lender may accept it without losing any of Lender's rights under this Note, and Borrower will remain obligated to pay any further amount owed to Lender. All written communications concerning disputed amounts, including any check or other payment instrument that indicates that the payment constitutes "payment in full" of the amount owed or that is tendered with other conditions or limitations or as full satisfaction of a disputed amount must be mailed or delivered to Lender at its address provided in Section 1 of this Note (unless Lender provided Borrower another address to use for such purposes in which case such address should be used).

5. **REVOLVING LINE OF CREDIT**. This Note evidences a revolving line of credit. Advances under this Note, as well as directions for payment from Borrower's accounts, may be requested orally or in writing by Borrower or any person authorized in writing to do so by Borrower. Lender may, but need not, require that all oral requests be confirmed in writing. Borrower agrees to be liable for all sums either: (A) advanced in accordance with Borrower's or Borrower's authorized representative's instructions; or (B) credited to any of Borrower's accounts with Lender. The unpaid principal balance owing on this Note at any time will be evidenced by Lender's internal records.

6. **DEFAULT**. If any sum payable by Borrower under this Note is not paid within ten (10) days after the date on which the payment is due (irrespective of whether Borrower has received any notice of such nonpayment) or if Borrower fails to perform fully and when due any other covenant or obligation of Borrower under this Note or the Loan Agreement and if Borrower fails to cure such default within the time frame for cure set forth in the Loan Agreement, then Borrower shall be in default hereunder and Lender may elect, without any further notice or demand to Borrower, to declare all principal and accrued but unpaid interest under this Note immediately due and payable. Any failure of Lender to make such election following a default or defaults shall not constitute a waiver of Lender's right to make the election in the event of any subsequent default.

7. **DEFAULT INTEREST.** Notwithstanding any provision in this Note to the contrary, upon the maturity of this Note, whether the scheduled maturity date or due to this loan being accelerated by Lender because of a default under this Note, the interest rate on this Note shall immediately increase by five percentage points ("Default Rate Margin"). However, in no event will the interest rate applied under this paragraph exceed the maximum interest rate permitted under applicable law. The Default Rate Margin shall also apply to each succeeding interest rate change that would have applied had there been no default.

8. **LATE PAYMENT CHARGE**. If any payment under this Note (whether of principal or interest or both and including the payment due on the Maturity Date or upon any acceleration of this Note) is not paid within ten (10) days after the date on which the payment is due, Borrower shall pay to Lender, in addition to the delinquent payment and without any requirement of notice or demand by Lender, a late payment charge equal to at the rate which is the sum of 5% of the amount of the regularly scheduled payment or $5.00, whichever is greater. Borrower expressly acknowledges and agrees that the foregoing late payment charge provision is reasonable under the circumstances existing on the date of this Note, that it would be extremely difficult and impractical to fix Lender's actual damages arising out of any late payment and that the foregoing late payment charge shall be presumed to be the actual amount of such damages incurred by Lender. No provision in this Note (including without limitation the provisions for a late payment charge and for interest on any amounts remaining unpaid after the Maturity Date) shall be construed as in any way excusing Borrower from its obligation to make each payment under this Note promptly when due.

9. **COSTS OF COLLECTION**. If either Lender or Borrower commences any legal action to enforce or interpret this Note or any provision hereof, the prevailing party shall be entitled to recover its attorneys' and experts' fees in addition to all other relief awarded by the court. Subject to the preceding sentence, Borrower and all endorsers jointly and severally promise to pay (a) all costs and expenses of collection, including without limitation attorneys' fees, in the event this Note or any portion of this Note is placed in the hands of attorneys for collection and such collection is effected without suit; (b) attorneys' fees, as determined by the court, and all other costs, expenses and fees incurred by Lender in the event suit is instituted to collect this Note or any portion of this Note; and (c) all costs and expenses, including without limitation attorneys' fees, incurred by Lender in connection with any bankruptcy, insolvency or reorganization proceeding or receivership involving Borrower or any affiliate of Borrower, including without limitation attorneys' fees incurred in making any appearances in any such proceeding or in seeking relief from any stay or injunction issued in or arising out of any such proceeding.

10. **OFFSETS**. No indebtedness evidenced by this Note shall be deemed to have been offset or shall be offset or compensated by all or part of any claim, cause of action, counterclaim or cross-claim, whether liquidated or unliquidated, which Borrower now or hereafter may have or may claim to have against Lender. Furthermore, in respect to the present indebtedness of, or any future indebtedness incurred by, Borrower to Lender, Borrower waives, to the fullest extent permitted by law, the benefits of any applicable law, regulation, or procedure which substantially provides that, where cross-demands for money have existed between persons at any point in time when neither demand was barred by the applicable statute of limitations, and an action is thereafter commenced by one such person, the other may assert in his answer the defense of payment in that the two demands are compensated so far as they equal each other, notwithstanding that an independent action asserting the claim would at the time of filing the answer be

barred by the applicable statute of limitations.

11. **CERTAIN WAIVERS**. Borrower and all endorsers jointly and severally waive diligence, grace, demand, presentment for payment, exhibition of this Note, protest, notice of protest, notice of dishonor, notice of demand, notice of nonpayment, and any and all exemption rights against the indebtedness evidenced by this Note, and agree to any and all extensions or renewals from time to time without notice and to any partial payments of this Note made before or after maturity and that no such extension, renewal or partial payment shall release any one or all of them from the obligation of payment of this Note or any installment of this Note, and consent to offsets of any sums owed to any one or all of them by Lender at any time.

12. **LOSS, THEFT, DESTRUCTION OR MUTILATION OF NOTE**. In the event of the loss, theft or destruction of this Note, upon Borrower's receipt of a reasonably satisfactory indemnification agreement executed in favor of Borrower by the party who held this Note immediately prior to its loss, theft or destruction, or in the event of the mutilation of this Note, upon Lender's surrender to the Borrower of the mutilated Note, Borrower shall execute and deliver to such party or Lender, as the case may be, a new promissory note in form and content identical to this Note in lieu of the lost, stolen, destroyed or mutilated Note.

13. **OBLIGATIONS JOINT AND SEVERAL**. If Borrower consists of more than one person or entity, each shall be jointly and severally liable for the performance of each of the obligations of Borrower to Lender hereunder.

14. **EFFECTIVE DATE**. Notwithstanding the date on which this Note is actually signed by Borrower, the terms and conditions of this Note shall be applied, with full force and effect, as of the date of this Note provided above.

15. **CONSTRUCTION OF NOTE**. Captions in this Note are included solely for convenience and are not to be referred to in construing or interpreting this Note. Each reference in this Note to a particular paragraph is a reference to a paragraph of this Note unless otherwise expressly indicated. The terms "include," "includes" and "including" are not used in any limiting sense, but rather by way of example or illustration. If any portion of this Note is declared invalid, illegal or unenforceable by any court of competent jurisdiction, such portion shall be deemed severed from this Note and the remaining portions shall continue in full force and effect. Time is strictly of the essence of each and every provision of this Note. This Note shall be governed by and interpreted and enforced according to the laws of the State of Illinois.

[*Remainder of Page Intentionally Left Blank*]

PRIOR TO EXECUTING THIS NOTE, BORROWER READ AND UNDERSTOOD ALL OF THE PROVISIONS OF THIS NOTE, INCLUDING THE VARIABLE INTEREST RATE PROVISIONS. BORROWER AGREES TO THE TERMS OF THIS NOTE, AND ACKNOWLEDGES RECEIPT OF A COMPLETED COPY OF THIS NOTE.

DATE: November 1, 2023

BORROWER:

PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION, a California nonprofit public benefit corporation
By_____
Name_____
Title_____

PAJARO VALLEY HEALTHCARE DISTRICT, a California nonprofit public benefit corporation
By_____
Name_____
Title_____

COMMERCIAL GUARANTY
(Limited)

This Commercial Guaranty ("Guaranty") is entered into by and between **SANTA CRUZ COUNTY BANK**, a California state-chartered bank ("Lender"), and **COMMUNITY FOUNDATION SANTA CRUZ COUNTY**, a California nonprofit public benefit corporation ("Guarantor"), and is effective November 1, 2023 ("Effective Date").

In order to induce Lender to extend and/or to continue to extend financial accommodations to **PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION**, a California nonprofit public benefit corporation ("PVHDHC"), and **PAJARO VALLEY HEALTHCARE DISTRICT PROJECT**, a California nonprofit public benefit corporation ("PVHD") (PVHDHC and PVHD are together referred to herein as "Borrower"), pursuant to any present or future promissory note, or other present or future agreement between Lender and Borrower including any modifications, extensions, revisions or substitutions thereof including all other agreements entered into in connection with and for the purpose of executing any of the loan documents referenced herein, (collectively, "Loan Documents"), and in consideration thereof, and in consideration of any loans, advances, or financial accommodations granted by Lender to or for the account of Borrower pursuant to the Loan Documents, Guarantor hereby guarantees, promises and undertakes as follows:

1. OBLIGATION

Guarantor unconditionally, absolutely and irrevocably guarantees and promises to pay to Lender, or order, on demand, in lawful money of the United States, any and all present or future indebtedness and/or obligations of Borrower owing to Lender (including, but not limited to, the repayment to Lender of all sums which may be presently due and owing and of all sums which shall in the future become due and owing from Borrower) arising under the Loan Documents or other agreements, except as may be limited by Section 3 below and as otherwise provided herein. The terms "indebtedness" and "obligations" (hereinafter collectively referred to as the "Obligations") are used herein in their most comprehensive sense and include each of the following: (i) any and all advances, debts, obligations, and liabilities of Borrower arising under that certain promissory note dated November 1, 2023 and in the initial original principal amount of **FIVE MILLION DOLLARS** ($5,000,000.00) (the "Promissory Note") which principal amount decreases over time as provided in the Promissory Note, together with any amendments, extensions, modifications, renewals, replacement or substitutions thereto; (ii) the Loan Documents executed in connection with the Promissory Note, together with any amendments, extensions, modifications, renewals, replacement or substitutions to the Loan Documents; and (iii) further including, without limitation, any and all premiums, charges, and/or interest owed by Borrower to Lender, under the Promissory Note or other Loan Documents, whether due or not due, absolute or contingent, liquidated or unliquidated, determined or undetermined, whether Borrower may be liable individually or jointly with others, whether recovery upon such indebtedness may be or hereafter becomes barred by any statute of limitations or whether such indebtedness may be or hereafter becomes otherwise unenforceable, and includes Borrower's prompt, full and faithful performance, observance and discharge of each and every term, condition, agreement, representation, warranty, undertaking and provision to be performed by Borrower under the Loan Documents, and including any and all attorneys' fees and costs incurred by Lender directly or indirectly in connection with the collection of any amount owned by Borrower under the Loan Documents and/or incurred by Lender directly or indirectly in connection with enforcement of this Guaranty.

2. CONSIDERATION

This Guaranty is given for the purpose of guaranteeing the continued obligations of Borrower under the terms of the Loan Documents. Guarantor represents and warrants to Lender that Guarantor has a material interest and will benefit, directly or indirectly from, the loan made to Borrower and evidenced by the Promissory Note and Loan Documents (the "Loan"). If this Guaranty is not executed contemporaneously with the Loan Documents, then Guarantor has executed and delivered this Guaranty to Lender in consideration of the Loan.

3. GUARANTY LIMITS AND TERMINATION

The Obligations of Borrower are also guaranteed by: (i) County of Santa Cruz (the "County Guarnator"); and (ii) Salud Para La Gente, a California nonprofit public benefit corporation (the "Salud Guarnator"). Together the County Guarantor and Salud Guarantor are referred to herein as the "Other Guarantors" and each individually referred to as "Other Guarantor."

Gurantor's guarantee of the Obligations shall not exceed Three Million Dollars ($3 million) of the Obligations, and is further limited to the following amounts (the following amounts, which are not to exceed $3 million, are referred to herein as the "Guaranty Amount"): (i) sixty percent (60%) of all dollar amounts owed by

Borrower under the Loan Documents that were incurred during the first year following the date of the Promissory Note; (ii) fifty percent (50%) of all dollar amounts owed by Borrower under the Loan Documents that were incurred during the period beginning one (1) year after the date of the Promissory Note; and (iii) thirty three and 1/3 percent (33.333%) of all dollar amounts owed by Borrower under the Loan Documents that were incurred beginning two (2) years after the date of the Promissory Note. Notwithstanding the foregoing, if any Other Guarantor fails to pay a portion or all of the amounts that such Other Guarantor is required to pay under the guaranty executed by the Other Guarantor, then such occurance shall not reduce the amounts Guarantor is required to pay to Lender under this Guaranty. Additionally, Guarantor acknowledges, understands and agrees that, except as provided above, Lender's recourse against Guarantor, and Lender's rights and remedies under this Guaranty, are not limited (or otherwise affected) by the guaranties provided by the Other Guarantors.

Any termination of this Guaranty shall be applicable only to transactions having their inception after the effective date of termination and shall not affect any rights or Obligations arising out of transactions having their inception prior to such date even if subsequent to such termination the Obligations are modified, renewed, compromised, extended, or otherwise amended (including, but not limited to, an increase in the interest rate applicable to the Obligations). Any termination of this Guaranty shall only be effective upon actual receipt by Lender of a written notice of termination signed by Guarantor and shall be effective five (5) business days after the actual receipt by Lender of such notice of termination.

4. INDEPENDENT OBLIGATION

Guarantor agrees (i) that Guarantor is directly and primarily liable to Lender; (ii) that the obligations of Guarantor hereunder are separate and independent of the Obligations of Borrower, or of any other guarantor of Borrower's Obligations; and (iii) that Lender may file a separate action or actions at law against the Guarantor to enforce this Guaranty and may exercise any rights or remedies that Lender may have against collateral securing performance under the terms of this Guaranty.

5. INSOLVENCY OF GUARANTOR OR BORROWER

In the event that any bankruptcy, insolvency, receivership or similar proceeding is instituted by or against Guarantor and/or the Borrower or in the event that either the Guarantor or Borrower becomes insolvent, makes an assignment for the benefit of creditors, or attempts to effect a composition with creditors, at Lender's election, without notice or demand, the obligations of Guarantor created hereunder shall become due, payable and enforceable against Guarantor whether or not the Obligations are then due and payable.

6. WAIVERS

In consideration of the extension by Lender to Borrower of existing and future loans, credit facilities and other financial accommodations, Guarantor hereby knowingly and irrevocably waives each and all of the following:

6.1 The right to require Lender to prosecute or seek to enforce any remedies against Borrower or any other party liable to Lender on account of the Obligations and/or to require Lender to seek to enforce or resort to any remedies with respect to any security interests, liens or encumbrances granted to Lender to secure the Obligations before making demand under and/or seeking to enforce this Guaranty.

6.2 Any defense to the enforcement of this Guaranty arising out of or in any way related to (i) any modification, amendment, supplement, extension, accord and satisfaction, settlement or termination of the Loan Documents or other contract or agreement to which Lender and Borrower may hereafter agree, (ii) any modification, amendment, supplement, alteration, extension, accord and satisfaction or termination of the Obligations or any collateral at any time securing the Obligations (collectively, the "Collateral"), or (iii) any agreements or arrangements whatsoever between Lender and Borrower or with anyone else.

6.3 Any rights to assert against Lender any defense (legal or equitable), set-off, counterclaim, and/or claim which Guarantor now, or at any time hereafter, may have against Borrower and/or any other party liable to Lender in any way or manner.

6.4 Any and all defenses, counterclaims and offsets of any kind or nature, arising directly or indirectly from the present or future lack of perfection, sufficiency, validity and/or enforceability of the Loan Documents or this Guaranty including acts or omissions which may discharge Borrower due to the unenforceability of the Loan Documents or other guarantees. Guarantor further waives: Section 1111(b)(2) of the U. S. Bankruptcy Code (the "Code"); any extension of credit or grant of lien under Section 364 of the Code; any use of cash collateral under Section 363 of the Code; any agreement or stipulation as to the provision of adequate protection in any bankruptcy proceeding; the avoidance of any lien in favor of Lender for any reason; or any bankruptcy, insolvency, reorganization, arrangement or readjustment of debt, liquidation or dissolution proceeding commenced by or against Borrower, the undersigned or any other guarantor, maker or endorser, including

without limitation, any discharge of, or bar or stay against collecting, all or any of the indebtedness (or any interest thereon), in or as a result of any such proceeding; any indebtedness exceeding the Guarantor's liability hereunder. Guarantor further waives any rights or defenses it may have with regard to: any election by Lender under Section 9604 of the California Uniform Commercial Code as to any Collateral or any collateral securing any other guarantee of the Obligations; or any action taken by Lender that is authorized by this Guaranty.

6.5 All rights to assert any defense to the enforcement of this Guaranty on the grounds that (i) Lender has released voluntarily or involuntarily the Borrower or any other guarantor, (ii) Lender has modified the Loan Documents or any other contract between Borrower and Lender, or (iii) Lender has released or agreed to accept a substitution of all or any part of the Collateral without the consent of Guarantor. Guarantor further agrees that any releases which may be given by Lender to Borrower or any other guarantor or endorser shall not release any obligation of performance by Guarantor under the terms of this Guaranty. Guarantor further agrees that the Lender may proceed against the Guarantor and any collateral securing Guarantor's obligations under this Guaranty at any time and in any order that it chooses without regard to other guarantors, the Borrower or other available collateral and the Guarantor waives all rights to require the Lender to marshal the Collateral.

6.6 Any and all rights and defenses that Guarantor may have because any Obligation is secured by a lien on real property. This means, among other things: (i) Lender may collect from Guarantor without first foreclosing on any real or personal property that is included in the Collateral; (ii) if Lender forecloses on any real property Collateral: (a) the amount of the Obligation may be reduced only by the price for which that Collateral is sold at the foreclosure sale, even if the real estate Collateral is worth more than the sale price, (b) the Lender may collect from Guarantor even if Lender, by foreclosing on any real property that may be included in the Collateral, has destroyed any right Guarantor may have to collect from Borrower. This is an unconditional and irrevocable waiver of any rights and defenses Guarantor may have with regard to the Obligations. These rights and defenses include, but are not limited to, any rights and defenses based on Section 580a, 580b, 580d, or 726 of the California Code of Civil Procedure. As an illustration, without limiting the foregoing, Guarantor waives and relinquishes all rights, remedies and defenses that Guarantor may have: (1) under any law which may limit the amount of a deficiency judgment based on any obligation secured hereby; (2) under any bar to deficiency judgments; (3) any requirement of law that Lender exhaust any security for the Obligations guaranteed hereby before proceeding against Guarantor; (4) under any law which may prohibit Lender from enforcing its rights and remedies against Guarantor by both a private trustee's sale and an action in court; (5) under any law which requires that a court action to enforce Lender's rights by an action to foreclose any deed of trust; and (6) by reason of an election of remedies by Lender, including but not limited to the exercise of nonjudicial or judicial remedies against Borrower or any guarantor, Borrower's or any guarantor's real and/or personal property, or any other security for the Obligation guaranteed hereby in whatever order of manner Lender may determine, which may, in any manner, impair, affect, reduce, release, destroy, and/or extinguish Guarantor's subrogation rights, rights to proceed against Borrower for reimbursement, and/or other rights of Guarantor to proceed against Borrower, any guarantor, or against any other person or security including, without limitation, any loss of rights that Guarantor may suffer in connection with any anti-deficiency laws or any other laws limiting, qualifying or discharging indebtedness of or remedies against Borrower or any other person. Guarantor agrees that if all, or a portion, of the Obligation guaranteed hereby are at any time secured by any deed of trust or other interest in real property, Lender, in its sole discretion and without notice or demand and without affecting the security of any deed of trust, may exercise all its rights and remedies against Borrower or any guarantor, Borrower's or any guarantor's real and personal property, and any other security for the Obligation guaranteed hereby in whatever order or manner Lender may determine, including without limitation, nonjudicial foreclosure of any real property security. Without limiting the generality of the foregoing or any other provision hereof, Guarantor hereby expressly waives any and all benefits that might otherwise be available to Guarantor under California Civil Code Sections 2787 to 2855, 2899 and 3433 (as such sections may be amended or recodified from time to time), and California Code of Civil Procedure Sections 580a, 580b, 580d and 726 (as such sections may be amended or recodified from time to time). Guarantor hereby acknowledges and understands that Lender may obtain a judgment against Guarantor for the entire Obligation or any deficiency balance thereof following foreclosure of real or person property without regard to the fair market value of the property, the method of foreclosure or that fact that the Obligation arises from a purchase money transaction.

6.7 Any and all presentments, demands for performance, notices of non-performance, protests, notices of protest, notices of dishonor, notices of default, notice of acceptance of this Guaranty, and notices of the existence, creation, or incurring of new or additional indebtedness, and all other notices or formalities to which Guarantor may be entitled.

6.8 To the extent permitted by law, any and all rights to a jury trial in any action hereunder or arising out of Lender's transactions with Borrower.

7. INDEMNITY

Guarantor agrees to indemnify Lender and hold Lender harmless against all obligations, demands, claims and liabilities claimed or asserted by any other party and against all losses in any way suffered, incurred, or paid by Lender as a result of or in any way arising out of, following, or consequential to this Guaranty or to transactions with Borrower whether under the Loan Documents, or otherwise.

8. SCOPE OF LENDER'S AUTHORITY

Guarantor hereby irrevocably authorizes Lender, without notice or demand and without affecting its liability hereunder, from time to time to:

8.1 Renew, compromise, extend, accelerate, or otherwise change the time for payment or the terms of any of the Obligations, or any part thereof, including, without limitation, increasing or decreasing the rate of interest thereof;

8.2 Take and hold security for the payment of the Obligations guaranteed hereby, and exchange, enforce, waive, and release any such security without obtaining consent of Guarantors;

8.3 Apply such security and direct the order or manner of sale thereof as Lender in its discretion may determine;

8.4 Release or substitute any one or more endorser(s) or guarantor(s); and

8.5 Assign, without notice, this Guaranty in whole or in part and/or Lender's rights hereunder to anyone at any time.

Guarantor agrees that Lender may do any or all of the foregoing in such manner, upon such terms, and at such times as Lender, in its discretion, deems advisable, without, in any way or respect, impairing, affecting, reducing or releasing Guarantor. Guarantor hereby consents to each and all of the foregoing acts, events and/or occurrences.

9. SUBORDINATION OF OTHER DEBTS

Guarantor hereby subordinates and postpones any and all present and future debts and obligations of Borrower to Guarantor to the full payment and performance of all present and future debts and obligations of Borrower to Lender. All monies or other property of Guarantor at any time in Lender's possession may be held by Lender as security for any and all obligations of Guarantor to Lender no matter how or when arising, whether absolute or contingent, whether due or to become due, and whether under this Guaranty or otherwise. Guarantor also agrees that Lender's books and records showing the account between Lender and Borrower shall be admissible in any action or proceeding and shall be binding upon Guarantor for the purpose of establishing the terms set forth therein and shall constitute prima facie proof thereof. At the request of Lender, Borrower shall pay to Lender all or any part of such subordinated indebtedness and any amount so paid to Lender at its request shall be applied to payment of the indebtedness. Each payment on the indebtedness of Borrower to Guarantor received in violation of any of the provisions hereof shall be deemed to have been received by the Guarantor as trustee for Lender and shall be paid over to Lender immediately on account of the indebtedness, but without otherwise affecting in any manner Guarantor's liability under any of the provisions of this Guaranty. Guarantor agrees to file all claims against Borrower in any bankruptcy or other proceeding in which the filing of claims is required by law in respect of any indebtedness of Borrower to Guarantor, and Lender shall be entitled to all of Guarantor's rights thereunder. If, for any reason, Guarantor fails to file such claim at least 30 days prior to the last date on which such claim should be filed, Lender, as Guarantor's attorney in fact, is hereby authorized to do so in Guarantor's name or, in Lender's discretion, to assign such claim to and cause proof of claim to be filed in the name of Lender's nominee. In all cases, whether in administration, bankruptcy or otherwise, the person or persons authorized to pay such claim shall pay to Lender the full amount payable on the claim in the proceeding, and to the full extent necessary for that purpose, Guarantor hereby assigns Lender all Guarantor's rights to any payments or distributions to which Guarantor otherwise would be entitled.

10. GUARANTOR'S DUTY TO INVESTIGATE

Guarantor is presently informed of the financial condition of the Borrower and of all other circumstances which a diligent inquiry would reveal and which bear upon the risk of nonpayment of the Obligations. Guarantor hereby covenants that Guarantor will continue to keep itself informed of Borrower's financial condition, the status of other guarantors, if any, and of all other circumstances which bear upon the risk of nonpayment. Absent a written request for such information by Guarantor to Lender and written consent to the release of such information by Borrower, Guarantor hereby waives Guarantor's rights, if any, to require Lender to disclose to it any information which Lender may now or hereafter acquire concerning such condition or circumstances including, but not limited to, the release of or revocation by any other guarantor, the substitution of collateral securing the primary obligation or any guaranty, or any act, event or condition which may constitute an event of default of any guaranty or the Loan Documents.

11. REVIVAL OF GUARANTY

If any payments of money or transfers of property made to Lender by Borrower, or other guarantor, any maker or any endorser should for any reason subsequently be declared to be, or in Lender's counsel's good faith opinion be determined to be, fraudulent (within the meaning of any state or federal law relating to fraudulent conveyances), preferential or otherwise voidable or recoverable in whole or in part for any reason (hereinafter collectively called "voidable transfer"), the amount repaid or restored and all costs and expenses (including attorney's fees) of Lender related thereto, Guarantor's liability hereunder shall automatically be revived, reinstated and restored and shall exist as though such voidable transfer had never been made to Lender. In the event Lender shall have returned this Guaranty to Guarantor and subsequently be required or advised by counsel to restore or repay any such voidable transfer, the amount thereof, or any portion thereof, Guarantor shall remain liable as provided herein to the same extent as if this Guaranty had not been returned to Guarantor.

12. TERM OF OBLIGATIONS

This Guaranty shall continue in full force and effect until Borrower's Obligations are fully paid, performed and discharged and Lender give the Guarantor written notice of that fact. Borrower's Obligations shall not be considered fully paid, performed and discharged unless and until all payments by Borrower to Lender are no longer subject to any right on the part of any person whomsoever, including but not limited to Borrower, Borrower as a debtor in possession, and/or any trustee in bankruptcy, to set aside such payments or seek to recoup the amount of such payments, or any part thereof. The foregoing shall include, by way of example and not by way of limitation, all rights to recover preferences voidable under Title 11 of the United States Code. In the event that any such payments by Borrower to Lender are set aside after the making thereof, in whole or in part, or settled without litigation, to the extent of such settlement, all of which is within Lender's discretion, Guarantor shall be liable for the full amount Lender is required to repay plus costs, interest, attorneys' fees and all expenses which Lender paid or incurred in connection therewith.

13. FINANCIAL STATEMENTS AND TAX RETURNS

13.1 **Financial Statements**.

(a) Within one hundred twenty (120) days after the close of each fiscal year of Guarantor, Guarantor shall deliver to Lender audited financial statement(s) of Guarantor prepared by an independent certified public accountant acceptable to Lender. All financial statements delivered to Lender shall include a balance sheet and profit and loss statement, and an independent certified public accountant's letter to management regarding the preparation of the financial statements.

(b) Guarantor shall deliver to Lender a certificate signed by the chief financial officer of Guarantor to the effect that all reports, statements, or computer-prepared information of any kind or nature delivered or caused to be delivered to Lender under this Guaranty are accurate, true and fairly present the financial condition of Guarantor.

13.2 **Tax Returns**. If Guarantor files a federal income tax return with the Internal Revenue Service, then within one hundred twenty (120) days after the filing Guarantor shall provide Lender with a copy of the signed tax return filed with the Internal Revenue Service as filed by Guarantor.

13.3 **Other Reports**. Guarantor shall deliver to Lender other reports reasonably requested by Lender relating to the financial condition of Guarantor.

14. WAIVER OF RIGHT OF SUBROGATION

Guarantor expressly waives and releases any and all rights of subrogation, reimbursement, indemnity or contribution which it may now or hereafter have against: (1) Borrower, any other guarantor or any person who now or hereafter has direct or contingent liability (whether by contract, at law or in equity) for all or any portion of the Obligations guaranteed hereby; or (2) against any property which now or hereafter serves as collateral security for the obligations guaranteed hereby. If and to the extent such waiver and release is unenforceable, Guarantor hereby agrees that all such rights of subrogation, reimbursement, indemnity and contribution shall be junior and subordinate to the right of Lender to obtain payment and performance of the Obligations guaranteed hereby and to all rights of Lender in and to any property which now or hereafter serves as collateral security for such Obligations.

15. SURVIVAL

This Guaranty shall be binding upon the successors and assigns of the Guarantor and shall inure to the benefit of Lender's successors and assigns, including all receivers, trustees, administrators and other successors in interest of Guarantor. The death of Guarantor and the incapacity, lack of authority, death, disability or revocation hereof by any other guarantor shall not terminate or otherwise impair this Guaranty. All Obligations hereunder shall survive the foregoing events and shall be fully satisfied before Guarantor may proceed with action to obtain subrogation, contribution or reimbursement against Borrower.

16. MODIFICATIONS

No modification of this Guaranty shall be effective for any purpose unless it is in writing and executed by an officer of Lender authorized to do so. This Guaranty merges all negotiations, stipulations and provisions relating to the subject matter of this Guaranty which proceed or may accompany the execution of this Guaranty.

17. EXCLUSIVE AGREEMENT

Guarantor acknowledges and agrees that this Guaranty represents the sole and exclusive and final expression of the agreement between the Lender and the Guarantor and that it supersedes and extinguishes all prior negotiations, oral and written representations, covenants or conditions including other agreements between the Guarantor and the Lender but explicitly does not supersede prior guaranties which are intended to guaranty other obligations of the same Borrower or other borrowers. In the event that there is a prior guaranty of the Obligation this Guaranty does not supersede such prior guaranties between Guarantor and Lender but is intended to be a separate and additional guaranty of the obligation. Guarantor declares that he/she/it has not relied on any warranty, representation, covenant or condition made by Lender which may qualify this Guaranty or contains any different terms than provided for herein. Further, Guarantor has not signed any other agreement or document in connection with guaranteeing the obligations hereunder which in any way modifies or restricts Guarantor's obligation to perform under the terms of this Guaranty. Guarantor waives any right to have any term or condition of this Guaranty modified or changed by the introduction of prior discussions or negotiations of the parties whether written or oral. Guarantor understands and acknowledges all of the waivers contained in this Guaranty and has consulted legal counsel or other sources to understand the nature and extent of the waivers and acknowledges that the waivers are enforceable. If any such waivers are determined to be against public policy, the waiver shall be enforced to the extent appropriate under law.

18. TERMS OF THE GUARANTY

Guarantor acknowledges and agrees that he/she/it has read the guaranty and fully understands all of the terms thereof. The Guarantor further agrees that the guaranty is the complete and accurate expression of the Guarantor's understanding of the agreement between the Guarantor and the Lender and that Guarantor has not relied on any other agreement or representations in executing this Guaranty.

19. ATTORNEY FEES

Guarantor agrees to pay reasonable attorneys' fees and all other costs and expenses which may be incurred by Lender in the enforcement of this Guaranty or in any way arising out of, following, or consequential to the enforcement of Borrower's Obligations, whether under this Guaranty, the Agreement, or otherwise.

20. GOVERNING LAW AND VENUE

20.1 **Demand; Protest, etc**. Guarantor waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension or renewal of any commercial paper, accounts, documents, instruments, chattel paper, and guarantees at any time held by Lender on which Guarantor may in any way be liable.

20.2 **Jury Trial**. Unless prohibited under the laws that govern an action or proceeding relating to this Guaranty or related agreements entered into in connection herewith, Guarantor waives any right to trial by jury in any action or proceeding relating to this Guaranty or any of the agreements entered into in connection herewith.

20.3 **Choice of Law and Venue**. The validity of this Guaranty, its construction, interpretation, and enforcement, and the rights of the parties hereunder and concerning the Collateral, shall be determined under, governed by, and construed in accordance with the laws of the State of California. The parties agree that all actions or proceedings arising in connection with this Guaranty shall be tried and litigated only in the state and federal courts located in the County of Santa Cruz. Guarantor waives any right it may have to assert the doctrine of *forum non conveniens* or to object to such venue and hereby consents to any court ordered relief.

21. COUNTERPART EXECUTION

This Guaranty may be executed in several counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same Guaranty.

22. NOTICES

Except as otherwise provided herein, any notice or other communication required or permitted to be given under this Guaranty shall be in writing and shall be personally served by messenger, or sent by a commercial overnight delivery service (such as Federal Express), or by certified mail, return receipt requested, and shall be deemed given on the date actually received if served by messenger, or on the next business day after deposit with an overnight delivery service, or on the date of receipt as shown on the return receipt if sent by certified mail. The addresses of the parties to which notices and other communications shall be sent (until notice of a change thereof is served as provided herein) are set forth below. Any party to this Guaranty may change its address for giving notices or demands hereunder by written notice of such change to the other party in accordance with the provisions hereof. Guarantor shall promptly notify Lender of any change of its mailing address in the manner prescribed by this paragraph.

GUARANTOR:
Name: COMMUNITY FOUNDATION SANTA CRUZ COUNTY
Address: COMMUNITY FOUNDATION SANTA CRUZ COUNTY
Attn: Susan True
7807 Soquel Drive
Aptos, CA 95003

LENDER:
Name: SANTA CRUZ COUNTY BANK
Address: SANTA CRUZ COUNTY BANK
Attn: Note Department
P.O. Box 8426
Santa Cruz, CA 95061

23. PLURAL

If more than one Guarantor executes this Guaranty, all references to Guarantor shall be changed to mean all Guarantors and all Guarantors shall be jointly and severally liable for all Obligations hereunder unless expressly provided otherwise by this Guaranty.

[*Remainder of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, this Guaranty is executed on behalf of the Guarantor on the date provided below.

Date: November 1, 2023

GUARANTOR:

COMMUNITY FOUNDATION SANTA CRUZ COUNTY, a
California nonprofit public benefit corporation

By: _____
Name:Susan True
Title: CEO

COMMERCIAL GUARANTY
(Limited)

This Commercial Guaranty ("Guaranty") is entered into by and between **SANTA CRUZ COUNTY BANK**, a California state-chartered bank ("Lender"), and **COUNTY OF SANTA CRUZ**, a county within the state of California ("Guarantor"), and is effective November 1, 2023 ("Effective Date").

In order to induce Lender to extend and/or to continue to extend financial accommodations to **PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION**, a California nonprofit public benefit corporation ("PVHDHC") and **PAJARO VALLEY HEALTHCARE DISTRICT PROJECT**, a California nonprofit public benefit corporation ("PVHD") (PVHDHC and PVHD are together referred to herein as "Borrower"), pursuant to any present or future promissory note, or other present or future agreement between Lender and Borrower including any modifications, extensions, revisions or substitutions thereof including all other agreements entered into in connection with and for the purpose of executing any of the loan documents referenced herein, (collectively, "Loan Documents"), and in consideration thereof, and in consideration of any loans, advances, or financial accommodations granted by Lender to or for the account of Borrower pursuant to the Loan Documents, Guarantor hereby guarantees, promises and undertakes as follows:

1. OBLIGATION

Guarantor unconditionally, absolutely and irrevocably guarantees and promises to pay to Lender, or order, on demand, in lawful money of the United States, any and all present or future indebtedness and/or obligations of Borrower owing to Lender (including, but not limited to, the repayment to Lender of all sums which may be presently due and owing and of all sums which shall in the future become due and owing from Borrower) arising under the Loan Documents or other agreements, except as may be limited by Section 3 below and as otherwise provided herein. The terms "indebtedness" and "obligations" (hereinafter collectively referred to as the "Obligations") are used herein in their most comprehensive sense and include each of the following: (i) any and all advances, debts, obligations, and liabilities of Borrower arising under that certain promissory note dated November 1, 2023 and in the initial original principal amount of **FIVE MILLION DOLLARS** ($5,000,000.00) (the "Promissory Note") which principal amount decreases over time as provided in the Promissory Note, together with any amendments, extensions, modifications, renewals, replacement or substitutions thereto; (ii) the Loan Documents executed in connection with the Promissory Note, together with any amendments, extensions, modifications, renewals, replacement or substitutions to the Loan Documents; and (iii) further including, without limitation, any and all premiums, charges, and/or interest owed by Borrower to Lender, under the Promissory Note or other Loan Documents, whether due or not due, absolute or contingent, liquidated or unliquidated, determined or undetermined, whether Borrower may be liable individually or jointly with others, whether recovery upon such indebtedness may be or hereafter becomes barred by any statute of limitations or whether such indebtedness may be or hereafter becomes otherwise unenforceable, and includes Borrower's prompt, full and faithful performance, observance and discharge of each and every term, condition, agreement, representation, warranty, undertaking and provision to be performed by Borrower under the Loan Documents, and including any and all attorneys' fees and costs incurred by Lender directly or indirectly in connection with the collection of any amount owned by Borrower under the Loan Documents and/or incurred by Lender directly or indirectly in connection with enforcement of this Guaranty.

2. CONSIDERATION

This Guaranty is given for the purpose of guaranteeing the continued obligations of Borrower under the terms of the Loan Documents. Guarantor represents and warrants to Lender that Guarantor has a material interest and will benefit, directly or indirectly from, the loan made to Borrower and evidenced by the Promissory Note and Loan Documents (the "Loan"). If this Guaranty is not executed contemporaneously with the Loan Documents, then Guarantor has executed and delivered this Guaranty to Lender in consideration of the Loan.

3. GUARANTY LIMITS AND TERMINATION

The Obligations of Borrower are also guaranteed by: (i) Community Foundation Santa Cruz County, a California nonprofit public benefit corporation (the "Community Foundation Guarantor"); and (ii) Salud Para La Gente, a California nonprofit public benefit corporation (the "Salud Guarnator"). Together the Community Fund Guarantor and Salud Guarantor are referred to herein as the "Other Guarantors" and each individually referred to as "Other Guarantor."

Gurantor's guarantee of the Obligations shall not exceed One Million Dollars ($1 million) of the Obligations, and is further limited to the following amounts (the following amounts, which are not to exceed $1 million, are

referred to herein as the "Guaranty Amount"): (i) twenty percent (20%) of all dollar amounts owed by Borrower under the Loan Documents that were incurred during the first year following the date of the Promissory Note; (ii) twenty-five percent (25%) of all dollar amounts owed by Borrower under the Loan Documents that were incurred during the period beginning one (1) year after the date of the Promissory Note; and (iii) thirty three and 1/3 percent (33.333%) of all dollar amounts owed by Borrower under the Loan Documents that were incurred beginning two (2) years after the date of the Promissory Note. Notwithstanding the foregoing, if any Other Guarantor fails to pay a portion or all of the amounts that such Other Guarantor is required to pay under the guaranty executed by the Other Guarantor, then such occurance shall not reduce the amounts Guarantor is required to pay to Lender under this Guaranty. Additionally, Guarantor acknowledges, understands and agrees that, except as provided above, Lender's recourse against Guarantor, and Lender's rights and remedies under this Guaranty, are not limited (or otherwise affected) by the guaranties provided by the Other Guarantors.

Any termination of this Guaranty shall be applicable only to transactions having their inception after the effective date of termination and shall not affect any rights or Obligations arising out of transactions having their inception prior to such date even if subsequent to such termination the Obligations are modified, renewed, compromised, extended, or otherwise amended (including, but not limited to, an increase in the interest rate applicable to the Obligations). Any termination of this Guaranty shall only be effective upon actual receipt by Lender of a written notice of termination signed by Guarantor and shall be effective five (5) business days after the actual receipt by Lender of such notice of termination.

4. INDEPENDENT OBLIGATION

Guarantor agrees (i) that Guarantor is directly and primarily liable to Lender; (ii) that the obligations of Guarantor hereunder are separate and independent of the Obligations of Borrower, or of any other guarantor of Borrower's Obligations; and (iii) that Lender may file a separate action or actions at law against the Guarantor to enforce this Guaranty and may exercise any rights or remedies that Lender may have against collateral securing performance under the terms of this Guaranty.

5. INSOLVENCY OF GUARANTOR OR BORROWER

In the event that any bankruptcy, insolvency, receivership or similar proceeding is instituted by or against Guarantor and/or the Borrower or in the event that either the Guarantor or Borrower becomes insolvent, makes an assignment for the benefit of creditors, or attempts to effect a composition with creditors, at Lender's election, without notice or demand, the obligations of Guarantor created hereunder shall become due, payable and enforceable against Guarantor whether or not the Obligations are then due and payable.

6. WAIVERS

In consideration of the extension by Lender to Borrower of existing and future loans, credit facilities and other financial accommodations, Guarantor hereby knowingly and irrevocably waives each and all of the following:

6.1 The right to require Lender to prosecute or seek to enforce any remedies against Borrower or any other party liable to Lender on account of the Obligations and/or to require Lender to seek to enforce or resort to any remedies with respect to any security interests, liens or encumbrances granted to Lender to secure the Obligations before making demand under and/or seeking to enforce this Guaranty.

6.2 Any defense to the enforcement of this Guaranty arising out of or in any way related to (i) any modification, amendment, supplement, extension, accord and satisfaction, settlement or termination of the Loan Documents or other contract or agreement to which Lender and Borrower may hereafter agree, (ii) any modification, amendment, supplement, alteration, extension, accord and satisfaction or termination of the Obligations or any collateral at any time securing the Obligations (collectively, the "Collateral"), or (iii) any agreements or arrangements whatsoever between Lender and Borrower or with anyone else.

6.3 Any rights to assert against Lender any defense (legal or equitable), set-off, counterclaim, and/or claim which Guarantor now, or at any time hereafter, may have against Borrower and/or any other party liable to Lender in any way or manner.

6.4 Any and all defenses, counterclaims and offsets of any kind or nature, arising directly or indirectly from the present or future lack of perfection, sufficiency, validity and/or enforceability of the Loan Documents or this Guaranty including acts or omissions which may discharge Borrower due to the unenforceability of the Loan Documents or other guarantees. Guarantor further waives: Section 1111(b)(2) of the U. S. Bankruptcy Code (the "Code"); any extension of credit or grant of lien under Section 364 of the Code; any use of cash collateral under Section 363 of the Code; any agreement or stipulation as to the provision of adequate protection in any bankruptcy proceeding; the avoidance of any lien in favor of Lender for any reason; or any bankruptcy, insolvency, reorganization, arrangement or readjustment of debt, liquidation or dissolution proceeding

commenced by or against Borrower, the undersigned or any other guarantor, maker or endorser, including without limitation, any discharge of, or bar or stay against collecting, all or any of the indebtedness (or any interest thereon), in or as a result of any such proceeding; any indebtedness exceeding the Guarantor's liability hereunder. Guarantor further waives any rights or defenses it may have with regard to: any election by Lender under Section 9604 of the California Uniform Commercial Code as to any Collateral or any collateral securing any other guarantee of the Obligations; or any action taken by Lender that is authorized by this Guaranty.

6.5 All rights to assert any defense to the enforcement of this Guaranty on the grounds that (i) Lender has released voluntarily or involuntarily the Borrower or any other guarantor, (ii) Lender has modified the Loan Documents or any other contract between Borrower and Lender, or (iii) Lender has released or agreed to accept a substitution of all or any part of the Collateral without the consent of Guarantor. Guarantor further agrees that any releases which may be given by Lender to Borrower or any other guarantor or endorser shall not release any obligation of performance by Guarantor under the terms of this Guaranty. Guarantor further agrees that the Lender may proceed against the Guarantor and any collateral securing Guarantor's obligations under this Guaranty at any time and in any order that it chooses without regard to other guarantors, the Borrower or other available collateral and the Guarantor waives all rights to require the Lender to marshal the Collateral.

6.6 Any and all rights and defenses that Guarantor may have because any Obligation is secured by a lien on real property. This means, among other things: (i) Lender may collect from Guarantor without first foreclosing on any real or personal property that is included in the Collateral; (ii) if Lender forecloses on any real property Collateral: (a) the amount of the Obligation may be reduced only by the price for which that Collateral is sold at the foreclosure sale, even if the real estate Collateral is worth more than the sale price, (b) the Lender may collect from Guarantor even if Lender, by foreclosing on any real property that may be included in the Collateral, has destroyed any right Guarantor may have to collect from Borrower. This is an unconditional and irrevocable waiver of any rights and defenses Guarantor may have with regard to the Obligations. These rights and defenses include, but are not limited to, any rights and defenses based on Section 580a, 580b, 580d, or 726 of the California Code of Civil Procedure. As an illustration, without limiting the foregoing, Guarantor waives and relinquishes all rights, remedies and defenses that Guarantor may have: (1) under any law which may limit the amount of a deficiency judgment based on any obligation secured hereby; (2) under any bar to deficiency judgments; (3) any requirement of law that Lender exhaust any security for the Obligations guaranteed hereby before proceeding against Guarantor; (4) under any law which may prohibit Lender from enforcing its rights and remedies against Guarantor by both a private trustee's sale and an action in court; (5) under any law which requires that a court action to enforce Lender's rights by an action to foreclose any deed of trust; and (6) by reason of an election of remedies by Lender, including but not limited to the exercise of nonjudicial or judicial remedies against Borrower or any guarantor, Borrower's or any guarantor's real and/or personal property, or any other security for the Obligation guaranteed hereby in whatever order of manner Lender may determine, which may, in any manner, impair, affect, reduce, release, destroy, and/or extinguish Guarantor's subrogation rights, rights to proceed against Borrower for reimbursement, and/or other rights of Guarantor to proceed against Borrower, any guarantor, or against any other person or security including, without limitation, any loss of rights that Guarantor may suffer in connection with any anti-deficiency laws or any other laws limiting, qualifying or discharging indebtedness of or remedies against Borrower or any other person. Guarantor agrees that if all, or a portion, of the Obligation guaranteed hereby are at any time secured by any deed of trust or other interest in real property, Lender, in its sole discretion and without notice or demand and without affecting the security of any deed of trust, may exercise all its rights and remedies against Borrower or any guarantor, Borrower's or any guarantor's real and personal property, and any other security for the Obligation guaranteed hereby in whatever order or manner Lender may determine, including without limitation, nonjudicial foreclosure of any real property security. Without limiting the generality of the foregoing or any other provision hereof, Guarantor hereby expressly waives any and all benefits that might otherwise be available to Guarantor under California Civil Code Sections 2787 to 2855, 2899 and 3433 (as such sections may be amended or recodified from time to time), and California Code of Civil Procedure Sections 580a, 580b, 580d and 726 (as such sections may be amended or recodified from time to time). Guarantor hereby acknowledges and understands that Lender may obtain a judgment against Guarantor for the entire Obligation or any deficiency balance thereof following foreclosure of real or person property without regard to the fair market value of the property, the method of foreclosure or that fact that the Obligation arises from a purchase money transaction.

6.7 Any and all presentments, demands for performance, notices of non-performance, protests, notices of protest, notices of dishonor, notices of default, notice of acceptance of this Guaranty, and notices of the existence,

creation, or incurring of new or additional indebtedness, and all other notices or formalities to which Guarantor may be entitled.

6.8 To the extent permitted by law, any and all rights to a jury trial in any action hereunder or arising out of Lender's transactions with Borrower.

7. INDEMNITY

Guarantor agrees to indemnify Lender and hold Lender harmless against all obligations, demands, claims and liabilities claimed or asserted by any other party and against all losses in any way suffered, incurred, or paid by Lender as a result of or in any way arising out of, following, or consequential to this Guaranty or to transactions with Borrower whether under the Loan Documents, or otherwise.

8. SCOPE OF LENDER'S AUTHORITY

Guarantor hereby irrevocably authorizes Lender, without notice or demand and without affecting its liability hereunder, from time to time to:

8.1 Renew, compromise, extend, accelerate, or otherwise change the time for payment or the terms of any of the Obligations, or any part thereof, including, without limitation, increasing or decreasing the rate of interest thereof;

8.2 Take and hold security for the payment of the Obligations guaranteed hereby, and exchange, enforce, waive, and release any such security without obtaining consent of Guarantors;

8.3 Apply such security and direct the order or manner of sale thereof as Lender in its discretion may determine;

8.4 Release or substitute any one or more endorser(s) or guarantor(s); and

8.5 Assign, without notice, this Guaranty in whole or in part and/or Lender's rights hereunder to anyone at any time.

Guarantor agrees that Lender may do any or all of the foregoing in such manner, upon such terms, and at such times as Lender, in its discretion, deems advisable, without, in any way or respect, impairing, affecting, reducing or releasing Guarantor. Guarantor hereby consents to each and all of the foregoing acts, events and/or occurrences.

9. SUBORDINATION OF OTHER DEBTS

Guarantor hereby subordinates and postpones any and all present and future debts and obligations of Borrower to Guarantor to the full payment and performance of all present and future debts and obligations of Borrower to Lender. All monies or other property of Guarantor at any time in Lender's possession may be held by Lender as security for any and all obligations of Guarantor to Lender no matter how or when arising, whether absolute or contingent, whether due or to become due, and whether under this Guaranty or otherwise. Guarantor also agrees that Lender's books and records showing the account between Lender and Borrower shall be admissible in any action or proceeding and shall be binding upon Guarantor for the purpose of establishing the terms set forth therein and shall constitute prima facie proof thereof. At the request of Lender, Borrower shall pay to Lender all or any part of such subordinated indebtedness and any amount so paid to Lender at its request shall be applied to payment of the indebtedness. Each payment on the indebtedness of Borrower to Guarantor received in violation of any of the provisions hereof shall be deemed to have been received by the Guarantor as trustee for Lender and shall be paid over to Lender immediately on account of the indebtedness, but without otherwise affecting in any manner Guarantor's liability under any of the provisions of this Guaranty. Guarantor agrees to file all claims against Borrower in any bankruptcy or other proceeding in which the filing of claims is required by law in respect of any indebtedness of Borrower to Guarantor, and Lender shall be entitled to all of Guarantor's rights thereunder. If, for any reason, Guarantor fails to file such claim at least 30 days prior to the last date on which such claim should be filed, Lender, as Guarantor's attorney in fact, is hereby authorized to do so in Guarantor's name or, in Lender's discretion, to assign such claim to and cause proof of claim to be filed in the name of Lender's nominee. In all cases, whether in administration, bankruptcy or otherwise, the person or persons authorized to pay such claim shall pay to Lender the full amount payable on the claim in the proceeding, and to the full extent necessary for that purpose, Guarantor hereby assigns Lender all Guarantor's rights to any payments or distributions to which Guarantor otherwise would be entitled.

10. GUARANTOR'S DUTY TO INVESTIGATE

Guarantor is presently informed of the financial condition of the Borrower and of all other circumstances which a diligent inquiry would reveal and which bear upon the risk of nonpayment of the Obligations. Guarantor hereby covenants that Guarantor will continue to keep itself informed of Borrower's financial condition, the status of other guarantors, if any, and of all other circumstances which bear upon the risk of nonpayment. Absent a written request for such information by Guarantor to Lender and written consent to the release of such information by Borrower, Guarantor hereby waives Guarantor's rights, if any, to require Lender to disclose to it any information which Lender may now or hereafter acquire concerning such condition or circumstances including, but not limited to, the release of or revocation by any other guarantor, the substitution of collateral securing the primary obligation or any guaranty, or any act, event or condition which may constitute an event of default of any guaranty or the Loan Documents.

11. REVIVAL OF GUARANTY

If any payments of money or transfers of property made to Lender by Borrower, or other guarantor, any maker or any endorser should for any reason subsequently be declared to be, or in Lender's counsel's good faith opinion be determined to be, fraudulent (within the meaning of any state or federal law relating to fraudulent conveyances), preferential or otherwise voidable or recoverable in whole or in part for any reason (hereinafter collectively called "voidable transfer"), the amount repaid or restored and all costs and expenses (including attorney's fees) of Lender related thereto, Guarantor's liability hereunder shall automatically be revived, reinstated and restored and shall exist as though such voidable transfer had never been made to Lender. In the event Lender shall have returned this Guaranty to Guarantor and subsequently be required or advised by counsel to restore or repay any such voidable transfer, the amount thereof, or any portion thereof, Guarantor shall remain liable as provided herein to the same extent as if this Guaranty had not been returned to Guarantor.

12. TERM OF OBLIGATIONS

This Guaranty shall continue in full force and effect until Borrower's Obligations are fully paid, performed and discharged and Lender give the Guarantor written notice of that fact. Borrower's Obligations shall not be considered fully paid, performed and discharged unless and until all payments by Borrower to Lender are no longer subject to any right on the part of any person whomsoever, including but not limited to Borrower, Borrower as a debtor in possession, and/or any trustee in bankruptcy, to set aside such payments or seek to recoup the amount of such payments, or any part thereof. The foregoing shall include, by way of example and not by way of limitation, all rights to recover preferences voidable under Title 11 of the United States Code. In the event that any such payments by Borrower to Lender are set aside after the making thereof, in whole or in part, or settled without litigation, to the extent of such settlement, all of which is within Lender's discretion, Guarantor shall be liable for the full amount Lender is required to repay plus costs, interest, attorneys' fees and all expenses which Lender paid or incurred in connection therewith.

13. FINANCIAL STATEMENTS AND TAX RETURNS

13.1 **Financial Statements**.

(a) Within one hundred twenty (120) days after the close of each fiscal year of Guarantor, Guarantor shall deliver to Lender audited financial statement(s) of Guarantor prepared by an independent certified public accountant acceptable to Lender. All financial statements delivered to Lender shall include a balance sheet and profit and loss statement, and an independent certified public accountant's letter to management regarding the preparation of the financial statements.

(b) Guarantor shall deliver to Lender a certificate signed by the chief financial officer of Guarantor to the effect that all reports, statements, or computer-prepared information of any kind or nature delivered or caused to be delivered to Lender under this Guaranty are accurate, true and fairly present the financial condition of Guarantor.

13.2 **Tax Returns**. If Guarantor files a federal income tax return with the Internal Revenue Service, then within one hundred twenty (120) days after the filing Guarantor shall provide Lender with a copy of the signed tax return filed with the Internal Revenue Service as filed by Guarantor.

13.3 **Other Reports**. Guarantor shall deliver to Lender other reports reasonably requested by Lender relating to the financial condition of Guarantor.

14. WAIVER OF RIGHT OF SUBROGATION

Guarantor expressly waives and releases any and all rights of subrogation, reimbursement, indemnity or contribution which it may now or hereafter have against: (1) Borrower, any other guarantor or any person who now or hereafter has direct or contingent liability (whether by contract, at law or in equity) for all or any portion of the Obligations guaranteed hereby; or (2) against any property which now or hereafter serves as collateral security for the obligations guaranteed hereby. If and to the extent such waiver and release is unenforceable, Guarantor hereby agrees that all such rights of subrogation, reimbursement, indemnity and contribution shall be junior and subordinate to the right of Lender to obtain payment and performance of the Obligations guaranteed hereby and to all rights of Lender in and to any property which now or hereafter serves as collateral security for such Obligations.

15. SURVIVAL

This Guaranty shall be binding upon the successors and assigns of the Guarantor and shall inure to the benefit of Lender's successors and assigns, including all receivers, trustees, administrators and other successors in interest of Guarantor. The death of Guarantor and the incapacity, lack of authority, death, disability or revocation hereof by any other guarantor shall not terminate or otherwise impair this Guaranty. All Obligations hereunder shall survive the foregoing events and shall be fully satisfied before Guarantor may proceed with action to obtain subrogation, contribution or reimbursement against Borrower.

16. MODIFICATIONS

No modification of this Guaranty shall be effective for any purpose unless it is in writing and executed by an officer of Lender authorized to do so. This Guaranty merges all negotiations, stipulations and provisions relating to the subject matter of this Guaranty which proceed or may accompany the execution of this Guaranty.

17. EXCLUSIVE AGREEMENT

Guarantor acknowledges and agrees that this Guaranty represents the sole and exclusive and final expression of the agreement between the Lender and the Guarantor and that it supersedes and extinguishes all prior negotiations, oral and written representations, covenants or conditions including other agreements between the Guarantor and the Lender but explicitly does not supersede prior guaranties which are intended to guaranty other obligations of the same Borrower or other borrowers. In the event that there is a prior guaranty of the Obligation this Guaranty does not supersede such prior guaranties between Guarantor and Lender but is intended to be a separate and additional guaranty of the obligation. Guarantor declares that he/she/it has not relied on any warranty, representation, covenant or condition made by Lender which may qualify this Guaranty or contains any different terms than provided for herein. Further, Guarantor has not signed any other agreement or document in connection with guaranteeing the obligations hereunder which in any way modifies or restricts Guarantor's obligation to perform under the terms of this Guaranty. Guarantor waives any right to have any term or condition of this Guaranty modified or changed by the introduction of prior discussions or negotiations of the parties whether written or oral. Guarantor understands and acknowledges all of the waivers contained in this Guaranty and has consulted legal counsel or other sources to understand the nature and extent of the waivers and acknowledges that the waivers are enforceable. If any such waivers are determined to be against public policy, the waiver shall be enforced to the extent appropriate under law.

18. TERMS OF THE GUARANTY

Guarantor acknowledges and agrees that he/she/it has read the guaranty and fully understands all of the terms thereof. The Guarantor further agrees that the guaranty is the complete and accurate expression of the Guarantor's understanding of the agreement between the Guarantor and the Lender and that Guarantor has not relied on any other agreement or representations in executing this Guaranty.

19. ATTORNEY FEES

Guarantor agrees to pay reasonable attorneys' fees and all other costs and expenses which may be incurred by Lender in the enforcement of this Guaranty or in any way arising out of, following, or consequential to the enforcement of Borrower's Obligations, whether under this Guaranty, the Agreement, or otherwise.

20. GOVERNING LAW AND VENUE

20.1 **Demand; Protest, etc**. Guarantor waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension or renewal of any commercial paper, accounts, documents, instruments, chattel paper, and guarantees at any time held by Lender on which Guarantor may in any way be liable.

20.2 **Jury Trial**. Unless prohibited under the laws that govern an action or proceeding relating to this Guaranty or related agreements entered into in connection herewith, Guarantor waives any right to trial by jury in any action or proceeding relating to this Guaranty or any of the agreements entered into in connection herewith.

20.3 **Choice of Law and Venue**. The validity of this Guaranty, its construction, interpretation, and enforcement, and the rights of the parties hereunder and concerning the Collateral, shall be determined under, governed by, and construed in accordance with the laws of the State of California. The parties agree that all actions or proceedings arising in connection with this Guaranty shall be tried and litigated only in the state and federal courts located in the County of Santa Cruz. Guarantor waives any right it may have to assert the doctrine of *forum non conveniens* or to object to such venue and hereby consents to any court ordered relief.

21. COUNTERPART EXECUTION

This Guaranty may be executed in several counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same Guaranty.

22. NOTICES

Except as otherwise provided herein, any notice or other communication required or permitted to be given under this Guaranty shall be in writing and shall be personally served by messenger, or sent by a commercial overnight delivery service (such as Federal Express), or by certified mail, return receipt requested, and shall be deemed given on the date actually received if served by messenger, or on the next business day after deposit with an overnight delivery service, or on the date of receipt as shown on the return receipt if sent by certified mail. The addresses of the parties to which notices and other communications shall be sent (until notice of a change thereof is served as provided herein) are set forth below. Any party to this Guaranty may change its address for giving notices or demands hereunder by written notice of such change to the other party in accordance with the provisions hereof. Guarantor shall promptly notify Lender of any change of its mailing address in the manner prescribed by this paragraph.

GUARANTOR:
Name: COUNTY OF SANTA CRUZ
Address: COUNTY OF SANTA CRUZ
Attn: Director of Finance
809 Center Street
Santa Cruz, CA 95060

LENDER:
Name: SANTA CRUZ COUNTY BANK
Address: SANTA CRUZ COUNTY BANK
Attn: Note Department
P.O. Box 8426
Santa Cruz, CA 95061

23. PLURAL

If more than one Guarantor executes this Guaranty, all references to Guarantor shall be changed to mean all Guarantors and all Guarantors shall be jointly and severally liable for all Obligations hereunder unless expressly provided otherwise by this Guaranty.

[*Remainder of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, this Guaranty is executed on behalf of the Guarantor on the date provided below.

Date: November 1, 2023

GUARANTOR:

COUNTY OF SANTA CRUZ, a county within the state of California

By: _____
Name: _____
Title: _____

COMMERCIAL GUARANTY
(Limited)

This Commercial Guaranty ("Guaranty") is entered into by and between **SANTA CRUZ COUNTY BANK**, a California state-chartered bank ("Lender"), and **SALUD PARA LA GENTE**, a California nonprofit public benefit corporation ("Guarantor"), and is effective November 1, 2023 ("Effective Date").

In order to induce Lender to extend and/or to continue to extend financial accommodations to **PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION**, a California nonprofit public benefit corporation ("PVHDHC") and **PAJARO VALLEY HEALTHCARE DISTRICT PROJECT**, a California nonprofit public benefit corporation ("PVHD") (PVHDHC and PVHD are together referred to herein as "Borrower"), pursuant to any present or future promissory note, or other present or future agreement between Lender and Borrower including any modifications, extensions, revisions or substitutions thereof including all other agreements entered into in connection with and for the purpose of executing any of the loan documents referenced herein, (collectively, "Loan Documents"), and in consideration thereof, and in consideration of any loans, advances, or financial accommodations granted by Lender to or for the account of Borrower pursuant to the Loan Documents, Guarantor hereby guarantees, promises and undertakes as follows:

1. OBLIGATION

Guarantor unconditionally, absolutely and irrevocably guarantees and promises to pay to Lender, or order, on demand, in lawful money of the United States, any and all present or future indebtedness and/or obligations of Borrower owing to Lender (including, but not limited to, the repayment to Lender of all sums which may be presently due and owing and of all sums which shall in the future become due and owing from Borrower) arising under the Loan Documents or other agreements, except as may be limited by Section 3 below and as otherwise provided herein. The terms "indebtedness" and "obligations" (hereinafter collectively referred to as the "Obligations") are used herein in their most comprehensive sense and include each of the following: (i) any and all advances, debts, obligations, and liabilities of Borrower arising under that certain promissory note dated November 1, 2023 and in the initial original principal amount of **FIVE MILLION DOLLARS** ($5,000,000.00) (the "Promissory Note") which principal amount decreases over time as provided in the Promissory Note, together with any amendments, extensions, modifications, renewals, replacement or substitutions thereto; (ii) the Loan Documents executed in connection with the Promissory Note, together with any amendments, extensions, modifications, renewals, replacement or substitutions to the Loan Documents; and (iii) further including, without limitation, any and all premiums, charges, and/or interest owed by Borrower to Lender, under the Promissory Note or other Loan Documents, whether due or not due, absolute or contingent, liquidated or unliquidated, determined or undetermined, whether Borrower may be liable individually or jointly with others, whether recovery upon such indebtedness may be or hereafter becomes barred by any statute of limitations or whether such indebtedness may be or hereafter becomes otherwise unenforceable, and includes Borrower's prompt, full and faithful performance, observance and discharge of each and every term, condition, agreement, representation, warranty, undertaking and provision to be performed by Borrower under the Loan Documents, and including any and all attorneys' fees and costs incurred by Lender directly or indirectly in connection with the collection of any amount owned by Borrower under the Loan Documents and/or incurred by Lender directly or indirectly in connection with enforcement of this Guaranty.

2. CONSIDERATION

This Guaranty is given for the purpose of guaranteeing the continued obligations of Borrower under the terms of the Loan Documents. Guarantor represents and warrants to Lender that Guarantor has a material interest and will benefit, directly or indirectly from, the loan made to Borrower and evidenced by the Promissory Note and Loan Documents (the "Loan"). If this Guaranty is not executed contemporaneously with the Loan Documents, then Guarantor has executed and delivered this Guaranty to Lender in consideration of the Loan.

3. GUARANTY LIMITS AND TERMINATION

The Obligations of Borrower are also guaranteed by: (i) County of Santa Cruz (the "County Guarnator"); and (ii) Community Foundation Santa Cruz County, a California nonprofit public benefit corporation (the "Community Foundation Guarantor"). Together the County Guarantor and Community Foundation Guarantor are referred to herein as the "Other Guarantors" and each individually referred to as "Other Guarantor."

Gurantor's guarantee of the Obligations shall not exceed One Million Dollars ($1 million) of the Obligations, and is further limited to the following amounts (the following amounts, which are not to exceed $1 million, are referred to herein as the "Guaranty Amount"): (i) twenty percent (20%) of all dollar amounts owed by Borrower

under the Loan Documents that were incurred during the first year following the date of the Promissory Note; (ii) twenty-five percent (25%) of all dollar amounts owed by Borrower under the Loan Documents that were incurred during the period beginning one (1) year after the date of the Promissory Note; and (iii) thirty three and 1/3 percent (33.333%) of all dollar amounts owed by Borrower under the Loan Documents that were incurred beginning two (2) years after the date of the Promissory Note. Notwithstanding the foregoing, if any Other Guarantor fails to pay a portion or all of the amounts that such Other Guarantor is required to pay under the guaranty executed by the Other Guarantor, then such occurance shall not reduce the amounts Guarantor is required to pay to Lender under this Guaranty. Additionally, Guarantor acknowledges, understands and agrees that, except as provided above, Lender's recourse against Guarantor, and Lender's rights and remedies under this Guaranty, are not limited (or otherwise affected) by the guaranties provided by the Other Guarantors.

Any termination of this Guaranty shall be applicable only to transactions having their inception after the effective date of termination and shall not affect any rights or Obligations arising out of transactions having their inception prior to such date even if subsequent to such termination the Obligations are modified, renewed, compromised, extended, or otherwise amended (including, but not limited to, an increase in the interest rate applicable to the Obligations). Any termination of this Guaranty shall only be effective upon actual receipt by Lender of a written notice of termination signed by Guarantor and shall be effective five (5) business days after the actual receipt by Lender of such notice of termination.

4. INDEPENDENT OBLIGATION

Guarantor agrees (i) that Guarantor is directly and primarily liable to Lender; (ii) that the obligations of Guarantor hereunder are separate and independent of the Obligations of Borrower, or of any other guarantor of Borrower's Obligations; and (iii) that Lender may file a separate action or actions at law against the Guarantor to enforce this Guaranty and may exercise any rights or remedies that Lender may have against collateral securing performance under the terms of this Guaranty.

5. INSOLVENCY OF GUARANTOR OR BORROWER

In the event that any bankruptcy, insolvency, receivership or similar proceeding is instituted by or against Guarantor and/or the Borrower or in the event that either the Guarantor or Borrower becomes insolvent, makes an assignment for the benefit of creditors, or attempts to effect a composition with creditors, at Lender's election, without notice or demand, the obligations of Guarantor created hereunder shall become due, payable and enforceable against Guarantor whether or not the Obligations are then due and payable.

6. WAIVERS

In consideration of the extension by Lender to Borrower of existing and future loans, credit facilities and other financial accommodations, Guarantor hereby knowingly and irrevocably waives each and all of the following:

6.1 The right to require Lender to prosecute or seek to enforce any remedies against Borrower or any other party liable to Lender on account of the Obligations and/or to require Lender to seek to enforce or resort to any remedies with respect to any security interests, liens or encumbrances granted to Lender to secure the Obligations before making demand under and/or seeking to enforce this Guaranty.

6.2 Any defense to the enforcement of this Guaranty arising out of or in any way related to (i) any modification, amendment, supplement, extension, accord and satisfaction, settlement or termination of the Loan Documents or other contract or agreement to which Lender and Borrower may hereafter agree, (ii) any modification, amendment, supplement, alteration, extension, accord and satisfaction or termination of the Obligations or any collateral at any time securing the Obligations (collectively, the "Collateral"), or (iii) any agreements or arrangements whatsoever between Lender and Borrower or with anyone else.

6.3 Any rights to assert against Lender any defense (legal or equitable), set-off, counterclaim, and/or claim which Guarantor now, or at any time hereafter, may have against Borrower and/or any other party liable to Lender in any way or manner.

6.4 Any and all defenses, counterclaims and offsets of any kind or nature, arising directly or indirectly from the present or future lack of perfection, sufficiency, validity and/or enforceability of the Loan Documents or this Guaranty including acts or omissions which may discharge Borrower due to the unenforceability of the Loan Documents or other guarantees. Guarantor further waives: Section 1111(b)(2) of the U. S. Bankruptcy Code (the "Code"); any extension of credit or grant of lien under Section 364 of the Code; any use of cash collateral under Section 363 of the Code; any agreement or stipulation as to the provision of adequate protection in any bankruptcy proceeding; the avoidance of any lien in favor of Lender for any reason; or any bankruptcy, insolvency, reorganization, arrangement or readjustment of debt, liquidation or dissolution proceeding commenced by or against Borrower, the undersigned or any other guarantor, maker or endorser, including

without limitation, any discharge of, or bar or stay against collecting, all or any of the indebtedness (or any interest thereon), in or as a result of any such proceeding; any indebtedness exceeding the Guarantor's liability hereunder. Guarantor further waives any rights or defenses it may have with regard to: any election by Lender under Section 9604 of the California Uniform Commercial Code as to any Collateral or any collateral securing any other guarantee of the Obligations; or any action taken by Lender that is authorized by this Guaranty.

6.5 All rights to assert any defense to the enforcement of this Guaranty on the grounds that (i) Lender has released voluntarily or involuntarily the Borrower or any other guarantor, (ii) Lender has modified the Loan Documents or any other contract between Borrower and Lender, or (iii) Lender has released or agreed to accept a substitution of all or any part of the Collateral without the consent of Guarantor. Guarantor further agrees that any releases which may be given by Lender to Borrower or any other guarantor or endorser shall not release any obligation of performance by Guarantor under the terms of this Guaranty. Guarantor further agrees that the Lender may proceed against the Guarantor and any collateral securing Guarantor's obligations under this Guaranty at any time and in any order that it chooses without regard to other guarantors, the Borrower or other available collateral and the Guarantor waives all rights to require the Lender to marshal the Collateral.

6.6 Any and all rights and defenses that Guarantor may have because any Obligation is secured by a lien on real property. This means, among other things: (i) Lender may collect from Guarantor without first foreclosing on any real or personal property that is included in the Collateral; (ii) if Lender forecloses on any real property Collateral: (a) the amount of the Obligation may be reduced only by the price for which that Collateral is sold at the foreclosure sale, even if the real estate Collateral is worth more than the sale price, (b) the Lender may collect from Guarantor even if Lender, by foreclosing on any real property that may be included in the Collateral, has destroyed any right Guarantor may have to collect from Borrower. This is an unconditional and irrevocable waiver of any rights and defenses Guarantor may have with regard to the Obligations. These rights and defenses include, but are not limited to, any rights and defenses based on Section 580a, 580b, 580d, or 726 of the California Code of Civil Procedure. As an illustration, without limiting the foregoing, Guarantor waives and relinquishes all rights, remedies and defenses that Guarantor may have: (1) under any law which may limit the amount of a deficiency judgment based on any obligation secured hereby; (2) under any bar to deficiency judgments; (3) any requirement of law that Lender exhaust any security for the Obligations guaranteed hereby before proceeding against Guarantor; (4) under any law which may prohibit Lender from enforcing its rights and remedies against Guarantor by both a private trustee's sale and an action in court; (5) under any law which requires that a court action to enforce Lender's rights by an action to foreclose any deed of trust; and (6) by reason of an election of remedies by Lender, including but not limited to the exercise of nonjudicial or judicial remedies against Borrower or any guarantor, Borrower's or any guarantor's real and/or personal property, or any other security for the Obligation guaranteed hereby in whatever order of manner Lender may determine, which may, in any manner, impair, affect, reduce, release, destroy, and/or extinguish Guarantor's subrogation rights, rights to proceed against Borrower for reimbursement, and/or other rights of Guarantor to proceed against Borrower, any guarantor, or against any other person or security including, without limitation, any loss of rights that Guarantor may suffer in connection with any anti-deficiency laws or any other laws limiting, qualifying or discharging indebtedness of or remedies against Borrower or any other person. Guarantor agrees that if all, or a portion, of the Obligation guaranteed hereby are at any time secured by any deed of trust or other interest in real property, Lender, in its sole discretion and without notice or demand and without affecting the security of any deed of trust, may exercise all its rights and remedies against Borrower or any guarantor, Borrower's or any guarantor's real and personal property, and any other security for the Obligation guaranteed hereby in whatever order or manner Lender may determine, including without limitation, nonjudicial foreclosure of any real property security. Without limiting the generality of the foregoing or any other provision hereof, Guarantor hereby expressly waives any and all benefits that might otherwise be available to Guarantor under California Civil Code Sections 2787 to 2855, 2899 and 3433 (as such sections may be amended or recodified from time to time), and California Code of Civil Procedure Sections 580a, 580b, 580d and 726 (as such sections may be amended or recodified from time to time). Guarantor hereby acknowledges and understands that Lender may obtain a judgment against Guarantor for the entire Obligation or any deficiency balance thereof following foreclosure of real or person property without regard to the fair market value of the property, the method of foreclosure or that fact that the Obligation arises from a purchase money transaction.

6.7 Any and all presentments, demands for performance, notices of non-performance, protests, notices of protest, notices of dishonor, notices of default, notice of acceptance of this Guaranty, and notices of the existence, creation, or incurring of new or additional indebtedness, and all other notices or formalities to which Guarantor may be entitled.

6.8 To the extent permitted by law, any and all rights to a jury trial in any action hereunder or arising out of Lender's transactions with Borrower.

7. INDEMNITY

Guarantor agrees to indemnify Lender and hold Lender harmless against all obligations, demands, claims and liabilities claimed or asserted by any other party and against all losses in any way suffered, incurred, or paid by Lender as a result of or in any way arising out of, following, or consequential to this Guaranty or to transactions with Borrower whether under the Loan Documents, or otherwise.

8. SCOPE OF LENDER'S AUTHORITY

Guarantor hereby irrevocably authorizes Lender, without notice or demand and without affecting its liability hereunder, from time to time to:

8.1 Renew, compromise, extend, accelerate, or otherwise change the time for payment or the terms of any of the Obligations, or any part thereof, including, without limitation, increasing or decreasing the rate of interest thereof;

8.2 Take and hold security for the payment of the Obligations guaranteed hereby, and exchange, enforce, waive, and release any such security without obtaining consent of Guarantors;

8.3 Apply such security and direct the order or manner of sale thereof as Lender in its discretion may determine;

8.4 Release or substitute any one or more endorser(s) or guarantor(s); and

8.5 Assign, without notice, this Guaranty in whole or in part and/or Lender's rights hereunder to anyone at any time.

Guarantor agrees that Lender may do any or all of the foregoing in such manner, upon such terms, and at such times as Lender, in its discretion, deems advisable, without, in any way or respect, impairing, affecting, reducing or releasing Guarantor. Guarantor hereby consents to each and all of the foregoing acts, events and/or occurrences.

9. SUBORDINATION OF OTHER DEBTS

Guarantor hereby subordinates and postpones any and all present and future debts and obligations of Borrower to Guarantor to the full payment and performance of all present and future debts and obligations of Borrower to Lender. All monies or other property of Guarantor at any time in Lender's possession may be held by Lender as security for any and all obligations of Guarantor to Lender no matter how or when arising, whether absolute or contingent, whether due or to become due, and whether under this Guaranty or otherwise. Guarantor also agrees that Lender's books and records showing the account between Lender and Borrower shall be admissible in any action or proceeding and shall be binding upon Guarantor for the purpose of establishing the terms set forth therein and shall constitute prima facie proof thereof. At the request of Lender, Borrower shall pay to Lender all or any part of such subordinated indebtedness and any amount so paid to Lender at its request shall be applied to payment of the indebtedness. Each payment on the indebtedness of Borrower to Guarantor received in violation of any of the provisions hereof shall be deemed to have been received by the Guarantor as trustee for Lender and shall be paid over to Lender immediately on account of the indebtedness, but without otherwise affecting in any manner Guarantor's liability under any of the provisions of this Guaranty. Guarantor agrees to file all claims against Borrower in any bankruptcy or other proceeding in which the filing of claims is required by law in respect of any indebtedness of Borrower to Guarantor, and Lender shall be entitled to all of Guarantor's rights thereunder. If, for any reason, Guarantor fails to file such claim at least 30 days prior to the last date on which such claim should be filed, Lender, as Guarantor's attorney in fact, is hereby authorized to do so in Guarantor's name or, in Lender's discretion, to assign such claim to and cause proof of claim to be filed in the name of Lender's nominee. In all cases, whether in administration, bankruptcy or otherwise, the person or persons authorized to pay such claim shall pay to Lender the full amount payable on the claim in the proceeding, and to the full extent necessary for that purpose, Guarantor hereby assigns Lender all Guarantor's rights to any payments or distributions to which Guarantor otherwise would be entitled.

10. GUARANTOR'S DUTY TO INVESTIGATE

Guarantor is presently informed of the financial condition of the Borrower and of all other circumstances which a diligent inquiry would reveal and which bear upon the risk of nonpayment of the Obligations. Guarantor hereby covenants that Guarantor will continue to keep itself informed of Borrower's financial condition, the status of other guarantors, if any, and of all other circumstances which bear upon the risk of nonpayment. Absent a written request for such information by Guarantor to Lender and written consent to the release of such information by Borrower, Guarantor hereby waives Guarantor's rights, if any, to require Lender to disclose to it any information which Lender may now or hereafter acquire concerning such condition or circumstances including, but not limited to, the release of or revocation by any other guarantor, the substitution of collateral securing the primary obligation or any guaranty, or any act, event or condition which may constitute an event of default of any guaranty or the Loan Documents.

11. REVIVAL OF GUARANTY

If any payments of money or transfers of property made to Lender by Borrower, or other guarantor, any maker or any endorser should for any reason subsequently be declared to be, or in Lender's counsel's good faith opinion be determined to be, fraudulent (within the meaning of any state or federal law relating to fraudulent conveyances), preferential or otherwise voidable or recoverable in whole or in part for any reason (hereinafter collectively called "voidable transfer"), the amount repaid or restored and all costs and expenses (including attorney's fees) of Lender related thereto, Guarantor's liability hereunder shall automatically be revived, reinstated and restored and shall exist as though such voidable transfer had never been made to Lender. In the event Lender shall have returned this Guaranty to Guarantor and subsequently be required or advised by counsel to restore or repay any such voidable transfer, the amount thereof, or any portion thereof, Guarantor shall remain liable as provided herein to the same extent as if this Guaranty had not been returned to Guarantor.

12. TERM OF OBLIGATIONS

This Guaranty shall continue in full force and effect until Borrower's Obligations are fully paid, performed and discharged and Lender give the Guarantor written notice of that fact. Borrower's Obligations shall not be considered fully paid, performed and discharged unless and until all payments by Borrower to Lender are no longer subject to any right on the part of any person whomsoever, including but not limited to Borrower, Borrower as a debtor in possession, and/or any trustee in bankruptcy, to set aside such payments or seek to recoup the amount of such payments, or any part thereof. The foregoing shall include, by way of example and not by way of limitation, all rights to recover preferences voidable under Title 11 of the United States Code. In the event that any such payments by Borrower to Lender are set aside after the making thereof, in whole or in part, or settled without litigation, to the extent of such settlement, all of which is within Lender's discretion, Guarantor shall be liable for the full amount Lender is required to repay plus costs, interest, attorneys' fees and all expenses which Lender paid or incurred in connection therewith.

13. FINANCIAL STATEMENTS AND TAX RETURNS

13.1 **Financial Statements**.

(a) Within one hundred twenty (120) days after the close of each fiscal year of Guarantor, Guarantor shall deliver to Lender audited financial statement(s) of Guarantor prepared by an independent certified public accountant acceptable to Lender. All financial statements delivered to Lender shall include a balance sheet and profit and loss statement, and an independent certified public accountant's letter to management regarding the preparation of the financial statements.

(b) Guarantor shall deliver to Lender a certificate signed by the chief financial officer of Guarantor to the effect that all reports, statements, or computer-prepared information of any kind or nature delivered or caused to be delivered to Lender under this Guaranty are accurate, true and fairly present the financial condition of Guarantor.

13.2 **Tax Returns**. If Guarantor files a federal income tax return with the Internal Revenue Service, then within one hundred twenty (120) days after the filing Guarantor shall provide Lender with a copy of the signed tax return filed with the Internal Revenue Service as filed by Guarantor.

13.3 **Other Reports**. Guarantor shall deliver to Lender other reports reasonably requested by Lender relating to the financial condition of Guarantor.

14. WAIVER OF RIGHT OF SUBROGATION

Guarantor expressly waives and releases any and all rights of subrogation, reimbursement, indemnity or contribution which it may now or hereafter have against: (1) Borrower, any other guarantor or any person who now or hereafter has direct or contingent liability (whether by contract, at law or in equity) for all or any portion of the Obligations guaranteed hereby; or (2) against any property which now or hereafter serves as collateral security for the obligations guaranteed hereby. If and to the extent such waiver and release is unenforceable, Guarantor hereby agrees that all such rights of subrogation, reimbursement, indemnity and contribution shall be junior and subordinate to the right of Lender to obtain payment and performance of the Obligations guaranteed hereby and to all rights of Lender in and to any property which now or hereafter serves as collateral security for such Obligations.

15. SURVIVAL

This Guaranty shall be binding upon the successors and assigns of the Guarantor and shall inure to the benefit of Lender's successors and assigns, including all receivers, trustees, administrators and other successors in interest of Guarantor. The death of Guarantor and the incapacity, lack of authority, death, disability or revocation hereof by any other guarantor shall not terminate or otherwise impair this Guaranty. All Obligations hereunder shall survive the foregoing events and shall be fully satisfied before Guarantor may proceed with action to obtain subrogation, contribution or reimbursement against Borrower.

16. MODIFICATIONS

No modification of this Guaranty shall be effective for any purpose unless it is in writing and executed by an officer of Lender authorized to do so. This Guaranty merges all negotiations, stipulations and provisions relating to the subject matter of this Guaranty which proceed or may accompany the execution of this Guaranty.

17. EXCLUSIVE AGREEMENT

Guarantor acknowledges and agrees that this Guaranty represents the sole and exclusive and final expression of the agreement between the Lender and the Guarantor and that it supersedes and extinguishes all prior negotiations, oral and written representations, covenants or conditions including other agreements between the Guarantor and the Lender but explicitly does not supersede prior guaranties which are intended to guaranty other obligations of the same Borrower or other borrowers. In the event that there is a prior guaranty of the Obligation this Guaranty does not supersede such prior guaranties between Guarantor and Lender but is intended to be a separate and additional guaranty of the obligation. Guarantor declares that he/she/it has not relied on any warranty, representation, covenant or condition made by Lender which may qualify this Guaranty or contains any different terms than provided for herein. Further, Guarantor has not signed any other agreement or document in connection with guaranteeing the obligations hereunder which in any way modifies or restricts Guarantor's obligation to perform under the terms of this Guaranty. Guarantor waives any right to have any term or condition of this Guaranty modified or changed by the introduction of prior discussions or negotiations of the parties whether written or oral. Guarantor understands and acknowledges all of the waivers contained in this Guaranty and has consulted legal counsel or other sources to understand the nature and extent of the waivers and acknowledges that the waivers are enforceable. If any such waivers are determined to be against public policy, the waiver shall be enforced to the extent appropriate under law.

18. TERMS OF THE GUARANTY

Guarantor acknowledges and agrees that he/she/it has read the guaranty and fully understands all of the terms thereof. The Guarantor further agrees that the guaranty is the complete and accurate expression of the Guarantor's understanding of the agreement between the Guarantor and the Lender and that Guarantor has not relied on any other agreement or representations in executing this Guaranty.

19. ATTORNEY FEES

Guarantor agrees to pay reasonable attorneys' fees and all other costs and expenses which may be incurred by Lender in the enforcement of this Guaranty or in any way arising out of, following, or consequential to the enforcement of Borrower's Obligations, whether under this Guaranty, the Agreement, or otherwise.

20. GOVERNING LAW AND VENUE

20.1 **Demand; Protest, etc**. Guarantor waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension or renewal of any commercial paper, accounts, documents, instruments, chattel paper, and guarantees at any time held by Lender on which Guarantor may in any way be liable.

20.2 **Jury Trial**. Unless prohibited under the laws that govern an action or proceeding relating to this Guaranty or related agreements entered into in connection herewith, Guarantor waives any right to trial by jury in any action or proceeding relating to this Guaranty or any of the agreements entered into in connection herewith.

20.3 **Choice of Law and Venue**. The validity of this Guaranty, its construction, interpretation, and enforcement, and the rights of the parties hereunder and concerning the Collateral, shall be determined under, governed by, and construed in accordance with the laws of the State of California. The parties agree that all actions or proceedings arising in connection with this Guaranty shall be tried and litigated only in the state and federal courts located in the County of Santa Cruz. Guarantor waives any right it may have to assert the doctrine of *forum non conveniens* or to object to such venue and hereby consents to any court ordered relief.

21. COUNTERPART EXECUTION

This Guaranty may be executed in several counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same Guaranty.

22. NOTICES

Except as otherwise provided herein, any notice or other communication required or permitted to be given under this Guaranty shall be in writing and shall be personally served by messenger, or sent by a commercial overnight delivery service (such as Federal Express), or by certified mail, return receipt requested, and shall be deemed given on the date actually received if served by messenger, or on the next business day after deposit with an overnight delivery service, or on the date of receipt as shown on the return receipt if sent by certified mail. The addresses of the parties to which notices and other communications shall be sent (until notice of a change thereof is served as provided herein) are set forth below. Any party to this Guaranty may change its address for giving notices or demands hereunder by written notice of such change to the other party in accordance with the provisions hereof. Guarantor shall promptly notify Lender of any change of its mailing address in the manner prescribed by this paragraph.

GUARANTOR:
Name: SALUD PARA LA GENTE
Address: SALUD PARA LA GENTE
Attn: Doris Rose
195 Aviation Way, Suite 200
Watsonville, CA 95076

LENDER:
Name: SANTA CRUZ COUNTY BANK
Address: SANTA CRUZ COUNTY BANK
Attn: Note Department
P.O. Box 8426
Santa Cruz, CA 95061

23. PLURAL

If more than one Guarantor executes this Guaranty, all references to Guarantor shall be changed to mean all Guarantors and all Guarantors shall be jointly and severally liable for all Obligations hereunder unless expressly provided otherwise by this Guaranty.

[*Remainder of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, this Guaranty is executed on behalf of the Guarantor on the date provided below.

Date: November 1, 2023

GUARANTOR:

SALUD PARA LA GENTE, a California nonprofit public benefit corporation

By: _____
Name: Donna Young
Title: CEO

SECURITY AGREEMENT

THIS SECURITY AGREEMENT ("Agreement") is dated for reference purpose November 1, 2023 ("Effective Date"), by PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION, a California nonprofit public benefit corporation ("Debtor") in favor of SANTA CRUZ COUNTY BANK, a California state-chartered bank ("Lender"), with references to the following recitals:

ARTICLE I: RECITALS

1.1 Lender has agreed to provide a revolving line of credit to Debtor and to PAJARO VALLEY HEALTHCARE DISTRICT, a California nonprofit public benefit corporation ("PVHD") in the initial original principal amount of FIVE MILLION DOLLARS ($5,000,000.00) (the "Loan"), to be evidenced by a promissory note in the original principal amount of the Loan and executed by Debtor and PVHD as co-borrowers to the order of Lender ("Note"). The credit limit on the Loan is to decrease as provided in the Note.

1.2 As a condition to making the Loan to Debtor, Lender has required that Debtor grant to Lender a security interest in certain personal property assets of Debtor (more particularly described in the definition of the term "Collateral" set forth below) to secure repayment of the Loan, all amounts payable by Debtor under this Agreement, the Note and any other agreement, document or instrument executed by Debtor (and/or PVHD) in connection with the Loan (collectively, the "Loan Documents") and to secure performance by Debtor of all other "Obligations" (as that term is defined below).

NOW THEREFORE, IN CONSIDERATION OF THE MUTUAL BENEFITS ACCRUING TO THE PARTIES HERETO AND OTHER VALUABLE CONSIDERATION, THE RECEIPT AND SUFFICIENCY OF WHICH IS HEREBY ACKNOWLEDGED, THE PARTIES HERETO DECLARE, UNDERSTAND AND AGREE TO THE FOLLOWING TERMS:

ARTICLE II: DEFINITIONS

Capitalized terms in this Agreement that are not defined when first used shall have the meanings set forth below.

2.1 Accounts. The term "Accounts" shall mean all presently existing and hereafter arising accounts, as such term is defined in the "UCC," including, without limitation, accounts receivable, contract receivables, receivables of any kind, deposit accounts, and all other forms of obligations owing to Debtor arising out of the sale or lease of goods or the rendition of services by Debtor, whether or not earned by performance, and any and all credit insurance, guaranties, and other security therefor, and Debtor's Books relating to any of the foregoing.

2.2 Cash Collateral. The term "Cash Collateral" shall mean all deposit accounts, monies, instruments, certificates of deposit, and related collateral.

2.3 Chattel Paper. The term "Chattel Paper" shall mean all chattel paper, as such term is defined in the UCC, now existing or hereinafter acquired, including, without limitation, leases, contracts, contracts now or hereinafter assigned to Debtor, and any other writing or writings which evidence a monetary obligation and a security interest in goods, and Debtor's Books relating to any of the foregoing.

2.4 Equipment. The term "Equipment" shall mean all of Debtor's present and hereafter acquired equipment, as such term is defined in the "UCC," including, without limitation, all machinery, machine tools, motors, furniture, furnishings, fixtures, tools, parts, dies, jigs, and any interest in any of the foregoing, and all attachments, accessories, accessions, replacements, substitutions, additions, and improvements to any of the foregoing, wherever located.

2.5 Event of Default. The term "Event of Default" shall mean the occurrence of one or more of the events described in Section 6 of this Agreement.

2.6 General Intangibles. The term "General Intangibles" shall mean all of Debtor's present and future general intangibles, as such term is defined in the UCC, including, without limitation, documents, documents of title, contract rights, leases, deposit accounts, insurance policies, guaranties, releases, any monies due from a factor, claims, choses or things in action, goodwill, patents, trade names, trademarks, service masks, rights arising under patent, copyright and trademark law, blueprints, drawings, purchase orders, customer lists,

monies due or recoverable from pension funds, route lists, infringement claims, computer programs, computer disks, computer tapes, literature, reports, catalogs, tax refunds and tax refund claims, and Debtor's books relating to any of the foregoing.

2.7 Instruments. The term "Instruments" shall mean all instruments, as such term is defined in the UCC, whether now existing or hereinafter acquired, including, without limitation, negotiable instruments, letters of credit, notes, drafts, documents of title, certificated and uncertificated securities, and any other writing which evidences a right to the payment of money, and Debtor's Books relating to any of the foregoing.

2.8 Inventory. The term "Inventory" shall mean all inventory, as such term is defined in the UCC, whether now existing or hereinafter acquired, including, without limitation, all used cars held by Debtor for sale or lease, all goods, machinery and equipment held by Debtor for sale or lease or to be furnished under a contract of service, all raw materials, work in progress, finished goods, packing and shipping materials, all goods returned or reclaimed relating to the foregoing, and all documents of title representing any of the foregoing, and Debtor's Books relating to any of the foregoing.

2.9 Obligations. The term "Obligations" shall mean: (i) all amounts owed by Debtor to Lender in connection with the Loan and under the Loan Documents, with interest thereon, and all other amounts payable by Debtor under the Loan Documents, whether direct or indirect, absolute or contingent, due or to become due, now existing or hereafter arising, and including any debt, liability, or obligation owing from Debtor to others which Lender may have obtained by assignment or otherwise, and further including all interest not paid when due which Debtor is required to pay or reimburse under the Loan Documents, by law or otherwise; and (ii) all non-monetary obligations of Debtor under the Loan Documents.

2.10 UCC. The term "UCC" shall mean the Uniform Commercial Code as enacted in the state whose law applies with respect to the creation, perfection and enforcement of Lender's rights as to the Collateral.

ARTICLE III: SECURITY INTEREST

3.1 Grant. As security for the due and timely performance of all Obligations, and the due and timely performance of all obligations of Debtor hereunder, Debtor hereby transfers, conveys, grants and assigns to Lender a security interest in the "Collateral" (as defined below).

The term "Collateral" shall include all of Debtor's rights, title and interests in each of the following: Accounts, Cash Collateral, Chattel Paper, Equipment, General Intangibles, Instruments, Inventory, all deposit accounts, all monies, all lock box accounts, and all other assets of Debtor which hereafter come into the possession, custody or control of Lender, and all proceeds whether tangible or intangible, of each and all of the foregoing including, without limitation, all rights under any insurance policies, and the proceeds thereof, insuring against loss, damage or destruction of the any of the foregoing.

3.2 Perfection of Security Interest. Debtor agrees to and shall take all actions that may be necessary or appropriate or that Lender may at any time or from time to time request as necessary in the opinion of Lender to perfect and maintain the perfection of Lender's security interest in the Collateral as a first priority lien, subject to no other liens or encumbrances. Specifically, but without limiting the generality of the foregoing, Debtor hereby irrevocably constitutes and appoints Lender the attorney-in-fact of Debtor to execute, deliver and, if appropriate, to file and/or record with the appropriate filing officer or office such security agreements, financing statements, notices, continuation statements and other instruments as Lender may request or require in order to impose, perfect or continue the perfection of Lender's security interest in the Collateral.

ARTICLE IV: DEBTOR'S REPRESENTATIONS AND WARRANTIES

4.1 Authority. Debtor has all requisite power and authority to enter into this Agreement and to grant to Lender a security interest in the Collateral.

4.2 No Violation of Any Agreement. The execution, delivery and performance of this Agreement by Debtor does not violate any agreement to which Debtor is a party or by which Debtor or Debtor's property is or may be bound, and no consent of, notice to, approval of or withholding of objection by any person or organization, including any governmental agency, is required in connection with such execution, delivery and performance.

4.3 Binding Obligation. This Agreement constitutes a legally valid and binding obligation of Debtor, enforceable against Debtor in accordance with its terms, except as limited by applicable bankruptcy, insolvency, or reorganization or similar laws affecting the enforcement of creditors' rights generally.

4.4 No Other Assignment. Debtor has not executed any other document or agreement assigning or otherwise transferring any interest in and to the Collateral or Debtor's rights therein, except pursuant to this Agreement.

4.5 No Action or Proceeding. There is no action or proceeding pending by or against Debtor before any court or administrative agency, and Debtor has no knowledge of any pending, threatened or imminent litigation, governmental investigation or claim, complaint, action or prosecution involving Debtor, except with regard to (i) ongoing collection matters in which Debtor is the plaintiff, and (ii) other matters heretofore disclosed, in writing, to Lender. If any of the foregoing arise during the term of this Agreement, Debtor shall immediately notify Lender in writing.

ARTICLE V: AFFIRMATIVE COVENANTS OF DEBTOR

Until all Obligations have been fully satisfied, unless Lender waives compliance in writing, Debtor agrees and covenants as follows:

5.1 Compliance with Terms of Loan Documents. Debtor shall comply with each and all of the terms and conditions contained in the Loan Documents.

5.2 Taxes, Assessments and Other Charges. Debtor shall duly and promptly pay and discharge, as the same become due and payable, all taxes, assessments, and governmental and other charges, levies or claims levied or imposed, or which if unpaid might become a lien or charge, upon the properties, assets, earnings or business of Debtor, except for such taxes, assessment, charges, levies or claims that are being diligently contested in good faith by Debtor and Debtor has made appropriate provisions, approved by Lender, to pay and discharge same upon resolution of any dispute. If Debtor fails to pay any such tax, assessment, charge, levy or claim, Lender may, in its sole and absolute discretion and without notice to Debtor, make payment of the same or any part thereof as Lender deems necessary to satisfy the liability therefor. Lender may conclusively rely on the usual statements of the amount owing or other official statements issued by the appropriate governmental agency.

5.3 Payment of Obligations. Debtor shall pay all of its liabilities and obligations when due and prior to the date on which penalties attach thereto and will keep all existing debts current.

5.4 Laws. Debtor shall comply with all applicable statutes and regulations affecting the ownership of its property and the conduct of its business.

5.5 Notice of Certain Events. Debtor shall give prompt written notice to Lender of: (i) all events of default under any of the terms or provisions of this Agreement or any other agreement entered into by Debtor; (ii) material changes in management of Debtor; (iii) litigation, arbitration, or filing of any judgment or lien with Debtor as a party; (iv) initiation of any bankruptcy proceeding with regard to Debtor; and (v) any other matter which has resulted in, or might reasonably be expected to result in, a material adverse change in Debtor's financial condition or operations.

5.6 Execution of Other Documents. Debtor shall promptly execute and deliver all supplements and amendments hereto, and all financing statements, fixture filings, continuation statements and such additional agreements, instruments and assurances in connection with this Agreement as Lender reasonably requests to effectuate the provisions hereof.

5.7 Asset Forfeiture. Debtor covenants and agrees that it has not committed and shall not commit any act or engage in any conduct which shall cause the Collateral or any assets of Debtor to be subject to any claim by the federal, state or local government, now or in the future, under the asset forfeiture laws or regulations promulgated thereunder and as may be amended from time to time.

5.8 Insurance. Debtor shall maintain insurance covering the Collateral and in accordance with the insurance requirements provided in the Loan Documents.

5.9 No Other Assignment. Debtor shall not execute any other document or agreement assigning or otherwise transferring any interest in and to the Collateral or Debtor's rights therein, except pursuant to this Agreement or upon Lender's express written consent.

5.10 Other Information. Debtor shall promptly supply Lender with such other information concerning its business and general financial condition as Lender may reasonably request from time to time.

ARTICLE VI: DEFAULT AND REMEDIES

6.1 Events of Default. Any one or more of the following shall constitute an "Event of Default" for purposes of this Agreement (references below to "Borrower" has the meaning provided in the Note):

(a) Debtor fails or neglects to perform, or observe when due, any term, provision, condition, covenant, warranty or representation contained in this Agreement;

(b) Borrower fails to pay within ten (10) days after the date due and payable, or after the date when declared due and payable, any amounts payable under the Note (whether of principal, interest, late payment charge, prepayment premium, or otherwise) and other Loan Documents;

(c) Any Borrower fails or neglects to perform, or observe when due, any term, provision, condition, covenant, warranty or representation contained in any Loan Documents, or in any other present or future agreement or arrangement between any Borrower and Lender, and such default shall not have been cured within the timeframe for curing such default as provided in the Loan Documents;

(d) There is a material impairment of the prospective of repayment of any portion of the amounts owing to Lender under the Note or other Loan Documents;

(e) There is a material impairment of the value or priority of Lender's security interests in any Collateral;

(f) Any material portion of any Borrower's assets are attached, seized, subjected to a writ or distress warrant, or are levied upon, or come into the possession of any judicial officer, or any lien is filed or recorded against the assets of than any Borrower by a governmental agency, or any judgment against the Borrower becomes a lien against any of any Borrower's assets;

(g) A voluntary or involuntary petition in bankruptcy or for reorganization or for an arrangement or any composition, readjustment, liquidation, dissolution or similar relief pursuant to the federal bankruptcy law or under similar present or future federal or state bankruptcy or insolvency law, is filed by or against any Borrower, and such petition is not dismissed within sixty (60) days thereafter;

(h) A receiver, trustee or liquidator (or other similar official) is appointed for any Borrower or for all or any substantial part of its assets and is not discharged within sixty (60) days thereafter;

(i) Any Borrower makes an assignment of all or any portion of its assets for the benefit of creditors;

(j) Any Borrower is enjoined, restrained, or in any way prevented by court order from continuing to conduct all or any material part of its business affairs;

(k) There is a default in any material agreement to which Borrower is a party with third parties resulting in a right by such third parties to accelerate the maturity of Borrower's indebtedness;

(l) Any guarantor of any of the Obligations dies, ceases to exist as going concern, terminates its guaranty, or becomes the subject of any insolvency proceeding;

(m) Any government agency files a lien or commences an action or any third party files a claim or lawsuit against Borrower in connection with a violation of state or federal environmental statutes, which claim may result in a substantial fine or penalty or the payment of damages;

(n) Any agency of the federal, state or local government commences any proceedings against Borrower or any guarantor, or the assets of either, for the purpose of enforcing forfeiture rights as provided by federal or state law, or Borrower or any guarantor is the subject of any investigation or any complaint or bill of indictment has been brought against Borrower or any guarantor in connection with conduct the penalty for which is forfeiture of all or any portion of Borrower's or guarantor's assets;

(o) Any Borrower suspends its business or ceases doing business as a going concern;

(p) Any other default occurs under the Loan Documents, and such default is not cured within the time period to cure (if applicable) as provided in the Loan Documents; and/or

(q) Any of the foregoing events occur with respect to any guarantor of any of the Obligations.

6.2 Remedies upon Default. Upon the occurrence of an Event of Default under this Agreement, Lender may, at its election, without notice and without demand, do any one or more of the following, all of which are authorized by Debtor (references below to "Borrower" has the meaning provided in the Note):

(a) Exercise any of Lender's rights and remedies under the Loan Documents.

(b) Without notice to or demand upon Debtor, make such payments and do such acts as Lender considers necessary or reasonable to protect its security interest in the Collateral, including without limitation to pay, purchase, contest or compromise any lien, encumbrance, interest or charge which, in the opinion of Lender, appears to be prior or superior to its security interest and to pay, on Debtor's behalf, all expenses incurred in connection therewith.

(c) Declare all amounts owed to Lender under the Loan Documents immediately due and payable;

(d) Cease extending credit to or for the benefit of any Borrower under the Loan Documents or under any other agreement between any Borrower and Lender.

(e) Without notice to or demand upon Debtor or any guarantor, make such payments and do such acts as Lender considers necessary or reasonable to protect its security interest in the Collateral as permitted by the UCC, at law or in equity, and Debtor agrees to immediately reimburse Lender in good and collectible funds for the full amount of such payments.

(f) Terminate this Agreement and any of the other Loan Documents as to any future liability or obligation of Lender, but without affecting Lender's rights and security interest in the Collateral and without affecting any amounts owing by any Borrower to Lender under the Loan Documents.

(g) Have and exercise all the rights and remedies provided to a secured party by the UCC with respect to all parts of the Collateral or from Debtor.

(h) Institute proceedings for the collection of all amounts owed to Lender under the Loan Documents, and whether by declaration or otherwise, enforce any judgment obtained and collect monies adjudged due from the Collateral or from Debtor.

(i) Take any other appropriate action to protect and enforce the rights and remedies of Lender hereunder.

6.3 Sale of Collateral. If Lender so elects, Lender may sell or dispose of, or cause the sale or disposal of, the Collateral at one or more public or private sales, or both, by way of one or more finance contracts or transactions, for cash or on terms, in such manner and at such places as is commercially reasonable in the opinion of Lender. It is not necessary that the Collateral be present at any such sale.

(a) Lender shall give notice of the sale or disposition of all or any part of Collateral as provided in the UCC, in effect on the date such notice is given.

(b) Lender may bid for and acquire any portion of the Collateral at any public sale, and may pay all or part of the purchase price of such Collateral by crediting against amounts owing on monetary Obligations to the Lender all or part of the net proceeds of such sale after deducting expenses incurred by Lender in connection with such sale. The evidence of the Loan to be so credited need not be produced in order to complete any such sale or in order to cause there to be credited thereon its share of such net proceeds.

(c) If requested by Lender, Debtor shall use its best efforts to obtain qualified purchasers for the Collateral in connection with any sale. Lender will consider any bids for the Collateral submitted by Debtor prior to any private sale, but Lender shall have no obligation to accept any such bid.

6.4 Application of Proceeds. All monies received upon sale or disposition of the Collateral or any part thereof pursuant to this section shall be applied from time to time by Lender in accordance with the UCC. Lender shall be entitled to include within the expenses described in said section, all reasonable attorneys' fees and legal expenses of Lender, its agents and counsel incurred in connection with its enforcement of this section or the maintenance, preparation for sale, lease or other disposition of the Collateral. All monies, earnings, revenues, proceeds, rents, issues, profits and income derived pursuant to the exercise of Lender's rights and remedies under this section (after deducting Lender's expenses and other proper charges), and all other money or property received or recovered by Lender pursuant to this Agreement, shall be applied from time to time by Lender to the monetary Obligations.

6.5 Remedies Cumulative. Lender's rights and remedies under this Agreement, any other Loan Documents, and all other agreements or instruments executed by Debtor (and/or PVHD) shall be cumulative and not alternative, and shall be in addition to all rights, powers and remedies given to Lender under the UCC, other applicable law and in equity. No exercise by Lender of one right or remedy shall be deemed an election, and no waiver by Lender of any Event of Default shall be deemed a continuing waiver. No delay by Lender shall constitute a waiver, election, or acquiescence by it.

6.6 Deficiency Balance. Unless prohibited by law, any deficiency which exists after the sale or disposition of the Collateral as provided above will be paid immediately by Debtor. Any excess will be returned, without interest and subject to the rights of third parties, to Debtor.

ARTICLE VII: MISCELLANEOUS PROVISIONS

7.1 Power of Attorney. Debtor hereby irrevocably appoints Lender as Debtor's attorney-in-fact and proxy, with full authority in the place and stead of Debtor and in the name of Debtor or otherwise, in such Lender's discretion, at any time upon the occurrence and during the continuance of an Event of Default, to take any action and to execute any instrument which such Lender may deem necessary or advisable to accomplish the purposes of this Agreement, including (without limitation): (i) to obtain and adjust insurance required to be paid to Lender under the Loan Documents; (ii) to ask, demand, collect, sue for, recover, compound, receive and give acquittance and receipts for moneys due and to become due under or in respect of any of the Collateral; (iii) to receive, endorse and collect any drafts or other instruments, documents and Chattel Paper in connection with clause (i) or clause (ii) above; (iv) to file any claims or take any action or institute any proceedings that such Lender may deem necessary or desirable for the collection of any of the Collateral or otherwise to enforce the rights of Lender with respect to any of the Collateral; (v) to execute and file one or more financing or continuation statements, and amendments thereto, relating to the Collateral; and (vi) execute any documents needed for purposes of carrying out Lender's remedies in the Event of Default as described in Section 6.2 above. Lender shall be under no duty to exercise or withhold the exercise of any of the rights, powers, privileges, and options expressly or implicitly granted to Lender in this Agreement, and shall not be responsible for any failure to do so or any delay in doing so. Lender shall not be liable for any act or omission or for any error of judgment or any mistake of fact or law in their individual capacity or in their capacity as attorney-in-fact except acts or omissions resulting from such Lender's willful misconduct or gross negligence. This power of attorney is conferred on Lender solely to protect, preserve and realize upon the security interests in the Collateral and to take actions with regard to Lender's exercising its remedies in an Event of Default. Lender shall not be responsible for any decline in the value of the Collateral and shall not be required to take any steps to preserve rights against prior parties or to protect, preserve or maintain any security interest or lien given to secure the Collateral. The powers granted herein are coupled with an interest and shall be irrevocable from the date hereof and so long as any amounts owed the Lender under the Loan Documents are outstanding.

7.2 Relationship to Other Security Agreements. This Agreement is in addition to any other security or pledge agreements executed by Debtor or another party in connection with the Loan to grant Lender a security interest in property, and this Agreement does not replace or negate any other such security or pledge agreement.

7.3 Time of the Essence. Time is hereby declared to be of the essence of this Agreement and of every part hereof.

7.4 Effective Date. Notwithstanding the date on which this Agreement is actually signed by Debtor and Lender, the terms and conditions of this Agreement shall be applied, with full force and effect, as of the Effective Date.

7.5 Entire Agreement; Amendment. This Agreement and any agreements, instruments or documents referred to herein constitute the entire agreement among the parties hereto regarding the subject matter hereof, and all prior and/or contemporaneous communications, verbal or written, between or among the parties hereto regarding the subject matter hereof shall be of no further effect or evidentiary value. No course of prior dealing between the parties, no usage of trade, and no parole or extrinsic evidence of any nature shall be used

to supplement or modify any term of this Agreement This Agreement can be amended only by a written agreement executed by duly authorized representatives of the parties hereto.

7.6 Construction of Agreement. This Agreement shall be construed as though drafted by both parties and shall not be construed against or in favor of any one party. On the contrary, this Agreement has been reviewed by all parties hereto and shall be construed and interpreted according to the ordinary meaning of the words used so as to fairly accomplish the purposes and intentions of the parties hereto. Unless the context of this Agreement clearly requires otherwise, references to the plural include the singular, references to the singular include the plural, and references to the part include the whole. The use of the word "including" shall be construed as providing examples only and shall not limit the generality of any provision in which it is used. The use of the word "or" has the inclusive meaning represented by the phrase "and/or." The words "hereof," "herein," "hereby," "hereunder" and similar terms used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. Section, subsection, clause, and exhibit references are to this Agreement unless otherwise specified.

7.7 Severability. Each provision of this Agreement shall be severable from every other provision of this Agreement for the purpose of determining the legal enforceability of any specific provision.

7.8 Waivers.

(a) Demand; Protest, etc. Debtor waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension or renewal of any commercial paper, accounts, documents, instruments, chattel paper, and guarantees at any time held by Lender on which Debtor may in any way be liable.

(b) Jury Trial. Unless prohibited under the laws that govern an action or proceeding relating to this Agreement or related agreements entered into in connection herewith, Debtor and Lender each waive any right to trial by jury in any action or proceeding relating to this Agreement or any of the agreements entered into in connection herewith.

7.9 Governing Law. The validity of this Agreement, its construction, interpretation, and enforcement, and the rights of the parties hereunder and concerning the Collateral, shall be determined under, governed by, and construed in accordance with the laws of the State of California. The parties agree that all actions or proceedings arising in connection with this Agreement shall be tried and litigated only in the state and federal courts located in Santa Cruz County, State of California. Debtor waives any right it may have to assert the doctrine of *forum non conveniens* or to object to such venue and hereby consents to any court ordered relief.

7.10 Counterpart Execution. This Agreement may be executed in several counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same Agreement.

7.11 Attorneys' Fees. In the event any party to this Agreement shall be required to commence any action or proceeding against any other party by reason of any breach or claimed breach of any provision of this Agreement, to commence any action in any way connected with this Agreement, or to seek a judicial declaration of rights under this Agreement, the party prevailing in such action or proceeding shall be entitled to recover from the other party, or parties, the prevailing party's reasonable attorneys' fees and costs including, without limitation, all witness fees and associated expenses, including matters on appeal whether or not the proceeding or action proceeds to judgment.

IN WITNESS WHEREOF, this Agreement is executed by or on behalf of each party by its duly authorized representative(s) on the date(s) indicated below and effective as of the date set forth above.

DATE: November 1, 2023	**DATE: November 1, 2023**
DEBTOR:	**LENDER:**
PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION, a California nonprofit public benefit corporation	**SANTA CRUZ COUNTY BANK**, a California state-chartered Bank
By_____ Name_____ Title_____	By_____ Name_____ Title_____

SECURITY AGREEMENT

THIS SECURITY AGREEMENT ("Agreement") is dated for reference purpose November 1, 2023 ("Effective Date"), by PAJARO VALLEY HEALTHCARE DISTRICT, a California nonprofit public benefit corporation ("Debtor") in favor of SANTA CRUZ COUNTY BANK, a California state-chartered bank ("Lender"), with references to the following recitals:

ARTICLE I: RECITALS

1.1 Lender has agreed to provide a revolving line of credit to Debtor and to PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION, a California nonprofit public benefit corporation ("PVHDHC") in the initial original principal amount of FIVE MILLION DOLLARS ($5,000,000.00) (the "Loan"), to be evidenced by a promissory note in the original principal amount of the Loan and executed by Debtor and PVHDHC as co-borrowers to the order of Lender ("Note"). The credit limit on the Loan is to decrease as provided in the Note.

1.2 As a condition to making the Loan to Debtor, Lender has required that Debtor grant to Lender a security interest in certain personal property assets of Debtor (more particularly described in the definition of the term "Collateral" set forth below) to secure repayment of the Loan, all amounts payable by Debtor under this Agreement, the Note and any other agreement, document or instrument executed by Debtor (and/or PVHDHC) in connection with the Loan (collectively, the "Loan Documents") and to secure performance by Debtor of all other "Obligations" (as that term is defined below).

NOW THEREFORE, IN CONSIDERATION OF THE MUTUAL BENEFITS ACCRUING TO THE PARTIES HERETO AND OTHER VALUABLE CONSIDERATION, THE RECEIPT AND SUFFICIENCY OF WHICH IS HEREBY ACKNOWLEDGED, THE PARTIES HERETO DECLARE, UNDERSTAND AND AGREE TO THE FOLLOWING TERMS:

ARTICLE II: DEFINITIONS

Capitalized terms in this Agreement that are not defined when first used shall have the meanings set forth below.

2.1 Accounts. The term "Accounts" shall mean all presently existing and hereafter arising accounts, as such term is defined in the "UCC," including, without limitation, accounts receivable, contract receivables, receivables of any kind, deposit accounts, and all other forms of obligations owing to Debtor arising out of the sale or lease of goods or the rendition of services by Debtor, whether or not earned by performance, and any and all credit insurance, guaranties, and other security therefor, and Debtor's Books relating to any of the foregoing.

2.2 Cash Collateral. The term "Cash Collateral" shall mean all deposit accounts, monies, instruments, certificates of deposit, and related collateral.

2.3 Chattel Paper. The term "Chattel Paper" shall mean all chattel paper, as such term is defined in the UCC, now existing or hereinafter acquired, including, without limitation, leases, contracts, contracts now or hereinafter assigned to Debtor, and any other writing or writings which evidence a monetary obligation and a security interest in goods, and Debtor's Books relating to any of the foregoing.

2.4 Equipment. The term "Equipment" shall mean all of Debtor's present and hereafter acquired equipment, as such term is defined in the "UCC," including, without limitation, all machinery, machine tools, motors, furniture, furnishings, fixtures, tools, parts, dies, jigs, and any interest in any of the foregoing, and all attachments, accessories, accessions, replacements, substitutions, additions, and improvements to any of the foregoing, wherever located.

2.5 Event of Default. The term "Event of Default" shall mean the occurrence of one or more of the events described in Section 6 of this Agreement.

2.6 General Intangibles. The term "General Intangibles" shall mean all of Debtor's present and future general intangibles, as such term is defined in the UCC, including, without limitation, documents, documents of title, contract rights, leases, deposit accounts, insurance policies, guaranties, releases, any monies due from a factor, claims, choses or things in action, goodwill, patents, trade names, trademarks, service masks, rights arising under patent, copyright and trademark law, blueprints, drawings, purchase orders, customer lists,

monies due or recoverable from pension funds, route lists, infringement claims, computer programs, computer disks, computer tapes, literature, reports, catalogs, tax refunds and tax refund claims, and Debtor's books relating to any of the foregoing.

2.7 Instruments. The term "Instruments" shall mean all instruments, as such term is defined in the UCC, whether now existing or hereinafter acquired, including, without limitation, negotiable instruments, letters of credit, notes, drafts, documents of title, certificated and uncertificated securities, and any other writing which evidences a right to the payment of money, and Debtor's Books relating to any of the foregoing.

2.8 Inventory. The term "Inventory" shall mean all inventory, as such term is defined in the UCC, whether now existing or hereinafter acquired, including, without limitation, all used cars held by Debtor for sale or lease, all goods, machinery and equipment held by Debtor for sale or lease or to be furnished under a contract of service, all raw materials, work in progress, finished goods, packing and shipping materials, all goods returned or reclaimed relating to the foregoing, and all documents of title representing any of the foregoing, and Debtor's Books relating to any of the foregoing.

2.9 Obligations. The term "Obligations" shall mean: (i) all amounts owed by Debtor to Lender in connection with the Loan and under the Loan Documents, with interest thereon, and all other amounts payable by Debtor under the Loan Documents, whether direct or indirect, absolute or contingent, due or to become due, now existing or hereafter arising, and including any debt, liability, or obligation owing from Debtor to others which Lender may have obtained by assignment or otherwise, and further including all interest not paid when due which Debtor is required to pay or reimburse under the Loan Documents, by law or otherwise; and (ii) all non-monetary obligations of Debtor under the Loan Documents.

2.10 UCC. The term "UCC" shall mean the Uniform Commercial Code as enacted in the state whose law applies with respect to the creation, perfection and enforcement of Lender's rights as to the Collateral.

ARTICLE III: SECURITY INTEREST

3.1 Grant. As security for the due and timely performance of all Obligations, and the due and timely performance of all obligations of Debtor hereunder, Debtor hereby transfers, conveys, grants and assigns to Lender a security interest in the "Collateral" (as defined below).

The term "Collateral" shall include all of Debtor's rights, title and interests in each of the following: Accounts, Cash Collateral, Chattel Paper, Equipment, General Intangibles, Instruments, Inventory, all deposit accounts, all monies, all lock box accounts, and all other assets of Debtor which hereafter come into the possession, custody or control of Lender, and all proceeds whether tangible or intangible, of each and all of the foregoing including, without limitation, all rights under any insurance policies, and the proceeds thereof, insuring against loss, damage or destruction of the any of the foregoing.

3.2 Perfection of Security Interest. Debtor agrees to and shall take all actions that may be necessary or appropriate or that Lender may at any time or from time to time request as necessary in the opinion of Lender to perfect and maintain the perfection of Lender's security interest in the Collateral as a first priority lien, subject to no other liens or encumbrances. Specifically, but without limiting the generality of the foregoing, Debtor hereby irrevocably constitutes and appoints Lender the attorney-in-fact of Debtor to execute, deliver and, if appropriate, to file and/or record with the appropriate filing officer or office such security agreements, financing statements, notices, continuation statements and other instruments as Lender may request or require in order to impose, perfect or continue the perfection of Lender's security interest in the Collateral.

ARTICLE IV: DEBTOR'S REPRESENTATIONS AND WARRANTIES

4.1 Authority. Debtor has all requisite power and authority to enter into this Agreement and to grant to Lender a security interest in the Collateral.

4.2 No Violation of Any Agreement. The execution, delivery and performance of this Agreement by Debtor does not violate any agreement to which Debtor is a party or by which Debtor or Debtor's property is or may be bound, and no consent of, notice to, approval of or withholding of objection by any person or organization, including any governmental agency, is required in connection with such execution, delivery and performance.

4.3 Binding Obligation. This Agreement constitutes a legally valid and binding obligation of Debtor, enforceable against Debtor in accordance with its terms, except as limited by applicable bankruptcy, insolvency, or reorganization or similar laws affecting the enforcement of creditors' rights generally.

4.4 No Other Assignment. Debtor has not executed any other document or agreement assigning or otherwise transferring any interest in and to the Collateral or Debtor's rights therein, except pursuant to this Agreement.

4.5 No Action or Proceeding. There is no action or proceeding pending by or against Debtor before any court or administrative agency, and Debtor has no knowledge of any pending, threatened or imminent litigation, governmental investigation or claim, complaint, action or prosecution involving Debtor, except with regard to (i) ongoing collection matters in which Debtor is the plaintiff, and (ii) other matters heretofore disclosed, in writing, to Lender. If any of the foregoing arise during the term of this Agreement, Debtor shall immediately notify Lender in writing.

ARTICLE V: AFFIRMATIVE COVENANTS OF DEBTOR

Until all Obligations have been fully satisfied, unless Lender waives compliance in writing, Debtor agrees and covenants as follows:

5.1 Compliance with Terms of Loan Documents. Debtor shall comply with each and all of the terms and conditions contained in the Loan Documents.

5.2 Taxes, Assessments and Other Charges. Debtor shall duly and promptly pay and discharge, as the same become due and payable, all taxes, assessments, and governmental and other charges, levies or claims levied or imposed, or which if unpaid might become a lien or charge, upon the properties, assets, earnings or business of Debtor, except for such taxes, assessment, charges, levies or claims that are being diligently contested in good faith by Debtor and Debtor has made appropriate provisions, approved by Lender, to pay and discharge same upon resolution of any dispute. If Debtor fails to pay any such tax, assessment, charge, levy or claim, Lender may, in its sole and absolute discretion and without notice to Debtor, make payment of the same or any part thereof as Lender deems necessary to satisfy the liability therefor. Lender may conclusively rely on the usual statements of the amount owing or other official statements issued by the appropriate governmental agency.

5.3 Payment of Obligations. Debtor shall pay all of its liabilities and obligations when due and prior to the date on which penalties attach thereto and will keep all existing debts current.

5.4 Laws. Debtor shall comply with all applicable statutes and regulations affecting the ownership of its property and the conduct of its business.

5.5 Notice of Certain Events. Debtor shall give prompt written notice to Lender of: (i) all events of default under any of the terms or provisions of this Agreement or any other agreement entered into by Debtor; (ii) material changes in management of Debtor; (iii) litigation, arbitration, or filing of any judgment or lien with Debtor as a party; (iv) initiation of any bankruptcy proceeding with regard to Debtor; and (v) any other matter which has resulted in, or might reasonably be expected to result in, a material adverse change in Debtor's financial condition or operations.

5.6 Execution of Other Documents. Debtor shall promptly execute and deliver all supplements and amendments hereto, and all financing statements, fixture filings, continuation statements and such additional agreements, instruments and assurances in connection with this Agreement as Lender reasonably requests to effectuate the provisions hereof.

5.7 Asset Forfeiture. Debtor covenants and agrees that it has not committed and shall not commit any act or engage in any conduct which shall cause the Collateral or any assets of Debtor to be subject to any claim by the federal, state or local government, now or in the future, under the asset forfeiture laws or regulations promulgated thereunder and as may be amended from time to time.

5.8 Insurance. Debtor shall maintain insurance covering the Collateral and in accordance with the insurance requirements provided in the Loan Documents.

5.9 No Other Assignment. Debtor shall not execute any other document or agreement assigning or otherwise transferring any interest in and to the Collateral or Debtor's rights therein, except pursuant to this Agreement or upon Lender's express written consent.

5.10 Other Information. Debtor shall promptly supply Lender with such other information concerning its business and general financial condition as Lender may reasonably request from time to time.

ARTICLE VI: DEFAULT AND REMEDIES

6.1 Events of Default. Any one or more of the following shall constitute an "Event of Default" for purposes of this Agreement (references below to "Borrower" has the meaning provided in the Note):

(a) Debtor fails or neglects to perform, or observe when due, any term, provision, condition, covenant, warranty or representation contained in this Agreement;

(b) Borrower fails to pay within ten (10) days after the date due and payable, or after the date when declared due and payable, any amounts payable under the Note (whether of principal, interest, late payment charge, prepayment premium, or otherwise) and other Loan Documents;

(c) Any Borrower fails or neglects to perform, or observe when due, any term, provision, condition, covenant, warranty or representation contained in any Loan Documents, or in any other present or future agreement or arrangement between any Borrower and Lender, and such default shall not have been cured within the timeframe for curing such default as provided in the Loan Documents;

(d) There is a material impairment of the prospective of repayment of any portion of the amounts owing to Lender under the Note or other Loan Documents;

(e) There is a material impairment of the value or priority of Lender's security interests in any Collateral;

(f) Any material portion of any Borrower's assets are attached, seized, subjected to a writ or distress warrant, or are levied upon, or come into the possession of any judicial officer, or any lien is filed or recorded against the assets of than any Borrower by a governmental agency, or any judgment against the Borrower becomes a lien against any of any Borrower's assets;

(g) A voluntary or involuntary petition in bankruptcy or for reorganization or for an arrangement or any composition, readjustment, liquidation, dissolution or similar relief pursuant to the federal bankruptcy law or under similar present or future federal or state bankruptcy or insolvency law, is filed by or against any Borrower, and such petition is not dismissed within sixty (60) days thereafter;

(h) A receiver, trustee or liquidator (or other similar official) is appointed for any Borrower or for all or any substantial part of its assets and is not discharged within sixty (60) days thereafter;

(i) Any Borrower makes an assignment of all or any portion of its assets for the benefit of creditors;

(j) Any Borrower is enjoined, restrained, or in any way prevented by court order from continuing to conduct all or any material part of its business affairs;

(k) There is a default in any material agreement to which Borrower is a party with third parties resulting in a right by such third parties to accelerate the maturity of Borrower's indebtedness;

(l) Any guarantor of any of the Obligations dies, ceases to exist as going concern, terminates its guaranty, or becomes the subject of any insolvency proceeding;

(m) Any government agency files a lien or commences an action or any third party files a claim or lawsuit against Borrower in connection with a violation of state or federal environmental statutes, which claim may result in a substantial fine or penalty or the payment of damages;

(n) Any agency of the federal, state or local government commences any proceedings against Borrower or any guarantor, or the assets of either, for the purpose of enforcing forfeiture rights as provided by federal or state law, or Borrower or any guarantor is the subject of any investigation or any complaint or bill of indictment has been brought against Borrower or any guarantor in connection with conduct the penalty for which is forfeiture of all or any portion of Borrower's or guarantor's assets;

(o) Any Borrower suspends its business or ceases doing business as a going concern;

(p) Any other default occurs under the Loan Documents, and such default is not cured within the time period to cure (if applicable) as provided in the Loan Documents; and/or

(q) Any of the foregoing events occur with respect to any guarantor of any of the Obligations.

6.2 Remedies upon Default. Upon the occurrence of an Event of Default under this Agreement, Lender may, at its election, without notice and without demand, do any one or more of the following, all of which are authorized by Debtor (references below to "Borrower" has the meaning provided in the Note):

(a) Exercise any of Lender's rights and remedies under the Loan Documents.

(b) Without notice to or demand upon Debtor, make such payments and do such acts as Lender considers necessary or reasonable to protect its security interest in the Collateral, including without limitation to pay, purchase, contest or compromise any lien, encumbrance, interest or charge which, in the opinion of Lender, appears to be prior or superior to its security interest and to pay, on Debtor's behalf, all expenses incurred in connection therewith.

(c) Declare all amounts owed to Lender under the Loan Documents immediately due and payable;

(d) Cease extending credit to or for the benefit of any Borrower under the Loan Documents or under any other agreement between any Borrower and Lender.

(e) Without notice to or demand upon Debtor or any guarantor, make such payments and do such acts as Lender considers necessary or reasonable to protect its security interest in the Collateral as permitted by the UCC, at law or in equity, and Debtor agrees to immediately reimburse Lender in good and collectible funds for the full amount of such payments.

(f) Terminate this Agreement and any of the other Loan Documents as to any future liability or obligation of Lender, but without affecting Lender's rights and security interest in the Collateral and without affecting any amounts owing by any Borrower to Lender under the Loan Documents.

(g) Have and exercise all the rights and remedies provided to a secured party by the UCC with respect to all parts of the Collateral or from Debtor.

(h) Institute proceedings for the collection of all amounts owed to Lender under the Loan Documents, and whether by declaration or otherwise, enforce any judgment obtained and collect monies adjudged due from the Collateral or from Debtor.

(i) Take any other appropriate action to protect and enforce the rights and remedies of Lender hereunder.

6.3 Sale of Collateral. If Lender so elects, Lender may sell or dispose of, or cause the sale or disposal of, the Collateral at one or more public or private sales, or both, by way of one or more finance contracts or transactions, for cash or on terms, in such manner and at such places as is commercially reasonable in the opinion of Lender. It is not necessary that the Collateral be present at any such sale.

(a) Lender shall give notice of the sale or disposition of all or any part of Collateral as provided in the UCC, in effect on the date such notice is given.

(b) Lender may bid for and acquire any portion of the Collateral at any public sale, and may pay all or part of the purchase price of such Collateral by crediting against amounts owing on monetary Obligations to the Lender all or part of the net proceeds of such sale after deducting expenses incurred by Lender in connection with such sale. The evidence of the Loan to be so credited need not be produced in order to complete any such sale or in order to cause there to be credited thereon its share of such net proceeds.

(c) If requested by Lender, Debtor shall use its best efforts to obtain qualified purchasers for the Collateral in connection with any sale. Lender will consider any bids for the Collateral submitted by Debtor prior to any private sale, but Lender shall have no obligation to accept any such bid.

6.4 Application of Proceeds. All monies received upon sale or disposition of the Collateral or any part thereof pursuant to this section shall be applied from time to time by Lender in accordance with the UCC. Lender shall be entitled to include within the expenses described in said section, all reasonable attorneys' fees and legal expenses of Lender, its agents and counsel incurred in connection with its enforcement of this section or the maintenance, preparation for sale, lease or other disposition of the Collateral. All monies, earnings, revenues, proceeds, rents, issues, profits and income derived pursuant to the exercise of Lender's rights and remedies under this section (after deducting Lender's expenses and other proper charges), and all other money or property received or recovered by Lender pursuant to this Agreement, shall be applied from time to time by Lender to the monetary Obligations.

6.5 Remedies Cumulative. Lender's rights and remedies under this Agreement, any other Loan Documents, and all other agreements or instruments executed by Debtor (and/or PVHDHC) shall be cumulative and not alternative, and shall be in addition to all rights, powers and remedies given to Lender under the UCC, other applicable law and in equity. No exercise by Lender of one right or remedy shall be deemed an election, and no waiver by Lender of any Event of Default shall be deemed a continuing waiver. No delay by Lender shall constitute a waiver, election, or acquiescence by it.

6.6 Deficiency Balance. Unless prohibited by law, any deficiency which exists after the sale or disposition of the Collateral as provided above will be paid immediately by Debtor. Any excess will be returned, without interest and subject to the rights of third parties, to Debtor.

ARTICLE VII: MISCELLANEOUS PROVISIONS

7.1 Power of Attorney. Debtor hereby irrevocably appoints Lender as Debtor's attorney-in-fact and proxy, with full authority in the place and stead of Debtor and in the name of Debtor or otherwise, in such Lender's discretion, at any time upon the occurrence and during the continuance of an Event of Default, to take any action and to execute any instrument which such Lender may deem necessary or advisable to accomplish the purposes of this Agreement, including (without limitation): (i) to obtain and adjust insurance required to be paid to Lender under the Loan Documents; (ii) to ask, demand, collect, sue for, recover, compound, receive and give acquittance and receipts for moneys due and to become due under or in respect of any of the Collateral; (iii) to receive, endorse and collect any drafts or other instruments, documents and Chattel Paper in connection with clause (i) or clause (ii) above; (iv) to file any claims or take any action or institute any proceedings that such Lender may deem necessary or desirable for the collection of any of the Collateral or otherwise to enforce the rights of Lender with respect to any of the Collateral; (v) to execute and file one or more financing or continuation statements, and amendments thereto, relating to the Collateral; and (vi) execute any documents needed for purposes of carrying out Lender's remedies in the Event of Default as described in Section 6.2 above. Lender shall be under no duty to exercise or withhold the exercise of any of the rights, powers, privileges, and options expressly or implicitly granted to Lender in this Agreement, and shall not be responsible for any failure to do so or any delay in doing so. Lender shall not be liable for any act or omission or for any error of judgment or any mistake of fact or law in their individual capacity or in their capacity as attorney-in-fact except acts or omissions resulting from such Lender's willful misconduct or gross negligence. This power of attorney is conferred on Lender solely to protect, preserve and realize upon the security interests in the Collateral and to take actions with regard to Lender's exercising its remedies in an Event of Default. Lender shall not be responsible for any decline in the value of the Collateral and shall not be required to take any steps to preserve rights against prior parties or to protect, preserve or maintain any security interest or lien given to secure the Collateral. The powers granted herein are coupled with an interest and shall be irrevocable from the date hereof and so long as any amounts owed the Lender under the Loan Documents are outstanding.

7.2 Relationship to Other Security Agreements. This Agreement is in addition to any other security or pledge agreements executed by Debtor or another party in connection with the Loan to grant Lender a security interest in property, and this Agreement does not replace or negate any other such security or pledge agreement.

7.3 Time of the Essence. Time is hereby declared to be of the essence of this Agreement and of every part hereof.

7.4 Effective Date. Notwithstanding the date on which this Agreement is actually signed by Debtor and Lender, the terms and conditions of this Agreement shall be applied, with full force and effect, as of the Effective Date.

7.5 Entire Agreement; Amendment. This Agreement and any agreements, instruments or documents referred to herein constitute the entire agreement among the parties hereto regarding the subject matter hereof, and all prior and/or contemporaneous communications, verbal or written, between or among the parties hereto regarding the subject matter hereof shall be of no further effect or evidentiary value. No course of prior dealing between the parties, no usage of trade, and no parole or extrinsic evidence of any nature shall be used to supplement or modify any term of this Agreement This Agreement can be amended only by a written agreement executed by duly authorized representatives of the parties hereto.

7.6 Construction of Agreement. This Agreement shall be construed as though drafted by both parties and shall not be construed against or in favor of any one party. On the contrary, this Agreement has been reviewed by all parties hereto and shall be construed and interpreted according to the ordinary meaning of the words used so as to fairly accomplish the purposes and intentions of the parties hereto. Unless the context of this Agreement clearly requires otherwise, references to the plural include the singular, references to the singular include the plural, and references to the part include the whole. The use of the word "including" shall be construed as providing examples only and shall not limit the generality of any provision in which it is used. The use of the word "or" has the inclusive meaning represented by the phrase "and/or." The words "hereof," "herein," "hereby," "hereunder" and similar terms used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. Section, subsection, clause, and exhibit references are to this Agreement unless otherwise specified.

7.7 Severability. Each provision of this Agreement shall be severable from every other provision of this Agreement for the purpose of determining the legal enforceability of any specific provision.

7.8 Waivers.

(a) Demand; Protest, etc. Debtor waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension or renewal of any commercial paper, accounts, documents, instruments, chattel paper, and guarantees at any time held by Lender on which Debtor may in any way be liable.

(b) Jury Trial. Unless prohibited under the laws that govern an action or proceeding relating to this Agreement or related agreements entered into in connection herewith, Debtor and Lender each waive any right to trial by jury in any action or proceeding relating to this Agreement or any of the agreements entered into in connection herewith.

7.9 Governing Law. The validity of this Agreement, its construction, interpretation, and enforcement, and the rights of the parties hereunder and concerning the Collateral, shall be determined under, governed by, and construed in accordance with the laws of the State of California. The parties agree that all actions or proceedings arising in connection with this Agreement shall be tried and litigated only in the state and federal courts located in Santa Cruz County, State of California. Debtor waives any right it may have to assert the doctrine of *forum non conveniens* or to object to such venue and hereby consents to any court ordered relief.

7.10 Counterpart Execution. This Agreement may be executed in several counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same Agreement.

7.11 Attorneys' Fees. In the event any party to this Agreement shall be required to commence any action or proceeding against any other party by reason of any breach or claimed breach of any provision of this Agreement, to commence any action in any way connected with this Agreement, or to seek a judicial declaration of rights under this Agreement, the party prevailing in such action or proceeding shall be entitled to recover from the other party, or parties, the prevailing party's reasonable attorneys' fees and costs including, without limitation, all witness fees and associated expenses, including matters on appeal whether or not the proceeding or action proceeds to judgment.

IN WITNESS WHEREOF, this Agreement is executed by or on behalf of each party by its duly authorized representative(s) on the date(s) indicated below and effective as of the date set forth above.

DATE: November 1, 2023	**DATE: November 1, 2023**
DEBTOR: **PAJARO VALLEY HEALTHCARE DISTRICT**, a California nonprofit public benefit corporation By_____ Name_____ Title_____	**LENDER:** **SANTA CRUZ COUNTY BANK**, a California state-chartered Bank By_____ Name_____ Title_____