

**Contract Number**

21-178 A-1

SAP Number

Arrowhead Regional Medical Center

Department Contract Representative	<u>Andrew Goldfrach</u>
Telephone Number	<u>(909) 580-6150</u>
Contractor	<u>CapsuleTech, Inc.</u>
Contractor Representative	<u>Jennifer Clancy</u>
Telephone Number	<u>(310) 697-6589</u>
Contract Term	<u>March 9, 2021 through March 8, 2026</u>
Original Contract Amount	<u>\$936,875</u>
Amendment Amount	<u>\$15,990</u>
Total Contract Amount	<u>\$952,865</u>
Cost Center	<u>9177204200</u>

IT IS HEREBY AGREED AS FOLLOWS:**AMENDMENT NO. #1**

This Amendment No. 1 (Amendment) dated June 25, 2024 is made by and between CapsuleTech, Inc. (Contractor), and San Bernardino County (County) and modifies the terms to agreement executed between the parties as of March 9, 2021 (Contract).

1. Add the attached Quote S46512 to Schedule A, Order of the Contract.
2. Add the attached Statement of Work to Schedule F, SOW.
3. **Campaign Contribution Disclosure (SB1439).** Contractor has disclosed to the County using Attachment A - Campaign Contribution Disclosure Senate Bill 1439, whether it has made any campaign contributions of more than \$250 to any member of the Board of Supervisors or other County elected officer [Sheriff, Assessor-Recorder-Clerk, Auditor-Controller/Treasurer/Tax Collector and the District Attorney] within the earlier of: (1) the date of the submission of Contractor's proposal to the County, or (2) 12 months before the date this Amendment is approved by the Board of Supervisors. Contractor acknowledges that under Government Code section 84308, Contractor is prohibited from making campaign contributions of more than \$250 to any member of the County Board of Supervisors or other County elected officer for 12 months after the County's consideration of the Amendment. Campaign contributions include those made by any agent/person/entity on behalf of the Contractor or by a parent, subsidiary or otherwise related business entity of Contractor.

- 4. Full Force and Effect.** The Contract, as amended by this Amendment, remains in full force and effect.
- 5. Capitalized Terms.** Any capitalized term used but not defined in this Amendment shall have the meaning given to it in the Contract or the Addendum, as applicable.
- 6. Counterparts.** This Amendment may be executed in any number of counterparts, each of which so executed shall be deemed to be an original, and such counterparts shall together constitute one and the same Amendment. The parties shall be entitled to sign and transmit an electronic signature of this Amendment (whether by facsimile, PDF or other email transmission), which signature shall be binding on the party whose name is contained therein. Each party providing an electronic signature agrees to promptly execute and deliver to the other party an original signed Amendment upon request.

SAN BERNARDINO COUNTY

►

Dawn Rowe, Chair, Board of Supervisors

Dated: _____
SIGNED AND CERTIFIED THAT A COPY OF THIS
DOCUMENT HAS BEEN DELIVERED TO THE
CHAIRMAN OF THE BOARD

Lynna Monell
Clerk of the Board of Supervisors
San Bernardino County

By _____
Deputy

CAPSULETECH, INC.

(Print or type name of corporation, company, contractor, etc.)

By ►

(Authorized signature - sign in blue ink)

Name _____
(Print or type name of person signing contract)

Title _____
(Print or Type)

Dated: _____

Address _____ 222 Jacobs Street

Cambridge, MA 02141

Approved as to Legal Form	Reviewed for Contract Compliance	Reviewed/Approved by Department
► Bonnie Uphold, Supervising Deputy, County Counsel	► _____	► Andrew Goldfrach, ARMC Chief Executive Officer
Date _____	Date _____	Date _____

FOR COUNTY USE ONLY



Proposal Surveillance Upgrade for Rover

Opportunity #: S-46512
Date: 6/13/2024

Bill to:
Arrowhead Regional Medical Center
400 N. Pepper Avenue
Colton, California 92324
United States
Contact:
Phone:
Email:

Ship to:
Arrowhead Regional Medical Center
400 N. Pepper Avenue
Colton, California 92324
United States
Contact:
Phone:
Email

The products and services listed on this Quote, and the products and services listed on any purchase order submitted by the customer in response to this quote, are governed by the terms and conditions of the Medical Device Information Platform Agreement (or predecessor DataCaptor agreement) executed by CapsuleTech, Inc. and the customer, and as may have been amended by the parties. For the avoidance of doubt, any other terms and conditions contained or referenced in the customer's purchase order do not apply. All products and services listed on this Quote must be delivered within 15 months of Order. This quote expires on 12/31/2024.

Professional Services

Qty.	Part Number	Description	Selling Price	Amount
20.00	CONSULTH-PM	Consulting Hour(s) - Project Manager	USD 248.00	USD 4,960.00
42.00	CONSULTH-TC	Consulting Hour(s) - Technical Consultant	USD 215.00	USD 9,030.00
1.00	PROJECT-EXP	Travel & Expenses	USD 2,000.00	USD 2,000.00
Professional Services TOTAL:				USD 15,990.00
Sub-Total:				USD 15,990.00
Tax:				
Shipping:				
Total:				USD 15,990.00

Invoicing Terms:

For applicable products ordered:

Professional services: Monthly as delivered. Travel & Expenses invoiced as incurred

Customer

Signature: _____
Full Name: _____
Title: _____
Date: ____/____/____

Thank you for your business
(Please Attach Customer's Purchase Order to Sales Order)

Arrowhead Regional Medical Center

Capsule Surveillance Upgrade

STATEMENT-OF-WORK

1 – April – 2024

Sales Manager: Jenny Clancy

Prepared by: David Fishbough

Version: v1.0 - PS Approved

SO No.: S-46512

CAPSULE SURVEILLANCE – STATEMENT OF WORK

This Statement of Work (“SOW”) is between **Arrowhead Regional Medical Center** (“Licensee” Or “Customer”) and CapsuleTech, Inc. (“Capsule”), and is effective as of the effective date of the Capsule Medical Device Information Platform Agreement (“Agreement”). This SOW is governed by the terms and conditions of the Capsule Medical Device Information Platform Agreement (“Agreement”) and incorporated by reference therein.

This document defines the problem statement, engagement’s objectives, scope, assumptions, and service offering based upon information gathered throughout the sales cycle and post-sales interviews. Modifications to information contained in this document occurring after approval will be considered a change in scope and managed through Capsule’s Change Control process.

CUSTOMER PROBLEM STATEMENT: (Describe the problem that the install of Capsule Surveillance solves; include the business drivers)

Customer reached out to have they Capsule Surveillance upgraded. Customer would like to change where the Surveillance data is connecting to.

- Currently connected to SpectraLink
- Customer wants to move this data to EPIC Rover
- Current Capsule Surveillance Version 3.2.

CUSTOMER EXPECTATION: (Describe expectations that will indicate success at the end of the project)

Capsule to assist customer with upgrade of Capsule Surveillance and the connection to their EPIC Rover solution.

A. STAKEHOLDERS:

TABLE 1: STAKEHOLDERS, CLINICAL SPONSOR, PROJECT TEAM				
ROLE	NAME	TITLE	EMAIL	PHONE
Executive Sponsor	Masaaki Takeda	IT	takedam@armc.sbcounty.gov	
Project Manager	TBD			
System Administrator	Ricardo Duran Nidal Rafeedie	IT Resp	duanR@armc.sbcounty.gov RafeedieN@armc.sbcounty.gov	
Clinical Engineering Lead	TBD			
Clinical Champion	TBD			
Alarm Representative	TBD			

B. PROJECT SCOPE:

TABLE 2: SITES, LOCATION & TIMING SCOPE					
#	SITE NAME	LOCATION (CITY, STATE)	# BEDS	SOLUTION (SURVEILLANCE, REPORTING & ANALYTICS)	GO-LIVE DATE
	Arrowhead Regional Medical Center	Colton, CA	366	Capsule Surveillance	TBD

TABLE 3: MEDICAL DEVICES							
FACILITY	ROOM LOCATION	QTY	TYPE (MONITOR, VENT, ETC.)	MANUFACTURER	MODEL	CONNECTIVITY (GATEWAY, NEURON, ETC.)	MDIP WORK
Upgrade Existing Capsule Surveillance Solution							None
							Choose an item.
							Choose an item.
							Choose an item.
							Choose an item.

TABLE 4: RULES & NOTIFICATIONS						
Rule Name	Rule Detail	Device Type	Design Group	Device Alarm or Parameter	Rule Type	Priority (H/M/L)
Example: Low heart rate	Low HR x 15 sec	Monitor		Device Alarm	Sustained	H
Upgrade of Surveillance Solution – should be no changes		Choose an item.		Choose an item.	Choose an item.	Choose an item.
		Choose an item.		Choose an item.	Choose an item.	Choose an item.
		Choose an item.		Choose an item.	Choose an item.	Choose an item.
		Choose an item.		Choose an item.	Choose an item.	Choose an item.
		Choose an item.		Choose an item.	Choose an item.	Choose an item.
		Choose an item.		Choose an item.	Choose an item.	Choose an item.

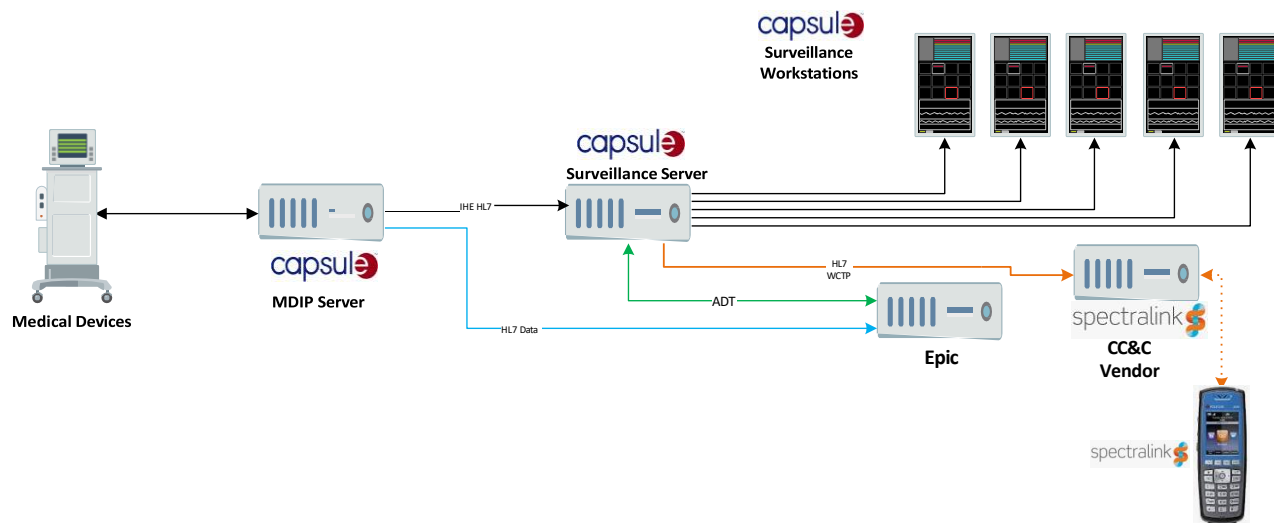
TABLE 5: WAVEFORMS	
DEVICE	WAVEFORMS (LIST DESIRED WAVEFORMS)
Surveillance upgrade only no scope change for this project.	

TABLE 6: SURVEILLANCE FEATURES	
FEATURE	DETAIL
Patient Context (<i>vendor providing ADT</i>)	EPIC
Staff Assignments	Epic
CC&C Destination	Epic Rover
VoiP/Pagers Destination	N/A
Traditional Alarm Management	N/A

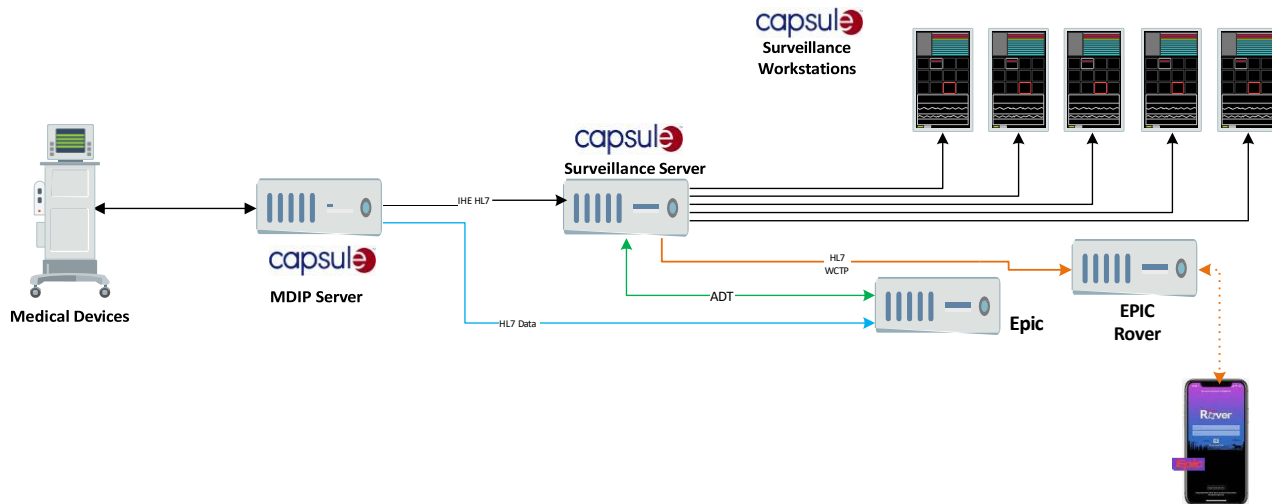
TABLE 7: SOLUTION DETAILS		
TYPE	QUANTITY	LOCATIONS (SPECIFIC UNITS, BUNKER)
Surveillance Instance	1	On Site Data Center
Surveillance Workstation (fka Cockpit)	5	On Site
Remote Viewer (fka web client)	Unknown	Unknown

C. SOLUTION ARCHITECTURE DIAGRAMS:

a. Current State: Capsule Surveillance to SpectraLink



b. Proposed Solution State: Upgrading Capsule Surveillance and sending patient data to EPIC Rover.



D. CAPSULE APPROACH, RESOURCES & DELIVERABLES:

a. Capsule Approach and Recommended Methodology:

Professional Services will support the project for up to four weeks after Go-Live, at which time the engagement will be transitioned to our support team. Go-Live is the day the Capsule surveillance system is activated and sending data to the production receiving system or endpoint.

PHASE 1: INITIATION	PHASE 2: PLANNING	PHASE 3: IMPLEMENTATION	PHASE 4: GO LIVE
<ul style="list-style-type: none"> Introduce project team <ul style="list-style-type: none"> Clinical Champion System Administrator Alarm Representative Confirm scope / expectations Review high level design requirements Review clinical workflow Gather technical requirements Document architecture Verify device types, quantities, and locations 	<ul style="list-style-type: none"> Conduct project kickoff Finalize project plan Build and install server(s) Perform initial testing <ul style="list-style-type: none"> ADT Device data LDAP Staff assignments Refine clinical design Conduct technical feasibility of design Obtain clinical signoff on design 	<ul style="list-style-type: none"> Configure and validate design Perform final testing <ul style="list-style-type: none"> Designed parameters Bed locations Outbound data feeds Review build and obtain clinical acceptance Deliver clinical train-the-trainer Customer trains end users 	<ul style="list-style-type: none"> Soft go-live for limited users Decide go/no-go Perform production cutover Go-live Transfer to Support Approve project closure

b. Capsule Resources:

- Project Manager** – A Capsule project manager will be assigned to coordinate and schedule resources and activities, working in partnership with the hospital project manager. Primary responsibilities and activities include:
 - Serve as the primary Capsule point of contact

- Coordinate and schedule Capsule resources
 - Conduct planning calls to define project scope, environment, resources, risks, and readiness
 - Prepare and lead kickoff
 - Review a project plan with tasks, responsibilities, deadlines, and deliverables
 - Support communication plan through regular status calls and reports
 - Offer recommendations on best practices and facilitate issue resolution
 - Monitor and control project scope, schedule, and budget
 - Manage risk and change through identification, evaluation, response, and monitoring
 - Obtain end-user acceptance for the deployed solution
- **Technical Consultant & Clinical Consultant** – Capsule will provide Consultant(s) and documentation on the solution. Consultants will provide expertise and support for hospital personnel responsible for maintaining the Capsule system. Primary responsibilities and activities include:
 - Provide server and interface specifications to ensure environment meets project requirements
 - Lead technical design sessions to finalize architecture, data flow and interfaces
 - Lead clinical design sessions on workflow, solution benefits and capabilities
 - Install and assist with configuration of Capsule software
 - Provide technical & clinical support, consulting & recommendations
 - Support inbound and outbound testing efforts
 - Engage clinical leadership to promote end user adoption and achieve high utilization
 - Provide clinical training to super users to enable end-user training
 - Support pre-live, go-live, and post-live events
- **Data Scientist** – A Capsule data scientist will provide analysis, including data collection, environmental analysis, reporting and executive presentation of findings. Responsibilities include:
 - Review clinical design outcomes to suggest improvements on current and future state workflow
 - Assist in the quantification and analysis of data to identify trends
 - Assist in the development and evaluation of smart rule candidates
 - Deliver Capsule findings to appropriate team members
 - Provide guidance on Capsule applications, features, and deployment

c. Capsule Engagement Deliverables

- Project activities will result in specific deliverables, such as system requirements, product datasheets, system diagram, project charter, roles/responsibilities, project plan and analysis which will be provided to the Customer. As part of an ongoing communication plan, regular status calls and reports will provide accomplishments, cost and schedule variance analysis, risk, issues, change, and upcoming tasks.

E. CUSTOMER RESOURCES

- Primary hospital staff resources required for this engagement:
 - **Project Manager:** Serve as a primary point of contact, provide committed Customer and 3rd party resources, control scope, schedule, budget, and risk and provide project acceptance
 - **System Administrator:** Serve as a technical contact, troubleshoot the Capsule system before and after go-live, perform back-ups, support testing sessions, and attend team meetings
 - **Biomedical or Clinical Engineer:** Provide access and documentation for medical equipment, support testing sessions, and facilitate 3rd party vendor communications
 - **Clinical Champion:** Serve as a primary clinical contact, provide leadership, facilitate design and workflow discussions, identify super-users, provide subject matter expert support, and resolve conflicts as well as champion solution adoption
 - **Alarm Committee Representative:** Provide guidance on identification and benefits of smart rules, facilitate use of surveillance tools and assessments, act as a liaison between the healthcare organization and Capsule
- Supporting hospital staff resources that may be required:
 - Network / IT / Server: Provide and configure server, network, and infrastructure in accordance with Capsule requirements
 - MSSQL DBA: Provide SQL infrastructure and access, facilitate installation and support deployment
 - Informatics Analyst: Support clinical initiatives, facilitate data collection, support assessments, quantify observations, assist with rule development, support testing and validation
 - Clinical Analyst: Provide guidance on flowsheet configuration and receiving system requirements
 - Subject Matter Experts: Provide guidance and documentation as needed
 - Third party Vendors: Provide guidance and documentation as needed

F. CUSTOMER RESPONSIBILITIES

- Provide infrastructure to meet Capsule's requirements and comply with agreed upon architecture, required by the solution but not expressly defined in the Capsule agreement:
 - Server count
 - Operating system
 - Third-party software
 - Mounts installed
 - Network cables/jacks and power cables installed
 - Workstations
- Manage 3rd parties to provide support in an efficient and timely manner:
 - Receiving Systems
 - Device Manufacturers
 - ADT provider
 - Staff assignment vendor
 - CC&C, Alarm Management

- Ensure availability of appropriate interface type based on the solution deployed
 - Validated (non-critical care) or non-validated (critical care) data flow
 - Staff assignments
 - WTCP
 - ADT
- Provide full security access via VPN (site-to-site or client-based) for remote configuration, testing, support, go-live and analysis
- Provide access to all locations required for system installation, configuration, and training
- Provide written authorization to Capsule to ship specific equipment to a specific location
- Manage standard Location Codes across all systems and facilities or provide translations
- Define, document, and execute clinical and integration test plans and workflow scenario scripts specific to the organization and unit where the solution is deployed

G. PROJECT ASSUMPTIONS AND LIMITATIONS

- All devices and data sources are connected and sending data 60 days prior to Go-Live
- Receiving systems will be built according to data parameters configured in Capsule solution
- Requirements for all in scope solutions will be promptly provided to Capsule
- HL7 messages will meet the requirements outlined in the Capsule HL7 Interface Specification and TCP/IP is the standard communication protocol
- End-point system will accept Capsule standard WTCP message format
- Any vendor integration not noted in this document will require additional validation
- Capsule professional services will be provided remotely except where described in the Professional Services Offering
- Customer will own responsibility for Capsule hardware assembly and deployment, except where described in the Professional Services Offering
- Using a Train-the-Trainer approach, select hospital personnel will be trained and then train >80% of end-users in each area implementing the solution and workflow before go-live
- Customer will perform any site assessments necessary to identify hardware, mounting and infrastructure needs, based on the requirements provided by Capsule
- Customer's medical device model and firmware are supported by Capsule's current solution
- Clinical design is based on current publications and industry practice guidelines (AARC, AAMI, ACLS, etc.) in conjunction with hospital practice, policy, and procedure, as well as understanding of the patient population

H. CHANGE CONTROL PROCESS

Change is a normal part of any project and unplanned changes will undoubtedly occur. Any deviations that impact the scope, schedule or cost agreed upon in this Statement of Work will be subject to the following Change Order procedure:

- A Change Order request will be submitted in writing to Capsule
- The involved personnel will review and discuss the proposed change and decide whether to include the change in the scope of the project
- If the change requires additional cost, Capsule will estimate the incremental cost and provide a quote
- The Change Order will be reviewed, and approval obtained by receipt of a PO for the additional services, hardware or licenses being requested.

This engagement is a time and materials project. The hours estimated in the quote are the best approximation for services required to prepare the deliverables. Actual hours delivered will not exceed the estimated hours without completion of this change control process.

- **If the change impacts the go-live date, the Customer is responsible for the communication to all project stakeholders**

I. PROFESSIONAL SERVICES OFFERING:

The Professional Services estimate is based on Capsule's experience in implementing surveillance solutions using industry standard project management methodologies. Our methodology is robust and responsive to individual project requirements and provides repeatability and a consistently high-quality Customer experience.

- The Professional Services estimate for this engagement is **\$13,990.00** and will be invoiced monthly as incurred.
- The Travel and Expense estimate for this engagement is **\$2,000.00** and will be invoiced monthly as incurred.
- The estimated duration of this project and corresponding Professional Service engagement is **2** months.
- Additional hours may be purchased at an hourly rate of \$215 for Technical Consulting, Clinical Lead, Data Scientist and \$248 for Project Management.
- Mutually agreed upon changes in scope, duration, requirements, or design will result in a reassessment of the Professional Service offering.

Service Product	Deliverables	Capsule		Rate	Onsite or Remote	Total
Project Management	Start, Track & Close Project	20	Hours	\$248	Remote	\$4,960
System Design	Refine Clinical Requirements & Workstation Design	10	Hours	\$215	Remote	\$2,150
System Implementation	Install and configure server environment(s)	12	Hours	\$215	Remote	\$2,580
Integration Testing & Consulting Support	Testing/config support/ad hoc technical support, consulting & recommendations	0	Hours	\$215	Remote	\$0
Clinical Support	Clinical End User training & Clinical Meetings	16	Hours	\$215	Remote	\$3,440
Go-Live Support	Clinical and Technical Resource Support	4	Hours	\$215	Onsite/Remote	\$860
Total		62				\$13,990
Travel	Estimated travel & Expenses					\$2,000

J. SIGNATURES:

Customer

Signature: _____

Full Name: _____

Title: _____

Date: _____

Capsule

Signature: _____

Full Name: Edith Gillet

Name: _____



Electronically signed by: Edith Gillet
Reason: "I Approve"
Date: Apr 2, 2024 12:19 PDT



ATTACHMENT A

Campaign Contribution Disclosure (SB 1439)

DEFINITIONS

Actively supporting the matter: (a) Communicate directly, either in person or in writing, with a member of the Board of Supervisors or other County elected officer [Sheriff, Assessor-Recorder-Clerk, District Attorney, Auditor-Controller/Treasurer/Tax Collector] with the purpose of influencing the decision on the matter; or (b) testifies or makes an oral statement before the County in a proceeding on the matter; or (c) communicates with County employees, for the purpose of influencing the County's decision on the matter; or (d) when the person/company's agent lobbies in person, testifies in person or otherwise communicates with the Board or County employees for purposes of influencing the County's decision in a matter.

Agent: A third-party individual or firm who is representing a party or a participant in the matter submitted to the Board of Supervisors. If an agent is an employee or member of a third-party law, architectural, engineering or consulting firm, or a similar entity, both the entity and the individual are considered agents.

Otherwise related entity: An otherwise related entity is any for-profit organization/company which does not have a parent-subsidary relationship but meets one of the following criteria:

- (1) One business entity has a controlling ownership interest in the other business entity;
- (2) there is shared management and control between the entities; or
- (3) a controlling owner (50% or greater interest as a shareholder or as a general partner) in one entity also is a controlling owner in the other entity.

For purposes of (2), "shared management and control" can be found when the same person or substantially the same persons own and manage the two entities; there are common or commingled funds or assets; the business entities share the use of the same offices or employees, or otherwise share activities, resources or personnel on a regular basis; or there is otherwise a regular and close working relationship between the entities.

Parent-Subsidiary Relationship: A parent-subsidiary relationship exists when one corporation has more than 50 percent of the voting power of another corporation.

Contractors must respond to the questions on the following page. If a question does not apply respond N/A or Not Applicable.

1. Name of Contractor: Philips Capsule_____

2. Name of Principal (i.e., CEO/President) of Contractor, if the individual actively supports the matter and has a financial interest in the decision: N/A

3. Name of agent of Contractor:

Company Name	Agent(s)
N/A	N/A

4. Name of any known lobbyist(s) who actively supports or opposes this matter:

Company Name	Contact
N/A	N/a

5. Name of Subcontractor(s) (including Principal and Agent(s)) that will be providing services/work under the awarded contract if the subcontractor (1) actively supports the matter and (2) has a financial interest in the decision and (3) will be possibly identified in the contract with the County or board governed special district.

Company Name	Subcontractor(s):	Principal and/or Agent(s):
N/A	N/A	N/A

6. Is the entity listed in Question No.1 a nonprofit organization under Internal Revenue Code section 501(c)(3)?

Yes ☐

No ☐

7. Name of any known individuals/companies who are not listed in Questions 1-5, but who may (1) actively support or oppose the matter submitted to the Board and (2) have a financial interest in the outcome of the decision:

Company Name	Individual(s) Name
N/A	N/A

8. Was a campaign contribution, of more than \$250, made to any member of the San Bernardino County Board of Supervisors or other County elected officer on or after January 1, 2023, by any of the individuals or entities listed in Question Nos. 1-7? N/A

No ☒ If **no**, please skip Question No. 9.

Yes ☐ If **yes**, please continue to complete this form.

9. Name of Board of Supervisor Member or other County elected officer: N/A

Name of Contributor: N / A _____

Date(s) of Contribution(s): n/a _____

Amount(s): N/A _____

Please add an additional sheet(s) to identify additional Board Members/County elected officer to whom anyone listed made campaign contributions.

By signing the Contract, Contractor certifies that the statements made herein are true and correct. Contractor understands that the individuals and entities listed in Question Nos. 1-7 are prohibited from making campaign contributions of more than \$250 to any member of the Board of Supervisors or other County elected officer while award of this Contract is being considered and for 12 months after a final decision by the County.