

**REPORT/RECOMMENDATION TO THE BOARD OF SUPERVISORS
OF SAN BERNARDINO COUNTY
AND RECORD OF ACTION**

January 14, 2025

FROM

ANDREW GOLDFRACH, ARMC Chief Executive Officer, Arrowhead Regional Medical Center

SUBJECT

Agreements with Edwards LifeSciences LLC for the Provision of the INSPIRIS RESILIA Aortic Valve

RECOMMENDATION(S)

1. Approve **Pricing Agreement No. 25-22**, including non-standard terms, with Edwards LifeSciences LLC for the provision of the INSPIRIS RESILIA Aortic Valve, from January 14, 2025 through January 13, 2028.
2. Approve **Consignment Agreement 25-23**, including non-standard terms, with Edwards LifeSciences LLC, for the provision of the INSPIRIS RESILIA Aortic Valve, in an amount not to exceed \$240,000, from January 14, 2025 through January 13, 2028.
(Presenter: Andrew Goldfrach, ARMC Chief Executive Officer, 580-6150)

COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES

Provide for the Safety, Health and Social Service Needs of County Residents.

FINANCIAL IMPACT

Approval of this item will not result in the use of Discretionary General Funding (Net County Cost). The cost of \$240,000 is funded by State Medi-Cal, Federal Medicare, private insurances, and other departmental revenue. Funding sources may change in the future pending any legislative activity related to the repeal and/or replacement of the Affordable Care Act. Adequate appropriation and revenue have been included in the Arrowhead Regional Medical Center (ARMC) 2024-25 budget and will be included in future recommended budgets.

BACKGROUND INFORMATION

The Pricing and Consignment Agreements with Edwards LifeSciences LLC (Edwards) will allow ARMC to consign, stock as inventory, and purchase the INSPIRIS RESILIA aortic valves (INSPIRIS Valves) to replace native or prosthetic aortic heart valves. The Pricing Agreement sets pricing for the product, while the Consignment Agreement allows these same products to be stored at ARMC and set shelf inventory levels. The INSPIRIS Valves deliver on the promise of better ongoing patient quality of life without the inconvenience of monitoring, dietary restrictions and reduction of participation in active lifestyles typically seen with a mechanical valve.

The INSPIRIS Valves offer many advantages over a mechanical valve such as freedom to live a more active lifestyle, fewer dietary restrictions, with no need for long term anticoagulants and no clicking sound with every heartbeat. It is built with RESILIA tissue (bovine pericardial tissue)

**Agreements with Edwards LifeSciences LLC for the Provision of the
INSPIRIS RESILIA Aortic Valve
January 14, 2025**

which is treated with special integrity preservation technology. It is designed to offer enhanced anti-calcification technology that potentially allows the valve to last longer.

ARMC will maintain on consignment an inventory of the INSPIRIS Valves to ensure the item is readily available when the need arises. ARMC will be billed for the INSPIRIS Valve(s) when the product is removed from inventory and used. All anticipated purchases of the consigned products will be governed by the terms and conditions of the Consignment Agreement and Pricing Agreement.

The agreements with Edwards LifeSciences LLC were negotiated by the parties and include the following non-standard contract terms or omits standard County contract terms as follows:

1. Payment terms are Net 30 days.
 - The County standard payment terms are Net 60 days with no interest or late payment penalties.
 - Potential Impact: County standard processing time is 60 days or more. Failing to pay within 30 days may result in a material breach of the agreements, which could allow Edwards to terminate the agreements and seek other legal remedies.
2. The County must notify Edwards of a request for disclosure of confidential information prior to the County disclosing such information where the disclosure is required by law.
 - The County standard contract does not require notice.
 - Potential Impact: The County will need to be aware of its obligation to notify Edwards prior to any disclosure, including in response to a Public Records Act request.
3. Venue is in the state or federal courts of California.
 - County Policy 11-05 requires venue for disputes in Superior Court of California, County of San Bernardino, San Bernardino District.
 - Potential Impact: Edwards is headquartered in Orange County, California. Having a venue in Orange County may result in additional expenses that the County might not need to incur if the venue was in San Bernardino County.
4. Edwards limits its general indemnity obligations to claims for bodily injury or property damage caused by (1) Edwards' negligent or wrongful act or omission and (2) any defect in its products. Additionally, its indemnity obligations do not apply to claims caused by the County's negligence, fault, willful misconduct, or modification or use of the products in a manner not contemplated. Further, Edwards will not indemnify the County if the County delays notifying Edwards of the claim and such delay prejudices Edwards' ability to defend the claim.
 - The County standard contract general indemnity provision requires the contractor to indemnify, defend, and hold County harmless from third party claims arising out of the acts, errors or omissions of any person. The contractor's indemnity obligation applies even if the claim is partially caused by the County's active and passive negligence.
 - Potential Impact: Edwards' indemnity obligation is more limited compared to the standard County general indemnity obligation. In the event a claim arises that falls outside the scope of Edwards' limited indemnity obligation, the County could be financially responsible for the defense of the claim and any resulting judgment/settlement.

**Agreements with Edwards LifeSciences LLC for the Provision of the
INSPIRIS RESILIA Aortic Valve
January 14, 2025**

5. Edwards is not required to comply with all of the standard County insurance requirements.
 - County policy requires contractors to carry appropriate insurance at limits and under conditions determined by the County's Risk Management Department and as set forth in County policy and in the County standard contract.
 - Potential Impact: Without all of the standard County insurance terms, the County has no assurance that Edwards will be financially responsible for claims that may arise under the agreements, which could result in expenses to the County.

6. The County is required to maintain property insurance to cover the consigned products and to provide Edwards with a certificate of insurance upon request.
 - The County standard contract does not impose any insurance obligations on the County.
 - Potential Impact: The County will need to be mindful of the insurance obligations under the agreements to ensure they comply with those requirements.

ARMC recommends approval of the agreements, including the non-standard terms, with Edwards as they will provide for the safety and health needs of county residents by ensuring ARMC has a sufficient supply of aortic valve implants that are designed to last longer and improve the quality of life for ARMC patients.

PROCUREMENT

The Purchasing Department supports this non-competitive procurement based on functional specifications. The INSPIRIS Valve is built with RESILIA tissue, not found in mechanical valves, and is designed to offer enhanced anti-calcification technology that potentially allows the valve to last longer than mechanical valves. The physician group working with aortic valve implants are currently only trained on the INSPIRIS Valves.

REVIEW BY OTHERS

This item has been reviewed by County Counsel (Charles Phan, Supervising Deputy County Counsel, 387- 5455) on December 2, 2024; Purchasing (Veronica Pedace, Buyer III, 387-2464) on December 3, 2024; Risk Management (Gregory Ustaszewski, Staff Analyst, 386-9008) on December 3, 2024; Finance (Chen Wu, Finance and Budget Officer, 580-3165) on December 17, 2024; Finance (Jenny Yang, Administrative Analyst, 387-4884) on December 18, 2024; and County Finance and Administration (Valerie Clay, Deputy Executive Officer, 387-5423) on December 18, 2024.

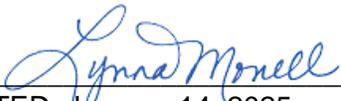
**Agreements with Edwards LifeSciences LLC for the Provision of the
INSPIRIS RESILIA Aortic Valve
January 14, 2025**

Record of Action of the Board of Supervisors
San Bernardino County

APPROVED (CONSENT CALENDAR)

Moved: Curt Hagman Seconded: Joe Baca, Jr.
Ayes: Col. Paul Cook (Ret.), Jesse Armendarez, Dawn Rowe, Curt Hagman, Joe Baca, Jr.

Lynna Monell, CLERK OF THE BOARD

BY  _____
DATED: January 14, 2025



cc: ARMC - Goldfrach w/agree
 Contractor - c/o ARMC w/agree
 File - w/agree
CCM 01/21/2025