

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

December 3, 2024

FROM

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

SUBJECT

Contract with Shockwave Medical, Inc. for the Purchase of Shockwave Intravascular Lithotripsy Equipment, Catheters, and Accessories

RECOMMENDATION(S)

Approve **Contract No. 24-1168**, including non-standard terms, with Shockwave Medical, Inc. for the purchase of Intravascular Lithotripsy Equipment, Catheters, and Accessories, in an amount not to exceed \$1,125,000, for the period of December 3, 2024, through December 2, 2027. (Presenter: Andrew Goldfrach, ARMC Chief Executive Officer, 580-6150)

COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES

Implement the Countywide Vision

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 \$1,125,000 is funded by the 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's (ARMC) 2024-25 budget and will be included in future recommended budgets.

BACKGROUND INFORMATION

The contract to purchase Intravascular Lithotripsy (IVL) equipment, catheters, and accessories (Contract) with Shockwave Medical, Inc. (Shockwave) will enable ARMC to treat patients with problematic calcium in their arteries. This will significantly improve patient care and safety, reassuring ARMC patients of ARMC's commitment to quality of service.

The products from Shockwave will allow ARMC to utilize a new minimally invasive procedure that uses sonic pressure waves to remove calcium deposits in arteries. Currently, patients that are at high risk of Percutaneous Coronary Intervention (PCI), require a Higher Level of Care (HLOC) and are transferred to another hospital for treatment. To prevent HLOC transfers, Cath Lab procedural services will need to be expanded. Eliminating gaps in the cardiac services line is necessary to develop and expand program.

The Contract with Shockwave is based on the standard County contract, negotiated by the parties, with the following non-standard terms:

**Contract with Shockwave Medical, Inc. for the Purchase of Shockwave Intravascular Lithotripsy Equipment, Catheters, and Accessories
December 3, 2024**

1. Payment terms are Net 45 days.
 - 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 45 days may result in a material breach of the Contract, which could allow Shockwave to terminate the Contract and seek other legal remedies.
2. Shockwave limits its general indemnity obligations to claims that arise out of any defect in any products or equipment provided under the Contract and its negligent or wrongful acts, errors, or omissions.
 - 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.
 - Potential Impact: Shockwave's 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 Shockwave's limited indemnity obligation, the County could be financially responsible for the defense of the claim and any resulting judgment/settlement.
3. Shockwave 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 requirements, the County has no assurance that Shockwave will be financially responsible for claims that may arise under the Contract, which could result in expenses to the County that exceed the total Contract amount.
4. The Contract requires the County to maintain commercial general liability insurance or a program of self-insurance in the minimum amount of \$1 million per occurrence and \$3 million in the aggregate.
 - The standard County contract does not impose any insurance obligations on the County.
 - Potential Impact: The County will need to be mindful of the insurance obligations imposed on the County under this Contract to ensure it maintains the necessary insurance policies or program of self-insurance to avoid breaching the terms of the Contract.

Use of the products for the new procedures was approved by the Value Analyst Committee (VAC), which vets requests from clinicians for new products and services. The VAC is a multidisciplinary group from ARMC, consisting of 21 members representing physicians, nurses, other healthcare representatives, compliance, supply chain, finance, information management, facilities, biomed, and healthcare operations. Through a hands-on assessment and discussion guided by ARMC's mission, the VAC's objective is to gain a balanced decision, supporting innovation, process improvement, waste reduction, and standardization. The VAC enhances the procurement requirements.

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ARMC recommends approval of the Contract, including the non-standard terms, as the purchase of the products will provide for the safety, health, and social services needs of County residents by expediting IVL, which will help treat patients with problematic calcium in their arteries.

PROCUREMENT

Purchasing supports this non-competitive procurement due to the functional specifications. The IVL products are only manufactured and distributed by Shockwave and not available from any other vendor. ARMC physicians have been trained to use such products.

REVIEW BY OTHERS

This item has been reviewed by County Counsel (Charles Phan, Supervising Deputy County Counsel, 387- 5455) on October 31, 2024; Purchasing (Veronica Pedace, Buyer III, 387-2464) on November 5, 2024; Risk Management (Gregory Ustaszewski, Staff Analyst, 386-9008) on November 6, 2024; ARMC Finance (Chen Wu, Finance and Budget Officer, 580-3165) on November 8, 2024; Finance (Jenny Yang, Administrative Analyst, 387-4884) on November 8, 2024; and County Finance and Administration (Valerie Clay, Deputy Executive Officer, 387-5423) on November 14, 2024.

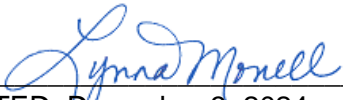
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Record of Action of the Board of Supervisors
San Bernardino County

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: December 3, 2024



cc: ARMC - Goldfrach w/ agree
 Contractor c/o ARMC w/ agree
 File w/ agree
JLL 12/4/2024