

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

August 25, 2020

FROM

WILLIAM L. GILBERT, Director, Arrowhead Regional Medical Center

SUBJECT

Agreements with Zimmer Biomet CMF and Thoracic LLC, Depuy Synthes CMF, Stryker Sales Corporation, and Osteomed, LLC for Cranio Maxillofacial Implants for Patients

RECOMMENDATION(S)

1. Approve **Agreement No. 20-671** with Zimmer Biomet CMF & Thoracic LLC, for Cranio Maxillofacial Implants for surgical patients, in the amount not to exceed \$500,000, for the period of August 25, 2020 through August 24, 2022.
2. Approve **Agreement No. 20-672** with Stryker Sales Corporation, for Cranio Maxillofacial Implants for surgical patients, in the amount not to exceed \$500,000, for the period of August 25, 2020 through August 24, 2022.
3. Approve **Agreement No. 20-673** with Depuy Synthes CMF, for Cranio Maxillofacial Implants for surgical patients, in the amount not to exceed \$500,000, for the period of August 25, 2020 through August 24, 2022.
4. Approve **Agreement No. 20-674** with Osteomed, LLC, for Cranio Maxillofacial Implants for surgical patients, in the amount not to exceed \$340,000, for the period of August 25, 2020 through August 24, 2022.

(Presenter: William L. Gilbert, Director, 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 Discretionary General Funding (Net County Cost). The total cost of \$1,840,000 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) 2020-21 budget and will be included in future recommended budgets.

The implants will be paid according to the following not-to-exceed amounts:

Zimmer Biomet CMF & Thoracic LLC	
Year	Not-to-exceed
Year 1 (August 25, 2020-August 24, 2021)	\$250,000
Year 2 (August 25, 2021-August 24, 2022)	\$250,000

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Stryker Sales Corporation	
Year	Not-to-exceed
Year 1 (August 25, 2020-August 24, 2021)	\$250,000
Year 2 (August 25, 2021-August 24, 2022)	\$250,000

Depuy Synthes CMF	
Year	Not-to-exceed
Year 1 (August 25, 2020-August 24, 2021)	\$250,000
Year 2 (August 25, 2021-August 24, 2022)	\$250,000

Osteomed, LLC	
Year	Not-to-exceed
Year 1 (August 25, 2020-August 24, 2021)	\$170,000
Year 2 (August 25, 2021-August 24, 2022)	\$170,000

BACKGROUND INFORMATION

Approval of the agreements with Zimmer Biomet CMF & Thoracic LLC (Zimmer), Stryker Sales Corporation (Stryker), Depuy Synthes CMF (Depuy), and Osteomed, LLC (Osteomed) will allow for the purchase of soft tissue and skeletal structure of the skull and face implants, collectively known as “Cranio Maxillofacial Implants” for certain surgical patients at ARMC. ARMC conducts elective and non-elective surgeries. Due to COVID-19, ARMC suspended elective surgeries. Now that these surgeries are taking place again, demand for procedures that require the Cranio Maxillofacial Implants has increased and ARMC needs sufficient supply of products. Zimmer, Depuy, Stryker, and Osteomed are suppliers of such products for ARMC.

The Statement of Economic Interest, Form 700, filed by physicians who will be using these products have been reviewed by the ARMC Compliance Department and no conflicts of interest were noted.

The Zimmer agreement is based on the County’s standard contract, with various provisions negotiated by the parties that differ from the standard County contract terms. The Depuy, Stryker, and Osteomed agreements are the vendors’ standard commercial agreements, negotiated by the parties, with various provisions that differ from the standard County contract terms. The non-standard terms for these agreements include the following:

Zimmer Agreement

Assignment

Zimmer may not assign the Agreement without the consent of the County, except that Zimmer may assign all or any parts of its rights and obligations without County counsel to any of its affiliate or, in the event of a merger, acquisition, change of control, reorganization or sale of substantially all of Zimmer’s assets.

- The County’s standard contract prohibits vendors from assigning the contract without the County’s consent.

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- Potential Impact: Zimmer may assign the Agreement to a third-party without the County's approval under certain circumstances. This could allow the Agreement to be assigned to a business with which the County is legally prohibited from doing business with due to issues of federal debarment or suspension and conflict of interest.

Insurance

Zimmer is not required to add the County as an additional insured under its policies.

- The County's standard contract requires vendors to add the County as an additional insured under its insurance policies.
- Potential Impact: By not being added as an additional insured, the County will be unable to make a claim for damages directly to Zimmer's insurer as an insured under Zimmer's insurance policies.

Limitation of Liability

Except for claims arising from bodily injury or death, neither party will be liable to the other for an amount greater than the total price of products ordered by the County for the year the claim arose.

- The County's standard contract does not limit the vendor's liability.
- Potential Impact: Zimmer caps its liability to the County at total price of the products the County pays to Zimmer during the year the claim arises. Claims could exceed the liability cap and the contract amount leaving the County financially liable for the excess. It should be noted County's liability to Zimmer is similarly limited.

Both parties waive the right to any indirect, special, incidental, exemplary, punitive, consequential or similar damages.

- The County's standard contract does not limit the right to recover any damages.
- Potential Impact: The County is waiving any right to recover the specified damages, meaning that if the County sustains any such damages, it will be financially responsible for those damages.

Payment

The payment terms are net 30 days.

- The County's standard contract payment term is Net 60 days.
- Potential Impact: ARMC administration must be mindful of this provision and ensure payment is made in timely manner. Notably, there are no provisions providing for any interest or penalty payments if payment is not made within 30 days.

Warranty

Other than the warranties explicitly stated in the Agreement, Zimmer disclaims any other express or implied warranties, including the implied warranty of fitness for a particular purpose and merchantability.

- The standard County contract requires the vendor to fully warrant its services without any limitation on remedies or time.
- Potential Impact: Zimmer's potential liability is limited by this disclaimer of warranty, meaning that the County will be limited in the warranty theories of liability it can make against Zimmer.

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Depuy Agreement

Payment

The payment terms are net 30 days.

- The County's standard contract payment term is Net 60 days.
- Potential Impact: ARMC administration must be mindful of this provision and ensure payment is made in timely manner. Notably, there are no provisions providing for any interest or penalty payments if payment is not made within 30 days.

Warranty

Other than the warranties explicitly stated in the implant package inserts, Depuy disclaims any other express or implied warranties, including the implied warranty of fitness for a particular purpose and merchantability.

- The standard County contract requires the vendor to fully warrant its services without any limitation on remedies or time.
- Potential Impact: Depuy's potential liability is limited by this disclaimer of warranty, meaning that the County will be limited in the warranty theories of liability it can make against Depuy.

Governing Law

The agreement is governed by New York law.

- The standard County contract requires the contract to be interpreted under California law.
- Potential Impact: The agreement will be interpreted under New York law. Any questions, issues or claims arising under this agreement may require the County to hire outside counsel licensed and competent to advise on New York law, which may result in fees that exceed the total contract amount.

Mediation and Venue

If the parties are unable to resolve any disputes, the parties are required to undergo mediation in New York. If the dispute is not resolved through mediation, any action that is brought must be brought in the state courts of New York or the U.S. District for the Southern District of New York.

- The standard County contract does not require mediation and requires any lawsuit to be brought only in the San Bernardino County Superior Court.
- Potential Impact: Because mediation would take place in New York and any lawsuit would be venued in New York, the County would need to retain attorneys licensed to practice law in New York, which may result in fees that exceed the total contract amount.

Waiver of Jury Trial

All parties waive the right the right to a jury trial.

- The standard County contract does not require either party to waive the right to a jury trial.
- Potential Impact: This means that any lawsuit that is brought will be tried before a judge, who will decide the verdict, which is normally reserved for a jury.

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Limitations of Damages

Both parties waive the right to any punitive, exemplary, cover, multiplied, consequential damages, prejudgment interests or attorneys' fees or costs except where required by law.

- The County's standard contract does not limit the right to recover any damages.
- Potential Impact: The County is waiving any right to recover the specified damages, meaning that if the County sustains any such damages, it will be financially responsible for those damages.

Termination

Either party may terminate the Agreement with 10 days written notice.

- The standard County contract permits termination of a contract for any reason with 30 days written notice.
- Potential Impact: The Agreement may be terminated with less than the standard 30 day notice.

Stryker Agreement

Indemnification

Stryker is not obligated to defend or indemnify the County against any claims based on the alleged infringement of intellectual property rights.

- The standard County contract requires the vendors of goods to defend and indemnify the County for any claims based on the infringement of intellectual property rights.
- Potential Impact: Stryker would have no contractual obligation to defend and indemnify the County if the County is sued for infringing the intellectual property rights of a third-party in the County's use of Stryker's products. The County may be financially liable for the cost of defending the claim and any resulting settlements or judgment, which may exceed the contract amount.

Payment

The Agreement provides that the County is to pay within 30 days of an invoice.

- The County's standard contract payment term is Net 60 days.
- Potential Impact: ARMC administration must be mindful of this provision and ensure payment is made in timely manner. Notably, there are no provisions providing for any interest or penalty payments if payment is not made within 30 days.

Warranty

Other than the warranties explicitly stated in the implant package inserts, Stryker disclaims any other express or implied warranties, including the implied warranty of fitness for a particular purpose and merchantability.

- The standard County contract requires the vendor to fully warrant its services without any limitation on remedies or time.
- Potential Impact: Stryker's potential liability is limited by this disclaimer of warranty, meaning that the County will be limited in the warranty theories of liability it can make against Stryker.

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Limitations of Damages

Both parties waive the right to any incidental, punitive, special, cover, exemplary, multiplied, or consequential damages, or attorneys' fees or costs.

- The County's standard contract does not limit the right to recover any damages.
- Potential Impact: The County is waiving any right to recover the specified damages, meaning that if the County sustains any such damages, it will be financially responsible for those damages.

Osteomed Agreement

Indemnification

The County agrees to defend and indemnify Osteomed for any claims attributable to (1) the County's breach of the agreement, (b) the County's any intentional or negligent act or omission.

- The County's standard contract does not provide for the indemnification of the vendor under any circumstance.
- Potential Impact: By agreeing to indemnify Osteomed, the County could be contractually waiving the protection of sovereign immunity. Claims that may otherwise be barred against the County, time limited, or expense limited could be brought against Osteomed without such limitations and the County would be responsible to defend and reimburse Osteomed for costs, expenses, and damages, which could exceed the total contract amount. It should be noted that Osteomed is similarly obligated to defend, indemnify, and hold harmless the County.

ARMC recommends approval of these agreements, including the non-standard terms, to ensure that ARMC has an adequate supply of Cranio Maxillofacial Implants for surgical procedures for its patients.

PROCUREMENT

Purchasing approves this procurement based on existing three-year term agreements that were secured via Request for Proposal (RFP). In 2017, County Purchasing, on behalf of ARMC, conducted a RFP (#MCR16-19) for Cranio Maxillofacial Implants. Zimmer, Depuy, Stryker, and Osteomed submitted proposals and were awarded contracts to provide the implants. The implants of these vendors are utilized as they maintain multiple implant systems that give ARMC a variety of products to choose from for surgical operations.

The Purchasing Agent for ARMC executed the first agreements with all of these vendors on January 9, 2017. Per County policy, agreements can carry a term of up to five years. Therefore, the vendors have agreed to new agreements for the term of August 25, 2020 through August 24, 2022, for Cranio Maxillofacial Implants with the County.

REVIEW BY OTHERS

This item has been reviewed by County Counsel (Charles Phan, Deputy County Counsel, 387-5455) on August 10, 2020; Purchasing (Ariel Gill, Buyer, 909-777-0722) on August 11, 2020; ARMC Finance (Chen Wu, Finance and Budget Officer, 580-3165) on August 11, 2020; Finance (Yael Verduzco, Administrative Analyst, 387-5285) on August 11, 2020; and County Finance and Administration (Matthew Erickson, Chief Financial Officer, 387-5423) on August 11, 2020.


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Record of Action of the Board of Supervisors
County of San Bernardino

APPROVED (CONSENT CALENDAR)

Moved: Josie Gonzales Seconded: Robert A. Lovingood
Ayes: Robert A. Lovingood, Janice Rutherford, Dawn Rowe, Curt Hagman, Josie Gonzales

Lynna Monell, CLERK OF THE BOARD

BY  _____
DATED: August 25, 2020



cc: ARMC- Gilbert w/agree
 Contractor- C/O ARMC w/agree
 File- w/agree
la 08/27/2020