

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

May 19, 2020

**FROM**

**WILLIAM L. GILBERT, Director, Arrowhead Regional Medical Center**

**SUBJECT**

Amendment to Agreement with INO Therapeutics LLC, dba Mallinckrodt, for the Provision of INOtherapy Services

**RECOMMENDATION(S)**

Approve **Amendment No. 1 to Contract No. 20-284** 4400012056 with INO Therapeutics LLC, dba Mallinckrodt ("Mallinckrodt"), to extend the contract period through May 31, 2021, for total contract period of June 1, 2019, through May 31, 2021, and increase the contract amount by \$77,664, for a total contract amount of \$161,992, for the provision of INOtherapy services. (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 use of Discretionary General Funding (Net County Cost). The additional cost of \$77,664 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) 2019-20 budget and will be included in future recommended budgets.

**BACKGROUND INFORMATION**

Approval of this Item will allow ARMC to continue receiving INOtherapy services from Mallinckrodt, which consists of the pharmaceutical drug INOMAX ® (nitric oxide) for inhalation and the delivery devices needed to administer the drug. The INOtherapy services will be used at the Neonatal Intensive Care Unit (NICU) at ARMC. Inhaled nitric oxide is a specific pulmonary medication that dilate blood vessels. It affects the muscles in the walls of the arteries and veins, preventing the muscles from tightening and the walls from narrowing. As a result, blood flows more easily through the vessels, reducing blood pressure and increasing oxygen supplies in the blood. Inhaled nitric oxide has been a proven safe and effective treatment for in term and late preterm infants with respiratory failure.

The amendment and underlying Inotherapy Services Agreement ("Agreement") contain several non-standard terms, including the following:

Notice Period for Termination

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Under the amendment, the Agreement may be terminated without cause upon 60 days written notice to the other party.

- The standard County contract permits the parties to terminate a contract for convenience with 30 days written notice.
- Potential Impact: The County would need to provide a longer period of notice prior to terminating the Agreement without cause.

Insurance

The underlying Agreement does not require Mallinckrodt to meet the County's insurance standards, including adding the County as an additional insured and waiver of subrogation rights. Instead, it only requires Mallinckrodt to maintain general liability coverage in such forms and amounts as are reasonable for the industry and for a provider of services of the type and size of Mallinckrodt.

- The County has an extensive list of insurance requirements with specific coverage limits, and requires vendors to add the County as an insured and to waive subrogation rights.
- Potential Impact: Because the Agreement does not specify the coverage and limits of the required insurance for Mallinckrodt, the County has no assurance that Mallinckrodt will have the financial support of an insurance company for the limits that the County generally requires of vendors, which could result in the County bearing financial responsibility if Mallinckrodt is unable to fulfill its obligations. Additionally, Mallinckrodt's insurance policy will not provide direct coverage to the County as a named insured. Lastly, without a waiver of subrogation, Mallinckrodt's insurers may bring suit against the County.

Limitations of Liability

Under the Agreement, the vendor disclaims any liability for any indirect, incidental, special, consequential, punitive, or exemplary damages.

- The County's standard contract does not include a limitation of liability provision.
- Potential Impact: Claims could exceed the liability cap and the contract amount, leaving the County financially liable for the excess

Warranty Limitation

Mallinckrodt disclaims any implied warranties for infringement, quiet enjoyment, merchantability, accuracy of results, or fitness for a particular purpose.

- The County's standard contract provides that the vendor fully warrants its services and products.
- Potential Impact: Mallinckrodt's liability is limited by this disclaimer of warranty.

**PROCUREMENT**

On May 30, 2019, Purchasing executed an Agreement with Mallinckrodt for the provision of INOtherapy Service for a one-year period. Purchasing approved the non-competitive procurement based on the vendor being the sole source for this therapy at the time of purchase on May 30, 2019. It was anticipated that ARMC would utilize a new vendor, Praxair, under a Countywide Contract, to receive INOtherapy services. However, Praxair recently informed ARMC that they could not provide services due to the increase demand brought on by the COVID-19 outbreak. Due to this, ARMC must extend the Agreement with Mallinckrodt by one-year, to ensure the provision of this critical service is met. The current procurement justification of INOtherapy services is based on the existing agreement with Mallinckrodt.

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**REVIEW BY OTHERS**

This item has been reviewed by County Counsel (Charles Phan, Deputy County Counsel, 387-5455) on May 11, 2020; Purchasing Department (Jacqueline Ambrose, Lead Buyer, 777-0722) on May 12, 2020; ARMC Finance (Chen Wu, Budget and Finance Officer, 909-580-3165) on May 11, 2020; Finance (Yael Verduzco, Administrative Analyst, 387-5285) on May 11, 2020; and County Finance and Administration (Matthew Erickson, County Chief Financial Officer, 387-5423) on May 12, 2020.

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

**APPROVED (CONSENT CALENDAR)**

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

Lynna Monell, CLERK OF THE BOARD

BY   
DATED: May 19, 2020



cc: ARMC- Gilbert w/agree  
Contractor- C/O ARMC w/agree  
File- w/agree  
la 05/22/2020