Sole Source

Inhaled Nitric Oxide

MUHC

In accordance with the Collected Rules and Regulations 80.010, MU Health Care (MUHC) requests approval for the sole source purchase of Inhaled Nitric Oxide (INOmax) from INO Therapeutics LLC d/b/a Mallinckrodt, Bedminster, New Jersey, for a total of $752,400 for a one-year term.

Inhaled Nitric Oxide is a FDA-approved pulmonary vasodilator intended to improve oxygenation in term and near-term (>34 weeks) neonates with hypoxic respiratory failure (HRF) associated with pulmonary hypertension. It is also frequently used off label for cardiac patients with increased pulmonary artery pressures and for patients that do not oxygenate very well due to acute respiratory distress syndrome (ARDS).

INOmax, approved by the FDA in 1999, is the only current FDA-approved inhaled nitric oxide gas regulated as a drug. INOmax inhaled nitric oxide may only be used with the FDA-approved INOmax DISR delivery system. Mallinckrodt distributes INOmax from its location in Hazelwood, Missouri. The gas, along with complete service, is available to MUHC 24 hours a day, 7 days a week, and 365 days a year.

Despite the lack of competitive options over the years, there is word the gas may be available in the future from other companies. However, due to the lack of development and FDA approval for the delivery equipment, a competitive opportunity is still not available to MUHC.

MUHC Respiratory Therapy has purchased INOmax for the Newborn Intensive Care Unit (NICU) and Cardiothoracic Surgery under one-year agreements for several years with spend less than $500,000/year. Due to significant increased services, product utilization and price, the total spend for the new upcoming one-year agreement is above $500,000 and thus requires Board approval.

The total $752,400 expenditure will be paid from the MU Health Care Respiratory Therapy operating funds.

No. 5

Recommended Action – Sole Source – Inhaled Nitric Oxide, MUHC

It was recommended by Chancellor Cartwright, endorsed by President Choi, recommended by the Finance Committee, moved by Curator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and seconded by Curator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, that the following action be approved:

that MUHC be authorized to purchase Inhaled Nitric Oxide from INO Therapeutics LLC d/b/a Mallinckrodt, Bedminster, New Jersey, at a total cost of $752,400.

Funding is as follows:

MUHC Respiratory Therapy Operating Fund H0703 733100

Roll call vote Finance Committee YES NO

Curator Brncic

Curator Chatman

Curator Layman

Curator Steelman

The motion .

Roll call vote Full Board: YES NO

Curator Brncic

Curator Chatman

Curator Farmer

Curator Graham

Curator Layman

Curator Phillips

Curator Snowden

Curator Steelman

Curator Sundvold

The motion .