

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, NCO 10 Contracting Activity, 6150 Oak Tree Blvd, Independence, OH 44131. The Surgical Department at the Cleveland VA Medical Center has requested supplies for purchase by submitting 2237# 541-13-4-033-5725
2. **Nature and/or Description of the Action Being Processed:** Non-IT Equipment —the order requested below will provide the Surgical Department with the essential supplies needed to conduct critical surgical procedures for Veteran patients. A firm fixed price purchase order for the Surgical Department is anticipated.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**

The following supplies are required from Medline:

Major Vascular Pack, CDS983816A, 15ea.

Total Knee Pack, CDS983821A, 15ea.

Lap Chole Pack, CDS983820B, 23ea.

Open Heart Pack, CDS840242k, 20ea.

General Lap Pack, CDS982964A, 20ea.

Total Hip Pack, CDS983875A, 15ea.

Minor Vascular Pack, CDS983819, 15ea.

Total price: \$107,044.30

Delivery Date: 9/15/2013

This request is for Medline brand equipment to be provided to the Surgical Department to ensure that lab procedures within the department meet the increasing patient demand at the VA Medical Center Cleveland.

4. **Statutory Authority Permitting Other than Full and Open Competition:**
 - (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
 - (2) Unusual and Compelling Urgency per FAR 6.302-2;
 - (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
 - (4) International Agreement per FAR 6.302-4
 - (5) Authorized or Required by Statute FAR 6.302-5;
 - (6) National Security per FAR 6.302-6;
 - (7) Public Interest per FAR 6.302-7;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** Due to the time required to adjust to a different manufacture there are several compelling reasons to sole source to Medline Custom Sterile Surgical Packs until new VISN or Central Region Contracts can be awarded. These reasons included: Changing pack manufacturers, components, or distributors takes several months to implement. Medline is the only vendor which has the ability to distribute any of the several manufacturers currently in use in **VISN 10**.

Failure to establish a contract will require individual orders for custom packs to be awarded through contracting activity, which will not allow for just in time delivery. Space concerns and current VA inventory metrics do not allow for overstocking of packs. Packs are generally bulky and Logistics must keep no more than 2-4 weeks of stock on hand to meet performance measures. The process from assembly to VAMC delivery takes 6-8 weeks. Failure to procure packs on a timely basis can affect scheduled surgeries, resulting in delayed or cancelled cases and a decrease in the quality of care. The statement of work requires the contractor to validate the sterilization process through the Association for Advancement of Medical Instrumentation (AAMI) must validate the sterilization process. Without adequate transition period to switch to a different Custom Surgical Packs manufacture this is risk that this validation could not occur in time. Improperly processed Custom Surgical Packs can cause delays and under certain circumstances cause serious complications in an essential aspect of the VA's mission of providing healthcare to our nation's veterans.

Accordingly, Medline is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** The Contracting Officer will ensure posting requirements to Federal Business Opportunities (FBO) are followed IAW FAR Part 6.302-1. In order to maintain patient services in VHA medical facilities, competition amongst more than one source has been deemed impracticable by the Contracting Officer based on the considerations set out above. However, the longer-term contract will be issued open market that will allow for competition to fulfill the Department of Veterans Affairs long term needs. This justification relates solely to the need of providing a bridge contract for this urgently needed requirement pending the award of the long term contract.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Currently, the contract pricing has been established fair and reasonable per FAR 8.404(d) and will be used as a benchmark for renegotiated pricing.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted concerning Custom Surgical Packs industry and it was discovered there are other providers currently in the market place. However, for the reasons stated above this procurement dictates that undue delays of potentially going with one of the other manufactures overrides the possibility of competing amongst all for this limited duration sole source contract.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:**
It is clinically imperative that the use of the Custom Sterile Surgical Packs continue in the interim until new VISN or Central Region contracts can be awarded. Medical centers employ the use of the Custom Sterile Surgical Packs in routine and emergency surgeries on a daily basis. Custom Sterile Surgical Packs are critical

to patient care and unanticipated undersupply situation if the same number of Custom Sterile Surgical Packs become unavailable due any delay or lapse in availability of Custom Sterile Surgical Packs pending the award of new contracts.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

None

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

IAW FAR 6.302-2 (d)(i)(B) the period of performance will not exceed the time necessary for the agency to enter into another contract for the required goods through the use of competitive procedures. To remove any barriers to competition in the future, prior to making subsequent acquisitions for Custom Surgical Packs competition will be sought.

12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

_____	<u>8/13/2013</u>
Name: Douglas T. Stranman	Date
Title: Chief, Distribution Section	
Facility: VA Medical Center	

13. Approvals in accordance with FAR 6.304

- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

_____	_____
Name: Thomas P. Moore	Date
Title: Contracting Officer	
Facility: Network Contract Office 10	

- a. **NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.

_____	_____
Name Terry L. Spitzmiller	Date
Network Contract Manager	
Network Contracting Office 10	