

LIMITED SOURCES JUSTIFICATION
FAR PART 8.405-6(d)¹

2237 Transaction # or Vista Equipment Transaction #: 540-14-1-070 9001

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source: Provide original manufacturer's name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, ALSO provide dealer information.)

Manufacturer/Contractor: Olympus America Inc.

Manufacturer/Contractor POC & phone number: Steven Wendt, 484-896-5436

Mfgr/Contractor Address: 3500 Corporate Parkway, P.O. Box 610, Center Valley, PA 18034-0610

Dealer/Rep address/phone number: Dailas Kelley, 800-848-9024 extension 106676

The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs
Louis A. Johnson, VA Medical Center (540)
1 Medical Center Drive
Clarksburg, WV 26301
4

VISN:

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

Requesting approval of a task order against a VA FSS schedule for brand name equipment from a sole source provider, Olympus America Inc., for a five-year lease of endoscopic equipment (national VHA standardized equipment) to be used in the Louis A. Johnson VAMC (LAJVAMC) operating room.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

The LAJVAMC needs newer video bronchoscopes, video gastroscopes, video colonoscopes, rhino laryngoscope, video processors, connection cables and other miscellaneous items needed to make the endoscopes functional. The acquisition will be a task order issued against Olympus America's VA FSS contract (V797P-2065D) via its VA NAC approved Master Lease Agreement for a period of 5 years.

(b) ESTIMATED DOLLAR VALUE: \$1,118,929.00

(c) REQUIRED DELIVERY DATE: March 1, 2014

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the require-

¹ FAR Version: "As of July 1, 2013"

ments to the exclusion of other sources:

Under FAR 8.405-6(b), the use of limited source procedures for Federal Supply Schedules may be used when only one source is capable of responding due to unique or specialized nature of the work. On December 6, 2010, DUSHOM published a memo, *VHA National Standardization of Endoscopes*, which mandated VA Medical Centers to standardize their endoscopy programs and procure endoscopic equipment via leasing agreements with one of the three major manufacturers—Olympus, Pentax, or Fuji—using their VA FSS contracts. (Fuji does not currently have a VA FSS contract for endoscopes; so, essentially, there are only two endoscope vendors: Olympus and Pentax.) Afterwards, the LAJVAMC entered into a 3-year endoscopy equipment lease agreement with Olympus America, Inc. and took steps towards standardizing its endoscopy program SOPs specifically for the Olympus endoscopy equipment. At that time, Olympus America was preferred because it offered the best endoscopes, as compared to the other two DUSHOM-mandated manufacturers. Currently, Olympus America is still preferred because it offers the best, most advanced endoscopes, according to the LAJVAMC Surgery personnel who use the endoscopes on a day-to-day basis.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.404(d) TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

The contracting officer will ensure that the items provided are consistent with Olympus America's VA FSS pricing which has already been determined to be fair and reasonable. Aside from price, Olympus scopes have been used at the LAJVAMC for a many years. These scopes have performed the LAJVAMC's medical staff's expectations. Their performance enhances lives of many of our Veterans. Performance of these scopes is also dependent upon the familiarity of the practitioner (physician) and staff who cleans, tests & stores them. Each of these groups has reached a level of expertise with Olympus scopes to the point of jeopardy to patient safety if acquisition of this brand is deviated. Olympus' past performance here has been proficient, professional, timely, and un-interruptive to Veteran care. Further, Olympus scopes offer technology which is most conducive with physician training and equipment operation. Therefore, the ability to maintain standardization of one brand of endoscopes will facilitate consistent Standard Operating Procedures (SOP) written IAW VHA Directive 2009-004.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

Market research was conducted on the VA NAC Contract Catalog Search Tool to confirm that the items required are on Olympus America's VA FSS contract and also to confirm that Olympus America is the only VA FSS source for the items required. LAJVAMC has used Olympus scopes for over twenty years with the exception of a couple of years where LAJVAMC used Pentax scopes—during the time that this facility used Pentax scopes there were multiple problems with the scopes. They did not hold up as well under the case load which was significantly lower than our current case load. They were sent out for repair more frequently and the company did not have a quality program for repairs and tracking. All staff is familiar with the proper set-up, use, pre-cleaning, cleaning, and high level disinfecting of the Olympus scopes.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

In FY12, LAJVAMC performed 1,816 endoscopic procedures (1,224 colonoscopies, 516 esophageal-gastro-duodenoscopies, 60 bronchoscopies and 16 flexible sigmoidoscopies). Currently, LAJVAMC is participating in a national VA colonoscopy trial and is required to perform 1,250 colonoscopies per year; participation in this trial is a requirement for LAJVAMC to obtain its cancer accreditation. In order to meet the expected demand of endoscopic procedures, LAJVAMC needs to lease 10 colonoscopes, 7 gastroscopes, 6 bronchoscopes and 3 rhinolaryngoscopes (including the scopes' components, e.g., processors, light sources, scope guides, cables, etc.). The new lease agreement will enable LAJVAMC to return its existing endoscopes and get newer, more advanced endoscopes. Olympus America's *Master Equipment Lease* agreement specifies that the lease must consist of a

base year (or less) plus 4 one-year options. The base year and each option year must expire on September 30 of each year. Depending on the date of award, the resulting task order will have an option term on the end of less than one year so that the full 60-month term can be fulfilled. The prices for each of the items requested to be included in the lease agreement (on purchase request 540-14-1-070-0001) represent the monthly price of the item over the term of the lease (the lease price for each piece of equipment is estimated by dividing Olympus America's VA FSS contract price for the item by the number of months it's being leased). Aside from the equipment, there will also be costs for maintenance (via a service agreement) and property taxes. The LAJVAMC has purchased many items over the years to support and enhance the Olympus endoscopes and the new lease will enable the facility to maintain compliance with the DUSHOM's VHA National Standardization of Endoscopes mandate. Sterile Processing Service (SPS) currently has five standard operating procedures that are in use; the new Olympus scopes will still have the same five standard operating procedures and competencies. However, if LAJVAMC were to go to another company (i.e., use other than Olympus scopes), then SPS and the Operating Room would have to completely rewrite all standard operating procedures and competencies for all items that would be received. This would entail the five standard operating procedures for the scopes plus the additional procedures for the video processor, light source, interface converter, flushing pump, printer, monitors, and ENT Laryngoscopes. This would be an additional in-service, standard operating procedures, and competencies. There would be a learning curve to switch all the above products to another company that would slow the process down. This would be frustration for the surgeons to become familiar with the scopes and also fewer procedures scheduled due to time constraints. LAJVAMC has all brushes, flush pumps, and leak testers that are needed to clean each individual scope. There are eleven different brushes that are currently being stocked for the cleaning of all Endoscopes and Bronchoscopes. If LAJVAMC were to change all new brushes would have to be ordered. The same with the two leak testers; there are two testers in the decontamination area and two testers in the operating room area that would need to be changed. Also the two flush pumps that are used to push fluid through the scope during the cleaning procedure would need to be changed. This would require additional funds to purchase these items, in addition to the new endoscopes.

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:

None.

(9) REQUIREMENTS CERTIFICATION: I certify that the requirement outlined in this justification is a bonafide 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*



 SIGNATURE
 Charles E. Loar, Jr.
 NAME

 DATE
 10/10/13
 DATE
 Facility, Chief Logistics Officer
 TITLE

Charles E. Loar 235823
Signature required by Charles E. Loar 235823
 The original document must be signed by the person
 whose name is on the signature line.
 Date: 2013-10-10 10:27:38 -0400

 Logistics
 SERVICE LINE/SECTION

Louis A. Johnson, VAMC (540) Clarksburg, WV
 FACILITY

(10) APPROVALS IN ACCORDANCE WITH FAR 8.405-6(d):

a. **CONTRACTING OFFICER'S CERTIFICATION (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Brent M. Burns 258222

Digitally signed by Brent M. Burns 258222
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=brent.burns@va.gov, cn=Brent M. Burns 258222
Date: 2013.10.10 15:03:40 -04'00'

CONTRACTING OFFICER'S SIGNATURE

DATE

Brent M. Burns, Supervisory Contract Specialist
NAME AND TITLE

Station #540, Clarksburg, WV
FACILITY

HIGHER LEVEL APPROVAL (For orders over \$3,000): REQUIRED NOT REQUIRED

b. **NCM** : I certify the justification meets requirements for restricting consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

Iachini, Benjamin P

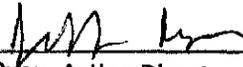
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ou=InternalStaff, cn=Iachini, Benjamin P
Date: 2013.10.31 11:23:40 -04'00'

10/31/2013

Benjamin P. Iachini, NCM, VISN 4

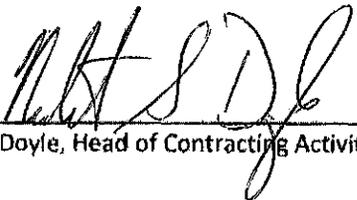
DATE

c. **SAO EAST** : I certify the justification meets requirements for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.


Jeffrey Ryan, Acting Director, SAO East

11/18/17
DATE

d. **VHA HCA'S REVIEW AND APPROVAL(over \$650,000 to \$12.5 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.


Norbert Doyle, Head of Contracting Activity (HCA)

11/18/13
DATE