

9/19/14

2014-0556-19 - Olympus America (w/g)

KAW

Attachment A: Request for Limited Sources Memo Format

LIMITED SOURCES JUSTIFICATION

ORDER >\$3,000

FAR PART 8.405-6(g)

2237 Transaction # or Vista Equipment Transaction #: 554 14 3-143-0048

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in paragraph 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 V797P-5065D

Manufacturer/Contractor POC & phone number: Marci Barner 720-839-0470

Mfr/Contractor Address: 3500 Corporate Parkway, P.O. BOX 610,

Dealer/Rep address/phone number Center Valley, PA 18034-0610

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

4100 E. Mississippi Ave, Suite 913

Glendale, CO 80246

Dave Geary

VISN:

10

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

The action will be awarded as a new lease ESS Order at a firm-fixed-price with Olympus America Inc, 3500 Corporate Parkway, PO Box 610, Center Valley PA 18034.

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

Scopes and equipment needed to perform various Gastroenterology (GI) procedures such as colonoscopy and Esophagogastroduodenoscopy (EGD). This includes gastrosopes, colonoscopes, Endoscopic Ultrasound (EUS) scopes and processors. This equipment is used to perform diagnostic and screening procedures of the GI tract on patients.

(b) ESTIMATED DOLLAR VALUE: \$312,797.88 Yearly, \$1,563,989.40 Total

(c) REQUIRED DELIVERY DATE: 10/1/2014

(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. (CHECK ALL THAT APPLY AND COMPLETE)

☒ 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

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requirements to the exclusion of other sources.

These scopes are cleaned and disinfected in one location and obtaining a different brand would necessitate getting the accompanied equipment for cleaning such as processors and video for other departments to be able to meet the cleaning requirements. While the other competitor does make scopes, they are inferior to the Olympus scope. Physicians have recorded that the design of other scope brands make it difficult to get into the cecum (the ending point of a colonoscopy) and increases the time it takes to do the procedure. In addition, physicians state that the [redacted] system does not have clear pictures making it difficult to see abnormalities if it would otherwise be used by other physicians, including surgeons, which directly affects the quality of patient care. In addition, the downtime that it would take to train staff and do an equipment change would dramatically restrict our patient procedures. Olympus Corporation has developed Narrow Band Imaging (NBI) to be used with colonoscopes and gastroscopes to provide superior image quality. No other vendor on the market uses NBI to achieve the high levels of detail of the mucosal surface, and the vessels underneath. This technology allows the provider to see the barriers of an abnormal growth more clearly, and assist in determining the best location to biopsy. This will provide improved patient care, and decrease in repeat procedures. Current delays already exist due to not having the necessary capital equipment to support current patient case load. There are currently 633 unresolved GI Endoscopy consults in VISTA, with the following distribution: 427 scheduled, 81 active and 125 pending.

☐ A patent, copyright or proprietary data limits competition. The proprietary data is:

☒ These are "direct replacements" parts/components for existing equipment already being used in the GI Department. If a different brand was purchased the equipment required to be used with the scopes would need to be replaced causing an increased cost in purchasing new equipment and a delay in patient care during trade out and training on new equipment.

☒ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.
Olympus scopes are seen as the industry standard and they are used at the majority of VAs across the county. Most other health care facilities use Olympus scopes, including the University of Colorado Hospital where most of our physicians have a joint appointment. Having a different scope system would not only make it difficult for our physicians (including fellows) to stay competent on two different systems but, it would also be costly. Currently we have several departments outside of GI that use Olympus scopes, including pulmonary, operating room, and bronchoscopy. These scopes are cleaned and disinfected in one location and obtaining a different brand would necessitate getting new scopes and the accompanied equipment such as processors and video for these departments as well.

☐ The new work is a logical follow on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

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☒ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays. The GI Department is currently working on reducing a backlog in completing patient procedures. With the recent news coverage of a delay in the VA providing patient services in a timely manner, there is an urgent need to purchase these scopes so that these procedures can continue without interruption in patient care.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

GSA/FSS has already determined the prices under the schedule contract is fair and reasonable. Even though the price has been determined fair and reasonable the VA is authorized to ask for additional discounts. Olympus has provided pricing below their FSS contract.

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

Olympus scopes are seen as the industry standard and they are used at the majority of VAs across the country. Most other health care facilities use Olympus scopes. Including the University of Colorado Hospital, where most of their physicians have a joint appointment. Having a different scope system would not only make it difficult for their physicians (including fellows) to stay competent on two different systems but, it would also be costly. Currently they have several departments outside of GI that use Olympus scopes, including pulmonary, operating room, and bronchoscopy. These scopes are cleaned and disinfected in one location and obtaining a different brand would necessitate getting new scopes and the accompanied equipment such as processors and video for these departments as well.

Denver VAMC's scopes have surpassed their life expectancy at seven years. Repair expenditures have risen dramatically in the past eight months, with a cost of \$9,000 for one scope as recent as February 2014. In a 2007 article in OR Manager the author states that the combined age of scopes in a study of comparable facilities was 3.4 years. Denver VAMC's most recent scopes are from 2011 and the majority of their other scopes are from 2007. With the increase in patient volume over the past seven years it is critical that they get these scopes replaced quickly before they find themselves with more of their scopes out for repair and in a predicament where patient procedures must be put on hold. Previously, Denver VAMC has purchased scopes. In this new procurement, leasing will allow them the flexibility of receiving replacement scopes when one is damaged or not working correctly and must be sent out for repair.

While the other competitor, [REDACTED], does make scopes, they do not meet the needs of the VA. Providers have stated that the design of the scope makes it difficult to get into the cecum (the ending point of a colonoscopy) and increases the time it takes to do the procedure. In addition, providers state that the [REDACTED] system does not have clear pictures making it difficult to see abnormalities that would otherwise be used by other physicians, including surgeons. In addition, the downtime that it would take to train staff and do an equipment change would dramatically restrict our patient procedures, and lead to further patient appointment delays.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

Olympus scopes are seen as the industry standard and are used at the majority of VA's and other major health care facilities across the United States because of their image quality and compatibility.

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(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:

Based on the professional medical judgment of the GI Interventionalists at Denver VA Medical Center, an alternative product would not meet all of the specifications necessary to treat veterans congruent with their clinical needs. In the future, new technology will be considered by other competitors.

(9) 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. 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 (and control point official, chief of service or someone with responsibility and accountability.)

Jean M. Brumbill
SIGNATURE
Jean M Brumbill
NAME
Denver VAMC
FACILITY

9/17/2014
DATE
Medicine Service
SERVICE LINE/SECTION

(10) APPROVALS IN ACCORDANCE WITH FAR 8.405-6(h).

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

Kim M. Cooper
CONTRACTING OFFICER'S SIGNATURE
Kim M. Cooper - CO
NAME AND TITLE

9/17/14
DATE
VAMC 19
FACILITY

HIGHER LEVEL APPROVAL: (REQUIRED \$3K and above)

b. QA OFFICER/Designee: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief

Angela Lakatos
SIGNATURE
Angela Lakatos, NCO 19 QA

9/16/14
DATE

c. NCM/PCM/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief

Curtis Jordan
SIGNATURE

9-18-2014
DATE

Curtis Jordan
NCO 19, Director of Contracting

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HIGHER LEVEL APPROVAL (Required For orders over \$500,000):

d. SAO: 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.

Delia A. Adams
SIGNATURE

9-19-14
DATE

Delia A. Adams MBA, CPCM
DIRECTOR, SAO WEST

e. VHA HCA REVIEW AND APPROVAL (over \$500,000 to \$10 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 S. Doyle
Norbert S. Doyle
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

9/22/14
DATE