

**LIMITED SOURCES JUSTIFICATION
ORDER >\$100,000
FAR PART 8.405-6(g)**

2237 Transaction # or Vista Equipment Transaction #: 526-11-4-641-0942

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is the only 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:

Olympus America Inc.
3500 Corporate Parkway
P.O. Box 610
Center Valley, PA 18034-0610

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

(1) AGENCY AND CONTRACTING ACTIVITY:

1. The Department of Veterans Affairs Network, VISN 3 Network Contracting Activity (10N3/NCA), 130 W. Kingsbridge Road, Bronx, New York 10468 has received a requirement to lease Medical Scopes and Related Equipment signed by the Medical Services at:
 - a. Northport VAMC
 - b. Manhattan VAMC
 - c. Bronx VAMC
 - d. Montrose VAMC
 - e. Castle Point VAMC
2. In accordance with FAR 8.405-6(b)1 and under the authority of FAR 6.302-1(a)(2) and the Statutory Authority of Â§ 41 U.S.C. 253(c)(1) we seek create a Blanket Purchase Agreement (BPA) via the FSS Schedule.

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

1. Negotiation shall be conducted to procure a lease with Olympus America Inc. per the VHA directive listed below to standardize the leasing of endoscopes to one manufacturer per site.
2. VISN3 intends to negotiate a lease agreement with Olympus America to provide the following equipment in an effort to standardize Gastrointestinal Endoscope equipment and repair services by replacing the Olympus scopes currently owned by the VISN3 sites listed above with brand-new leased equipment. No used of equipment of any kind will suffice.

3. The proposed contract vehicle shall be a BPA based on Olympus current mandatory FSS schedule with a period of up to 3 years.
4. The intention of this standardization effort is twofold,
 - a. first to avoid viral outbreaks (as has happened before), under VHA Directive 2009-004 and VHA Handbook 1761.1, VHA authority has mandated that standardization of equipment, processes and procedures be implemented immediately to ensure patient safety and health.
 - b. Secondly, to achieve the goal of establishing locally standardized GI endoscope inventories without incurring expense beyond that absolutely necessary.
5. In addition, substantial savings in operating expenses can be realized going forward if we "right-size" the equipment inventory at each facility in consideration of anticipated case load. This standardization effort provides a natural opportunity to realize these savings.

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

1. The VA of New York and New Jersey (VISN3) is required to lease Olympus medical scopes and related equipment and services to include: EGD endoscopes, enteroscopes, colonoscopes, sigmoidoscopes and duodenoscopes (ERCP endoscopes).
2. Olympus is only the source that meets the requirements to implement the mandated directive to standardize scopes via a leasing agreement.
3. All items leased must be compatible with existing Olympus equipment.
4. The following list below are the items that are on FSS schedule:

Olympus	Site	Models	Qty
	BX	CF-H180AL	1
		CLV-180	1
		CV-180	1
		GIF-H180J	1
		EU-ME1	1
		OEV-261H	1
		GF-UCT180	1
		MAJ-1597	1
	NY	GIF-H180	1
	NP	GIF-H180J	2
		PCF-H180AL	1
		CF-H180AL	2

(b) ESTIMATED DOLLAR VALUE (including option years): \$ 473,559.00

(c) REQUIRED DELIVERY DATE: As soon as possible

(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 requirements to the exclusion of other sources.

1. Under VHA Directive 2009-004 and VHA Handbook 1761.1, VHA authority has mandated that standardization of equipment, processes and procedures be implemented immediately to ensure patient safety and health.
2. The agency's minimum needs may only be satisfied by a supply or service that is unique and available from only one responsible source.
3. Olympus scopes characteristics are unique to Olympus. Olympus is the appropriate distributor of these items to Government Accounts. It is in the best interest of the Government to purchase these items from one manufacturer.
4. Per VHA Directive 2009-004 and VHA Handbook 1761.1, a needs assessment survey was completed for each facility. The assessment determined that the facilities listed in Section 1 above have purchased significant and current-generation GI endoscopic equipment from Olympus.
5. Purchasing universal alternatives would cause issues with standardization which would cause issues with cleaning and decontamination of these instruments.

This would cause serious bodily damage and harm as it did in viral outbreaks in Tennessee, Georgia and Florida which prompted the creation of the standardization procedures above.

Thus Olympus is the only contractor that can provide the necessary items and services to meet the needs of the facilities listed in Section 1 in VISN3. All items leased must be compatible with existing Olympus equipment.

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

☐ These are "direct replacements" parts/components for existing 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.

1. The Olympus equipment sought under this lease, and the service rendered, must be compatible in all aspects (form, fit and function) with the existing Olympus system presently installed.
2. The newly procured equipment must be compatible with the presently owned capital equipment, software and accessories.

☐ 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.

☐ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

(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:

1. The FSS Schedule pricing for leasing equipment is considered fair and reasonable.
2. The final cost to VISN3 is fair and reasonable as it will be less than or equal to the FSS Schedule pricing.
3. As a result, this procurement strategy represents the best value to the United States Government.

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

1. The market research conducted consisted of a needs assessment survey, and a special notice and pre-solicitation notice posted to fbo.gov
2. Currently, the sites own the scopes, and will have to replace and dispose of outdated equipment, and move all current generation equipment to a leasing agreement.
3. Per VHA Directive 2009-004 and VHA Handbook 1761.1, for health and safety purposes, a needs assessment survey was completed by each facility to determine the state of the scope inventory.
 - a. The assessment determined that the facilities listed in Section 1 above have purchased significant and current-generation GI endoscopic equipment from Olympus.
 - b. Olympus is the appropriate distributor of these items to Government Accounts.
 - c. Olympus was found to be the only company that leases new Olympus equipment.
4. One response was received to the special notice and pre-solicitation. It was from Medical Optics, an endoscope repair company. According to the information provided "they can provide all labor, parts, tools, equipment, materials, transportation and services necessary to provide preventative maintenance services of medical devices. "

5. Since Medical Optics cannot provide leasing for the new Olympus scopes VISN3 requires, they were deemed to have insufficient capabilities to meet VISN3 requirements.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

1. This request is pursuant to the authority of FAR Part 8.405-6(b)1, and FAR Part 6.302-1(a).
2. Under 8.405-6(b)1, the use of limited sources procedures for FSS schedules may be used when only one source is capable of responding due to the unique or specialized nature of the work. The sites listed in Section 1 above require the leasing of numerous medical scopes and related equipment for the gastroenterology department. In the past, these sites had simply purchased this equipment but due to standardization and technology demands, they must now lease their equipment.
3. Under VHA Directive 2009-004 and VHA Handbook 1761.1, VHA authority has mandated that standardization of equipment, processes and procedures be implemented immediately to ensure patient safety and health.
4. FAR Part 6.302-1(a) allows for the procurement of items through other than full and open competition; applicable when the agency's minimum needs may only be satisfied by a service that is unique and available from only one responsible source. Many of the required scopes may only be purchased through open market procedures. There are competing companies that can provide other scopes, but due to standardization requirements referenced above, only Olympus scopes can be purchased due to their leasing options. The requirement shall be posted as other than full and open competition which will not allow other contractors to reply to the solicitation.

(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:

1. This procurement involves replacing owned scopes with leased scopes that include a warranty period in conjunction with and/or followed by a repair service period which may become able to be competed amongst eligible repair companies.
2. In addition, this procurement shall be in the form of a Blanket Purchase Agreement, should a future contractor pose better pricing and exceptional lease terms, the Government may always opt out the proposed BPA and create a new BPA with other contractors to fulfill this need.

(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.)*

//SIGNED//

SIGNATURE

Salvatore Tatta

NAME

James S. Peters VAMC

FACILITY

DATE

2/10/12

Chief Biomedical Engineer

TITLE

Biomedical Engineering

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.

CHRISTOPHER WARD

CONTRACTING OFFICER'S SIGNATURE

VISN3 CONTRACTING OFFICER

SPECIAL PROJECTS COORDINATOR

DATE

2/10/12

NAME AND TITLE

FACILITY

HIGHER LEVEL APPROVAL (For orders over \$500,000): ☐ REQUIRED ☒ NOT REQUIRED

b. **QA OFFICER:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief. *This signature may be the VISN NCM/PCM if the Contracting Officer and Contracting Supervisor is the same individual.

SIGNATURE

DATE

N/A

NAME AND TITLE

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

SIGNATURE

DATE

NAME

VISN 3 NCM

- d. **SAO:** I certify the justification meets requirements for other than full and open competition.

N/A

Name
Director
Service Area Office, East

Date

- e. **VHA HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (over \$50 million), approve (up to \$ 50 million) for other than full and open competition.

N/A

Norbert Doyle
Acting Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

Date

- f. **VA Deputy Senior Procurement Executive Approval (over \$10 not exceeding \$50 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 other than full and open competition.

N/A

Iris B. Cooper
Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

Date

- g. **VHA Senior Procurement Executive Approval (over \$50 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 other than full and open competition.

N/A

Jan R. Frye
Deputy Assistant Secretary for Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs

Date