

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: [REDACTED]

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: LeAngela Alread 423-753-3110

Mfr/Contractor Address: 3500 Corporate Parkway, Center Valley, PA 18034-0610

Dealer/Rep address/phone number: Bart Teal 803-422-4976

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs
VHA, SAO East, NCO 7, Charleston, SC
Ralph H. Johnson VA Medical Center
109 Bee Street
Charleston, SC 29401
07

VISN:

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

Request for approval of FAR Part 8, firm fixed price, 36 Month Lease for Olympus GI Endoscopes, Bronchoscopes, and accessories which are solely and fully compatible with current, RHJVAMC on-site Olympus EVIS Exera III Video System; including all service, repair, training, shipping, technical support, and maintenance. The required Lease and associated services, repair, training, shipping, technical support, and maintenance are provided by Olympus America, Inc. under VA Mandatory Use VA NAC Contract: V797P-2065D. This request is the result of a VHA policy to standardize and lease endoscopes rather than purchase. The VHA Procurement and Logistics Office established an Integrated Product Team (IPT) to develop requirements for the national standardization of endoscopes throughout VHA. This IPT has determined that national standardization creates best value, enhances the safety and quality of patient care, and results in reduced variability in the number of different processes required for endoscope setup, use, and reprocessing, thus reducing the potential for negative patient outcomes and errors. In accordance with VA Deputy Under Secretary for Health for Operations and Management Memo, dated December 21, 2012, "facilities are expected to standardize endoscope inventories to one vendor through the use of national leasing contracts." This request is the result of VISN 7's decision to comply with the required standardization by leasing endoscopes from Olympus under VA Mandatory Use VA NAC Contract: V797P-2065D. This request is a RHJVAMC facility specific follow on to the former VISN 7 consolidated Olympus Endoscope requirement, which expires March 14, 2015. The anticipated period of performance is March 15, 2015 - March 14, 2016 with two (2), twelve month options.

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

The RHIVAMC requires the lease of Olympus Flexible GI Endoscopes, Flexible Bronchoscopes, and accessories including all service, repair, training, shipping, technical support, and maintenance to comply with VHA Standardization and Reprocessing Guidelines. The required Olympus scopes are fully and solely compatible with current, RHIVAMC, on-site EVIS Exera III Video Systems. The RHIVAMC requires the Olympus HD 190 Series Endoscopes for diagnostic and therapeutic GI procedures performed in the Endoscopy Dept. and OR. In addition, Olympus HD 190 Series Bronchoscopes are required for diagnostic and therapeutic procedures primarily in the Pulmonary Dept. The requested Olympus HD 190 Series Endoscopes and Bronchoscopes are the only market available endoscopes and bronchoscopes compatible with the RHIVAMC's already owned and installed Imaging Platforms located in the RHIVAMC's GI Dept., Pulmonary Dept., and OR. Olympus HD 190 Series Endoscopes and Bronchoscopes produce high quality imaging with advanced features for technical maneuvers. Olympus HD 190 Series Colonoscopes provide close focus function, variable stiffness, passive bending, high force transmission, and wider field of view. Olympus HD 190 Series Gastrosopes provide close focus function, built-in water jet, and superior visualization. Olympus HD 190 Series Bronchoscopes provide rotating control, increased angulation, and superior visualization. With the impending expiration of the VISN 7 consolidated requirement for Olympus GI, Pulmonary, and OR Leases, the Olympus 180 Series Endoscopes are scheduled for return to the company. Under this RHIVAMC specific requirement, Olympus 180 Series Endoscopes and Bronchoscopes are planned for trade-in credit. In order to address workflow demand and provide current, updated technology for Veteran patient care, the Olympus 190 Series Endoscopes and Bronchoscopes will comply with the VHA Endoscope Leasing Standardization requirements and meet RHIVAMC facility needs.

(b) ESTIMATED DOLLAR VALUE: \$ [REDACTED]

(c) REQUIRED DELIVERY DATE: March 16, 2016

(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.

In accordance with FAR 8.405-6(a)(1)(H)(B), there is only one source capable of providing the supplies and services required because the supplies and services are unique and highly specialized. These critically needed Olympus scopes are commonly used on a daily basis to diagnose various types of ailments that require immediate attention or follow-up screening. The constant turn-around/procedural usage of the scopes requires that instruments are readily available to administer patient care. A shortfall in not having sufficient scopes on hand will impact patient screening and diagnoses of ailments that would have otherwise caused further ailments or death to our nation's veterans. The requested Olympus HD 190 Series Endoscopes and Bronchoscopes are the only market available endoscopes and bronchoscopes compatible with the RHIVAMC's already owned and installed Imaging Platforms located in the RHIVAMC's GI Dept., Pulmonary Dept., and OR. Olympus HD 190 Series Endoscopes and Bronchoscopes produce high quality imaging with advanced features for technical maneuvers. Olympus HD 190 Series Colonoscopes provide close focus function, variable stiffness, passive bending, high force transmission, and wider field of view. Olympus HD 190 Series Gastrosopes provide close focus function, built-in water jet, and superior visualization. Olympus HD 190 Series Bronchoscopes provide

rotating control, increased angulation, and superior visualization. With the service contract as part of the lease, will better ensure the availability of these scopes in emergency situations to care for RHJVAMC Veteran patients.

In addition, the lease terms and conditions of Olympus's VA Mandatory Use F55 contract V797P-2065D, are available solely through Olympus. Olympus is the only authorized provider of the Olympus scopes which are solely and fully compatible the current, RHJVAMC on-site Olympus EVIS Exera III Imaging System. The required, associated maintenance and services are exclusively offered by Olympus due to proprietary rights and original equipment manufacturing of the Olympus scopes and EVIS Exera III Imaging Systems. There are no third party vendors authorized to perform these services, nor are there any manufacturers with qualified technicians outside of Olympus with the capabilities to perform maintenance on this equipment. Any individual performing maintenance on this equipment without proper certifications will void the warranties and cannot assure optimum operation of the required Olympus instruments. VHA Policy established by the Deputy Undersecretary for Health for Operations and Management requires that all facilities must standardize on a specific scope lease contract. The objective of the national standardization was to mitigate the risk of different processes for cleaning and handling. The current VISN 7 consolidated Olympus endoscope contract, expiring March 14, 2015, has further standardized processes and procedures for cleaning the required scopes in order to be in compliance with the VHA mandate. The current RHJVAMC competencies, equipment, training and procedures are specific to these standardized Olympus products. The required leased scopes must interface (as they do currently) with existing computer systems as well as the cleaning/sterilizing equipment currently in use at the RHJVAMC.

The Olympus scopes are solely and fully compatible with current RHJVAMC imaging systems. Standardization, and consequently the lease of Olympus scopes better ensures the lack of consumption of RHJVAMC resources on time, repair, and delayed Veteran patient care. Thus, Olympus is the only company capable of providing the required supplies and services with the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in meeting patient care requirements.

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

☒ These are "direct replacements" parts/components for existing equipment.

The RHJVAMC facility specific request to lease these updated instruments with all associated services is following the national standardization mandate and the VISN 7 consolidated requirement for Olympus GI, Pulmonary, and OR Leases. Under this RHJVAMC specific requirement the current Olympus 180 Series Endoscopes and Bronchoscopes are planned for trade-in credit. In order to address workflow demand and provide current, updated technology for Veteran patient care, the updated Olympus 190

Series Endoscopes and Bronchoscopes will comply with the VHA Endoscope Leasing Standardization requirements and meet RHJVAMC facility needs. In addition, the required Olympus scopes are solely and fully compatible the current, RHJVAMC on-site Olympus EVIS Exera III Imaging System.

☒ 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.

This required Olympus Endoscopes, accessories, and services are compatible in all aspects with the existing systems that the RHJVAMC currently uses, including the Olympus EVIS Exera III Imaging Systems. Presently the RHJVAMC has Olympus scopes in use for various areas performing surgical procedures such as GI and Bronchoscopy. Procuring additional scopes from the same vendor ensures the continuity of the RHJVAMC having the ability to sterilize the scopes before they are used in the next procedure. RHJVAMC Physicians, Nurses and other medical staff are trained to use these Olympus scopes and the facility can support these scopes. If a scope is in need of repair the RHJVAMC facility can use a replacement scope because of the compatibility to include the supporting devices, i.e. towers, monitors, this allows the medical staff to interchange the products preventing a delay in patient care. A change in product would demand additional cost in training, sterilization equipment, and establishing the required policies that direct usage, cleaning and maintenance procedures, all of which are currently established.

[REDACTED]

☐ 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 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

The pricing is identical to prices available on VA NAC Mandatory Use Contract: V797P-2065D, GSA Advantage and as provided for in the IGCE.

[REDACTED]

According to RHJVAMC Technical SME, Ginny Ross, the quoted costs for these items are in accordance with the average costs paid by other VA Medical Centers for the same requirement. This requirement is consistent with VHA National Standardization of Endoscopes – 3rd Year Lease Funding Memorandum, dated December 21, 2012, which provided for national standardization of endoscope leases throughout VHA in order to reduce variability in endoscope processing and use. The repair, maintenance and equipment upgrades are easier to maintain with the single vendor - Olympus. The required standardization reduces the variety of instruments and thus the number of SOP's for set-up and re-processing of medical equipment.

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

The mandatory sources available on GSA and the VA NAC Federal Supply Schedules were reviewed in addition to examining the acquisition history and experience with the marketplace. Olympus is the only entity offering the specific leasing requirement on a Mandatory FSS VA NAC contract. GSA Advantage, GSA e-Library and the VA NAC MedSurg Catalog were used to determine providers of Endoscopes and associated services under MAS/SIN #'s: 65 II A/A-200.A-9, and it has been determined that Olympus is the only company capable of providing these specific endoscopes and associated services under the required lease. Market research has demonstrated that the only source for obtaining these proprietary Olympus Endoscope leasing services is from the manufacturer. The Olympus Endoscopes contain technical data proprietary to Olympus and are licensed, sold, and distributed exclusively by Olympus on the Mandatory Use VA NAC Contract: V797P-2065D. The required Olympus scopes are compatible with all aspects of the current RHJVAMC systems and procedures. Market research did not produce any other potential sources capable of providing the specific, required leasing services. On February 9, 2015, Olympus provided an official letter stating that, "for all Olympus...branded products, Olympus America, Inc. is the exclusive distributor in the United States...The lease terms and conditions of Olympus's Federal Supply Schedule Contract (V797P-2065D) are available to our authorized government customers solely through Olympus... Olympus does not have any authorized third party repair service providers. Use of third party repair services and/or parts on Olympus endoscopes invalidates the Olympus limited product warranty. Since Olympus does not test or maintain material compatibility of third party repair parts, use of such parts also invalidates the manufacturer's instructions for cleaning, disinfection and sterilization of Olympus endoscopes." Olympus is the only schedule holder under VA NAC V797P-2065D. In accordance with VAAR 808.002, this FSS contract awarded by the VA NAC in FSC Group 65 is mandatory for use by the VA. There are no other schedule holders who provide these specialized, proprietary scopes and services under the required lease.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

Olympus is the only company capable of providing these specific scopes and associated services under the required lease. The only source for obtaining these proprietary, Olympus Scope leasing services is from the manufacturer - Olympus. The Olympus Scopes contain technical data proprietary to Olympus and are licensed, sold, and distributed exclusively by Olympus on the Mandatory Use VA NAC Contract: V797P-2065D. On February 9, 2015, Olympus provided an official letter stating that, "for all Olympus...branded products, Olympus America, Inc. is the exclusive distributor in the United States...The lease terms and conditions of Olympus's Federal Supply Schedule Contract (V797P-2065D) are available to our authorized government customers solely through Olympus... Olympus does not have any authorized third party repair service providers. Use of third party repair services and/or parts on Olympus endoscopes invalidates the Olympus limited product warranty. Since Olympus does not test or maintain material compatibility of third party repair parts, use of such parts also invalidates the manufacturer's instructions for cleaning, disinfection and sterilization of Olympus endoscopes." Olympus is the only schedule holder under VA NAC V797P-2065D. In accordance with VAAR 808.002, this FSS contract awarded by the VA NAC in FSC Group 65 is mandatory for use by the VA. There are no other schedule holders who provide these specialized, proprietary scopes and services under the required lease. This requirement in accordance with National Standardization for Endoscope Leases as required by VA Deputy Under Secretary for Health for Operations and Management Memo, dated December 21, 2012, "facilities are expected to standardize endoscope inventories to one vendor through the use of national leasing contracts."

(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:

The RHIVAMC will continue to look for new sources and investigate if any other scopes are compatible with national standardization objectives and current RHIVAMC imaging and recording systems.

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

Virginia L. Ross

2-19-15

SIGNATURE

DATE

Virginia L. Ross

Program Specialist, COR

Medical Service

NAME

TITLE

SERVICE LINE/SECTION

Ralph H. Johnson VA Medical Center (Charleston, SC)
FACILITY


(10) APPROVALS IN ACCORDANCE WITH THE VHAPM, Volume 6, Chapter VI: QFDC SOP: This part is filled out by Contracting Staff as part of the justification

Robin D.
Jones
171028

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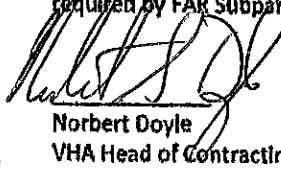
HIGHER LEVEL APPROVAL (Required For orders over \$650,000):

c. 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.

 3/9/15
SIGNATURE DATE

Eldred Jackson
Director, SAO EAST (Acting)

d. VHA HCA 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.

 3/11/15
Norbert Doyle DATE
VHA Head of Contracting Activity (HCA)