

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval
For
Other Than Full and Open Competition**

1. Contracting Activity:

Department of Veterans Affairs
SAO Central Network 15 Contracting Office
4101 South 4th St Trwy
Leavenworth KS 66048

2. Nature and/or Description of the Action Being Processed:

This is a request to issue a contract extension using other than full and open competition procedures for the continuation of a Indefinite Delivery, Indefinite Quantity (IDIQ) contract due to expire on June 30, 2013. This contract provides for vascular products such as: carotid stents, plaque excision devices, embolic protection devices and other related supplies used for the delivery and use of these devices such as various types of catheters; and guidewires. The contract allows for consignment and just in time terms from the incumbent. The contract extension period requested covers the time period of July 1, 2013 through December 31, 2013, a six month period. This is for a firm-fixed contract modification award. *Medtronic, Inc.* is the incumbent for the current contract, VA255-P-0551, which expires on June 30, 2013. The six month extension of this contract will bridge the gap between the expiration of the current contract and the new IDIQ contracts anticipated to be awarded by December 30, 2013. These contracts are expected to be competed promoting competition to the maximum extent practicable pursuant to FAR 13.104 procedures.

The reason for the extension request is to facilitate the solicitation time period needed to complete the action for new contract(s). It was anticipated that the requirements beyond June 30, 2013 would be able to be awarded by the cognizant Contracting Officer but this was not accomplished due to competing priorities. This extension action will ensure availability of essential devices and supplies utilized by the Prosthetics departments and Catherization labs of the following VISN 15 medical facilities; VAMC Wichita KS, VAMC Kansas City MO, Harry S. Truman Memorial VAMC Columbia MO, VAMC Saint Louis MO, VAMC Marion IL. The mentioned VAMCs require a short term solution to ensure availability and consistency of devices and supplies used for treatment of veterans under their care.

Background/Procurement History:

This indefinite delivery, indefinite quantity contract in question is one of 4 currently in place for use by the mentioned VISN 15 facilities for similar devices which were initially competed under full and open competition procedures in 2008. Two current contracts with Covidien/ev3 for similar devices were competed using under full and open competition procedures in 2012 which are also due to expire on 6-30-13. The incumbents of these contracts are; Abbott Laboratories, Boston Scientific, Medtronic, Johnson & Johnson, and Covidien/EV3. These stents and related devices/supplies are highly specialized in nature and required for specific patient care as prescribed by the treating physicians. Of the products available in the marketplace, the physician determines which devices are best suited to meet and treat the medical, health and life-style needs of the specific patient(s). It is essential that the entire breath of vascular devices in the market place be available for use as prescribed by physicians to ensure the fulfillment of VHAs mission of providing exceptional health care to veterans.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

Medtronic, Inc is the Contractor and the estimated price to the Government is \$143,000.00 for the requested six month period. The supplies provided by this contract are Carotid Stent Systems, Biliary Stent Systems, various types of Catheters, Guide Wires, Embolic Protection Systems, in various styles, models, lengths and diameters for appropriate patient care. These items include both implantable and disposable devices/supplies. The inventory is placed at the facility on a consignment basis and devices and supplies are available for just in time purchase requirements in accordance with the terms and conditions of the contract.

4. Statutory Authority Permitting Other than Full and Open Competition:

(X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

There is only one responsible source and no other supplies or services will satisfy the agencies requirements per FAR 6.302-1. The stents and related appliances/devices are Food and Drug Administration (FDA) approved for use for specific indications. Given that the comprehensive needs of each Veteran patient are unique as determined by a clinical evaluation, the clinicians have authority to prescribe the method of treatment to best address the medical condition and functional limitations of his/her patient. Additionally, VA Physicians have various clinical backgrounds (surgery, cardiology, radiology, vascular medicine, neurology, etc.). Whether in formal fellowship programs or formal training in practice pathways, VA physicians receive training on use of a particular type of highly specialized vascular appliance (stents and peripherals) supplied by many manufacturers of these vascular appliances/devices. When they receive this specialized training, they favor (for patient safety and improved results) the appliances they are trained on. The companies currently under contract with VISN 15 that supply these devices are Abbott Laboratories, Boston Scientific, Covidien/ev3, Johnson & Johnson, and Medtronic. This ensures flexibility to VISN physicians when selecting devices for specific indications. Therefore, to ensure VISN 15's capability of providing exceptional health care, it is imperative that the individually unique devices from all mentioned sources be available for physician prescription.

This extension will bridge the gap for six months, which will assist the Prosthetics Departments and Catherization Labs being an asset to the VA Medical Centers by remaining mission focused and accomplishing their goals to that end. Prosthetics departments and logistics are ordering against the existing (IDC-IDIQ) contract; without a contract in place, the Prosthetics Departments and Catherization labs will experience unacceptable delays in fulfilling the agencies requirements which will cause an adverse impact to patient care and result in substantial duplication of costs to the Government that is not expected to be recovered through competition FAR 6.302(1)(ii)(A). The primary mission of VHA is providing professional care for our Veterans and the lack of a contract for these devices and supplies would interrupt the primary mission of the respective VA Medical Centers. The incumbent is honoring prices of the current contract during the extension period. These prices have already been established as fair and reasonable. The incumbent is already set up to provide the necessary devices and supplies and they are proven capable and responsible.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**

The devices and supplies in question are necessary and imperative to the VISN wide patient care. Multiple awarded VISN-Wide contracts will be solicited as full and open competition to cover the needed supplies for the respective VISN 15 VAMCs. The contract(s) will include a base year and 4-option years. The anticipated effective date of new contract(s) is estimated to be by January 1, 2014 or before. Market research will be conducted to ensure maximum visibility to all potential sources.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**

The estimated cost is considered fair and reasonable; it was determined fair and reasonable when the last option was exercised on July 1, 2012. All inventories are on a consignment basis. The use of any item is entirely dependent on patient diagnosis and needed only as determined by the attending physician. The Contractor is paid only after items are implanted and/or used by the Government. The incumbent is honoring prices of the current contract so that there is no adverse effect to the Government during this gap period.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

Market research is a continuous action required by this procurement and these prices are still comparable to the market place. Upon soliciting for multiple award contracts, searches will be conducted on GSA Schedules, NAC Contract Catalog, SAM, VetBiz Registry, FBO, internet searches and consultation with requesting physician(s) for potential vendors.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:**

NA

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

Medtronic, Inc.

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:**

None

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.

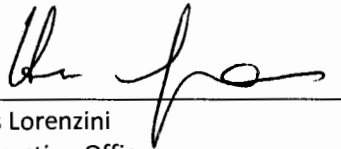


Derrek F. Aniconi
Chief Logistics Officer
VISN 15

6/28/13
Date

13. **Approvals in accordance with FAR 6.304**

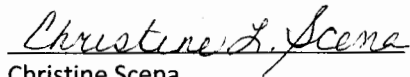
- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Hans Lorenzini
Contracting Officer
Network 15 Contracting Office

6-28-13
Date

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



Christine Scena
Network Contract Manager
Network 15 Contracting Office

6-28-2013
Date