

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA260-17-AP-7908

1. **Contracting Activity:** Department of Veterans Affairs, VISN 20, Portland VA Medical Center, Vancouver Campus, NCO-20. 648-17-4-188-0070.
2. **Nature and/or Description of the Action Being Processed:** In accordance with the VHA SOP for Other Than Full and Open Competition Justifications, the VA Portland Health Care System (VAPORHCS) requires acquisition of a Barrx Flex RFA Energy Generator and Barrx RFA Cart on a sole-source basis. The proposed contract action is for one unit. This new contract is required to continue critical services in providing direct VA patient care. The estimated value of the contract is \$161,000.00.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The facility requires one Barrx Flex RFA Energy Generator and Barrx RFA Cart to provide ablation treatment for dysplastic tissue in VA patients with Barrett's Esophagus. VAPORHCS needs to have this unit to provide care that is consistent with the standards in the community. Currently there are no VA facilities that provide this service within the VISN and treatment of these patients had previously needed to be outsourced which results in increasing cost and risk for complications.
4. **Statutory Authority Permitting Other than Full and Open Competition:** The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2). IAW FAR 13.501(a)(1)(ii), must prepare the justification using format outlined in FAR Part 6.

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The equipment requested is used to ablate dysplastic tissue in the treatment Veterans with Barrett's Esophagus. This condition causes injury to the lower lining of the esophagus. This injury can stimulate the conversion of normal tissue into precancerous tissue called dysplasia. There is widespread concurrence in the medical community that dysplasia significantly increases the risk of developing esophageal cancer. Current guidelines recommend the least invasive approach to treatment and ablation is indicated for large areas of disease. Currently, patients are either referred to surgery (which carries a

morbidity and mortality of 2% with 5-year-survival of 83%) or are outsourced for radiofrequency ablation/RFA, which requires several sessions. There is only 1 FDA approved device for RFA of Barrett's esophagus – the Covidien – Medtronic Barrx Radiofrequency Ablation System. It is the same system used by OHSU and is the standard device used in the community for ablation of Barrett's. In addition, there are no VA facilities that provide this service and with this purchase, we can provide this treatment option to patients within the VISN.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** An unrestricted Brand Name or equal Sources Sought was posted to FBO (VA260-17-N-0675) and closed on 09/04/2017 with no responses. Covidien is the manufacturer and provided the initial quote. This type of ablation system is not offered on FSS under SIN A-41 (Electrosurgical Apparatus) and the manufacturer is the sole provider of this equipment.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** There have been no recent purchases of this brand of ablation unit. There are various ablations units that have been purchased that can be used as a comparison:

VA255-17-P-5209 – Awarded: 08/11/2017 - \$96,763.00 – Microwave Ablation System
VA242-17-P-3439 – Awarded: 08/03/2017 - \$142,312.00 – Sonopet Ablation System
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Current research has found that there is no other technology that meets the criteria needed by VAPORHCS. This criteria includes, but is not limited to, compatibility with the current endoscopy unit's existing endoscopes and processors, and one for which the staff gastroenterologist has extensive experience in the use of the device eliminating the need for training or purchase of additional supportive equipment.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Covidien (the Manufacture) is the only company that has responded.
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:**
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.

Clinton Miller
Administrative Officer, DHSM
VA Portland Health Care System

9/6/17

Date

13. Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:

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

Robert Hamilton
Contracting Officer, NCO-20

09/06/2017
Date

- b. **Director of Contracting /Designee:** I certify the justification meets requirements for other than full and open competition.

Stacia Nunn
NCO 20, Chief, Division II

September 7, 2017
Date