

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 8, Orlando Medical Center, 2237# 675-13-1-4239-0016
2. **Nature and/or Description of the Action Being Processed:** This is a request by the Orlando VA Medical Center (OVAMC) for other than full and open competition (Brand Name) for the procurement of Fresenius dialysis machines. OVAMC has identified a need for 17 dialysis units to streamline the agency's dialysis department's workflow and gain the benefit of a paperless environment.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The 2008T hemodialysis machine is designed to provide hemodialysis treatment by controlling and monitoring both the dialysate and extracorporeal blood circuits. The system's unique feature, Clinical Data eXchange (CDX), allows for real-time access to lab values, medication profiles, progress notes, medical reports, trending data, and other treatment related data. The CDX allows for the transfer of clinical data between the 2008T and Fresenius Medical Information System (FMIS) scheduled for use at the Lake Nona Facility.
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;
 - () (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 2008T is manufactured by Fresenius. The Fresenius brand allows for easy and fast setup of the Intra Venus lines priming. Additionally, the input data on the main screen is streamlined requiring minimal data input to begin patient treatment. The Fresenius brand offers built-in access surveillance program that allows clinicians to monitor the health of a hemodialysis shunt. This is a function critical to the prevention of stenosis development over variable intervals in the great majority of vascular accesses. If detected and corrected, underdialysis can be minimized or avoided.

The Orlando VA bio-medical equipment support specialist is experienced in the function and maintenance of Fresenius systems. Having tacit and explicit knowledge with the Fresenius system will help facilitate equipment troubleshooting, maintenance, and training. Purchasing the Fresenius units allows the Orlando VAMC to benefit from using existing competencies, safety protocols, and maintenance policies. From a logistical perspective, alignment with outlying VA facilities increases accessibility to replacement parts, and affords VA concentrated buying power. Without having to overcome a learning curve due to equipment unfamiliarity the ease of personnel augmentation becomes an added benefit of purchasing the same systems already in use throughout VISN 8. Moreover, the Orlando Veterans Affairs is approved for utilization of the FMIS (patent product) thus creating a seamless integration with Fresenius hemodialysis machines. Features that are unique to the Fresenius dialysis system are the built-in CDX and surveillance capability, and FMIS.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Fresenius has certified small business distributors capable of meeting OVAMC's requirement. To ensure maximum participation, this requirement is being solicited as unrestricted. Teaming agreements are acceptable.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**
To determine price fair and reasonableness contracting representative will compare the Government's cost to open market pricing as well as previous purchase made from various medical centers throughout VA and VISN 8.

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

A thorough search of GSA Advantage, National Acquisition Center, and GSA Xcess did not yield any potential prospects capable of supplying dialysis units through federal supply schedule. Open market online search revealed several manufacturers of the dialysis units. Fresenius was among the leading manufacturers of dialysis machines. The features and functions mentioned in line five are specific to the Fresenius dialysis brand.

Market Price: \$16,500.00 (ea) Estimated Total Procurement Cost: \$280,500.00 NAICS: 334510

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

Discussions with Diego Ponce, Nurse Equipment Coordinator, connotes that throughout VISN 8 all medical facilities except Puerto Rico are equipped with Fresenius dialysis. Mr. Ponce's data was generated through dialogue with nursing staff from outlying facilities. Standardizing dialysis units establishes a single standard of care for veterans across VISN 8 essential for continuity and optimizing healthcare services. Research literature written by Associate Professor, University of Washington, Bessie Young, MD, MPH, FACP reveals that having knowledge of the dialysis machine is imperative to ensuring patient safety, providing quality care, and troubleshooting problems.

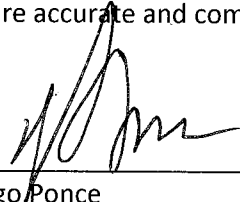
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

Fresenius
Medical Supply Systems

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:**

VA's transformation into a 21st Century organization focus is to improve customer service by delivering cutting-edge medical care. The functions described herein are unique to Fresenius' 2008T dialysis system. Removing or overcome barriers to competition requires that competitors outfit their products with technology catering to the needs of medical professionals, and patient care and comfort.

- 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.



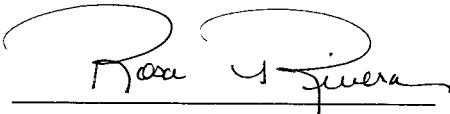
Diego Ponce
Nurse Equipment Coordinator
Orlando VAMC

06/13/2013

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.



Rosa I. Rivera
Contracting Officer
Orlando VAMC

Jun 13, 2013

Date

- b. **Product Line Supervisor (PLS):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Kenneth Williams
Contracting Supervisor
Orlando VAMC

Date

- c. **DNCM/NCM:** (SAT to \$500,000) I certify the justification meets requirements for other than full and open competition.

Mitchell Thomas
Network Contract Manager
VISN 8

Date

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

David M. Fitzgerald
Director
Service Area Office, East

Date

- e. **VHA HCA Review and Approval:** (over \$500,000) 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.

Norbert Doyle
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.

Iris B. Cooper
Executive Director
Office of Acquisition Operations
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.

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

Date