

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

1. Contracting Activity:

Department of Veterans Affairs, Network Contracting Office 16, Jackson, VA *Medical Center*,
1500 E Woodrow Wilson Drive, Jackson, MS 39216

Purchase Request #586-14-2-033-0091

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

This is for the monthly and quarterly service on one (1) Millennium, two (2) Zyza, one (1) 23G and five (5) WROH units. This is a new service contract to include a base and 4 option years. The contract will be awarded firm-fixed price. Period of Performance will be from 1 April 2014 – 30 September 2018.

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

The contractor shall provide preventive maintenance and repair the equipment in accordance with the MAR COR's (manufacturer) specifications. The contractor shall provide service which may consist of calibration, cleaning, oiling, adjusting, replacing parts, and maintaining the equipment, including all intervening calls necessary between regular services and calibrations. All required parts shall be available and must be MAR COR (manufacturer) parts. All DI and carbon tanks must be registered with the FDA as a medical device and manufactured in an ISO 13485 certified/FDA medical device manufacturing facility.

The contractor shall repair any components of the dialysis equipment that are not working properly, without any additional charge, provided replacement is due to normal wear and tear. Contractor must be fully trained on the specific equipment according to MAR COR (manufacturer) specifications in addition to medical water systems.

Contractor shall provide support for the following models and serial numbers:

Model	EE	Serial Number
Millennium	40022	117626
Zyza	32527	17964
Zyza	32526	17965

23G	29456	1224205
WROH	55832	1300350
WROH	55833	1300353
WROH	55834	1301187
WROH	55835	1301186
WROH	55836	1301188

The estimated value of this contract is \$364,826.94 (Base & 4 Options Years).

The Period of Performance is 1 April 2014 – 30 September 2018.

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):

FAR 6.302-1, exception to full and open competition applies to MAR COR who will complete this task as the sole manufacturer of all parts and labor of the existing equipment housed by the Jackson, VAMC, and is the only respective contractor with the requisite knowledge, experience, and technical capability to meet the governments needs in a timely manner.

MAR COR Purification, Inc is the sole manufacturer and is the only source available for training purposes. At the time of this procurement acquisition, there were no other vendors with this type of specialized training. Other contractors were contacted verbally which confirmed there are no other vendors available to perform preventive maintenance services on these specialized dialysis machines. Additionally, MAR COR Purification, Inc can also provide replacement parts as needed without a delay in ordering.

MAR COR Purification Inc is the sole manufacturer of all parts and labor of their equipment. No other vendor will be able to provide such services due to the manufacturer's warranty and

compatibility of the equipment. MAR COR shall provide all preventive maintenance and repair in accordance with ~~the~~ MAR COR's (Manufacturer) specifications. Additionally, MAR COR is fully trained on the specifications of the existing dialysis equipment. All maintenance, calibration, cleaning, and disinfection must be completed without interruption of service as patient care is optimal in accordance to The Joint Commission (TJC) requirements

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

The Contracting Officer conducted further research on 18 March 2014 with Mr. Jeff Bunch, MAR COR Regional Sales Specialist which further confirms that all Mar COR dialysis parts and equipment must be provided by the manufacturer (Mar COR). Due to the complexities of the equipment housed by the VAMC Jackson MS and other FDA compliance issues, it is a requirement that the manufacturer furnish and provide all MAR COR parts and labor. After further discussion with Mr. Bunch, it has been concluded that although services can be performed by other vendors, there were no specialized vendors with the proper training and certification to service the dialysis equipment. Other contractors were contacted verbally which confirmed there are no other vendors available to perform preventive maintenance services on these specialized dialysis machines. Contracting Officer also conducted SBA and VetBiz search with key word under NAICS 333318 the results returned in zero replies with capability.

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

The anticipated cost will be considered fair and reasonable from the onset pricing factor from the prior procurement history, other awarded contracts from government agencies, and a published price catalog on the internet to assist the Contracting Officer in conducting price analysis to determine fair and reasonable pricing. Furthermore, in comparison to Contract VA256-P-0643A which was funded for the amount of \$260,617 and the new contract which will be funded in an estimated amount of \$364,807, there will be an increase in pricing due to recent updates on our dialysis equipment.

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

Market Research was conducted and concluded that MAR COR Purification, Inc was the only source available to provided preventive maintenance and repair of the dialysis equipment.

Contracting Officer conducted SBA and VetBiz search with key word under NAICS 333318 the results returned in zero replies with capability. .

Contracting Officer conducted further research on 18 March 2014 with Mr. Jeff Bunch, MAR COR Regional Sales Specialist which further confirms that all Mar COR dialysis parts and equipment must be provided by the manufacturer (Mar COR). Due to the complexities of the equipment housed by the VAMC Jackson MS and other FDA compliance issues, it is a requirement that the manufacturer furnish and provides all MAR COR parts and labor. After

further discussion with Mr. Bunch, it has been concluded that although services can be performed by other vendors, there were no specialized vendors with the proper training and certification to service the dialysis equipment. Other contractors were contacted verbally which confirmed there are no other vendors available to perform preventive maintenance services on these specialized dialysis machines. Mr. Bunch also indicated that the purchase of new dialysis equipment will be much greater ^{than} that in costs and will not be ~~the~~ the best value to the government since the equipment is really not that dated. The average cost for a new dialysis system will cost around 400K compared to \$365K.

This procurement will be pursued as sole source acquisition for the existing dialysis equipment housed by the VAMC; Jackson MS ^{and} is exclusively manufactured by MAR COR Purification, INC.

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

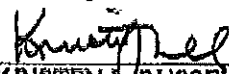
If service is not provided by the manufacturer (MAR COR) then direct patient care will be at risk which will ultimately delay patient care. Currently, there are no other alternatives for in house treatment. MAR COR has a manufacturer's warranty, if PMR is not performed by MARCOR it will void the dialysis equipment warranty. Due to the complexities of the equipment housed by the VAMC Jackson MS and other FDA compliance issues, it is a requirement that the manufacturer furnishes and provides all MAR COR parts and labor. After further discussion with Mr. Bunch, it has been concluded that although services can be performed by other vendors, there were no specialized vendors with the proper training and certification to service the dialysis equipment. Other contractors were contacted verbally which confirmed there are no other vendors available to perform preventive maintenance services on these specialized dialysis machines. Contracting Officer conducted SBA and VetBiz search with key word under NAICS 333318 the results returned in zero replies with capability.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: At the time of this request, there are no other vendor who could possibly meet the requirements of this transaction as MAR COR is the sole proprietor of all parts and labor of the existing dialysis equipment.

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: Unless existing equipment is replaced, there are no other contractors that will be able to provide such services for the dialysis equipment. Contracting Officer conducted further research on 18 March 2014 with Mr. Jeff Bunch; MAR COR Regional Sales Specialist which

further confirms that all Mar COR dialysis parts and equipment must be provided by the manufacturer (Mar COR). Due to the complexities of the equipment housed by the VAMC Jackson MS and other FDA compliance issues, it is a requirement that the manufacturer furnishes and provides all MAR COR parts and labor. After further discussion with Mr. Bunch, it has been concluded that although services can be performed by other vendors, there were no specialized vendors with the proper training and certification to service the dialysis equipment. Other contractors were contacted verbally which confirmed there are no other vendors available to perform preventive maintenance services on these specialized dialysis machines. Mr. Bunch also indicated that the purchase of new dialysis equipment will be much greater than that in costs and will not be the best value to the government since the existing equipment is really not that dated. The average cost for a new dialysis system will cost around 400K compared to \$365K.

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.


KRISTEN L. RUSSELL
Chief Biomedical Engineer
G.V. (Sonny) Montgomery VAMC

4/2/14

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.

Jennifer.adams
7@va.gov
JENNIFER ADAMS
Contracting Officer
VISN 16, P&C

Digitally signed by
jennifer.adams7@va.gov
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Date: 2014.04.02 10:52:42 -05'00'

04/02/2014

Date


b. **P&C:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

jeffery.farley@va.gov
JEFF FARLEY
CHIEF, PURCHASING AND CONTRACTING
DIVISION I SERVICE TEAM

Digitally signed by jeffery.farley@va.gov
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Date

c. **NCM/PCM:** I certify the justification meets requirements for other than full and open competition.


AARON VILLALPANDO
Director of Contracting
NCO16

7 Apr 2014

Date