

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. Contracting Activity:

U.S. Department of Veterans Affairs
Veteran's Health Administration
Network Contract Office (NCO) 15
3450 S 4th St Trafficway
Leavenworth KS 66048

PR 657-14-2-1110-0072 – Hemodialysis Equipment Maintenance & Repair Services

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

Establishment of a sole source, firm-fixed-price contract for OEM full service maintenance and repair of twenty-four (24) installed Gambro brand hemodialysis machines on-site at the St Louis MO VA Medical Center. Proposed contractor:

Gambro
14143 Denver West Parkway
Lakewood CO 80401

The contract will consist of a base and four (4) optional years to commence approximately 4/15/2014, with a total estimated contract price of \$280,620.00, to furnish full service maintenance and repair of Gambro brand hemodialysis machines located in the Hemodialysis Clinic at the following location:

VA St. Louis Health Care System
Jefferson Barracks Division
1 Jefferson Barracks Dr., 1st floor
St. Louis MO 63125

This will be a new contract. None of the equipment to be serviced was previously covered by a maintenance and repair contract. Prior to commencement of the contract the equipment may need to be inspected by the contractor in order to certify that each is in acceptable condition. The cost of this inspection and certification is included in the estimated contract price.

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

The services required are for the furnishing of full service maintenance and repair of installed Gambro brand hemodialysis equipment. Coverage includes all parts, installation, calibration, labor, and travel, tools, test equipment and other incidentals necessary to perform one (1) preventive maintenance every 12 months or every 4,000 hours, whichever comes first, and maintain or restore

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the listed equipment to operating specifications according to manufacturer's recommendations throughout the term of the contract. Support for unscheduled repair services must be responded to via telephone within two (2) hours after receipt and a qualified technician must respond on-site a maximum of twenty-four (24) hours after receipt of the initial request. Only new Original Equipment Manufacturer (OEM) or OEM approved parts can be used.

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):

Gambro is uniquely qualified to provide these services to the St Louis VA Medical Center based upon the following:

- a. The proper maintenance, repair and calibration of the hemodialysis equipment is extremely critical because of the major role this equipment plays in treating patients experiencing renal failure due to acute kidney injury or chronic kidney disease. The most common outcomes of hemodialysis equipment failure are the inability to treat those patients that rely on hemodialysis to treat their life-threatening conditions, and the necessity to fee out patients to alternative hospitals and/or clinics. Having this equipment operate properly is therefore critical to the health and well-being of patients. There is no room for any possible failure of parts, miscalibration or deviation from established maintenance or repair standards. Only factory trained and certified technicians, utilizing diagnostic software specifically designed for the equipment, and the utilization of Original Equipment Manufacturer (OEM) parts can assure that this critical equipment operates properly.
- b. Gambro has the legal rights to propriety equipment diagnostic software. Failure to utilize the propriety diagnostic software may result in the inability to identify equipment operating parameters and the inability to accurately calibrate the equipment.
- c. Gambro has access to OEM parts and supplies. Failure to utilize OEM parts may result in the improper operation of the equipment. Other vendors may have access to the required OEM parts, but they do not stock the full range of parts that is required to assure the maximum response times required by the VA Medical Centers. Only Gambro maintains a full inventory of spare parts

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- d. Gambro has factory trained and certified technicians who are specifically qualified to work on Gambro equipment. Gambro does not contract with any third party service providers.
6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

Sources Sought announcement #VA255-14-I-0620 was published in FedBizOpps commencing February 24, 2014 and was closed March 5, 2014 as required by FAR Subpart 5.2.

The announcement stated in part:

GAMBRO Phoenix Dialysis Equipment - Maintenance & Repair Services

INTRODUCTION:

This sources sought notice is for information and planning purposes only and shall not be construed as a solicitation or as an obligation on the part of the Department of Veterans Affairs (VA). The VA is currently conducting market research to locate qualified, experienced, and interested potential sources. Responses will not be considered as proposals, nor will any award be incurred by interested parties in responding to this sources sought announcement.

SCOPE OF WORK:

(a). Background:

The St. Louis VA Medical Center, John Cochran Division (St Louis VAMC), located in St. Louis MO, requires maintenance and repair services for twenty-four (24) dialysis machines used by Renal Service for direct patient care. Gambro brand "Phoenix X36" machines are currently used by the facility with great success. Continued maintenance and repair services for hemodialysis machines at St Louis VAMC is necessary to ensure ongoing high quality care for our veteran population, while allowing for fast and simple replacement of broken hemodialysis equipment without disruption of care or additional wait times for patients requiring care.

(b). Scope.

This RFI is being used to identify possible sources for furnishing repair and routine preventative maintenance parts and services on Gambro brand "Phoenix" hemodialysis systems used in both outpatient hemodialysis procedures and inpatient hemodialysis procedures on-site at the St Louis VAMC. These machines are used for direct patient care for our veteran population. A service contract for a base period of one (1) year with four (4) option years is contemplated.

The Contractor shall supply all labor, travel, materials, equipment, tools, supervision, any and all incidentals to complete on-site full service planned maintenance and repair of the equipment

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identified below, in accordance with design specifications and the specifications, terms, and conditions of the contract.

EE #	Manufacturer	Brief Description	Model	Serial #	Location
110501	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH25377	A174-01-JC
110502	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH25163	A174-01-JC
110503	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH25376	A174-01-JC
110505	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH25181	A174-01-JC
122264	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH27908	A174-01-JC
122265	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH27909	A174-01-JC
122266	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28102	A174-01-JC
122267	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28104	A174-01-JC
122268	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28105	A174-01-JC
122269	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28115	A174-01-JC
122270	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28116	A174-01-JC
122271	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28126	A174-01-JC
122272	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28132	A174-01-JC
122273	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28147	A174-01-JC
122274	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28155	A174-01-JC
122275	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28156	A174-01-JC
122276	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28161	A174-01-JC
122277	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28163	A174-01-JC
122278	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28170	A174-01-JC
122279	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28172	A174-01-JC
122280	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28173	A174-01-JC
122281	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28177	A174-01-JC
122282	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28178	A174-01-JC
122283	GAMBRO	DIALYSIS SYSTEM	PHOENIX X36	PH28185	A174-01-JC

(c). Summary: The service contract will be for an initial one-year term, but may be renewed annually for up to four years. It will provide preventative maintenance according to manufacturer's specifications and at the recommended intervals and frequency on the specified equipment at the St. Louis VA Health Care System, as well as labor, travel, expenses, and parts for that preventative maintenance. Additionally, it provides on-call corrective maintenance on equipment that is malfunctioning or inoperable, as well as labor, travel, expenses, and parts deemed necessary for that corrective maintenance.

(d). Hours of Coverage: Monday through Friday, 8:00AM to 5:00PM CST, excluding locally observed holidays. Any labor and travel required outside this period will be charged at per-call rates.

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(e). Specifications of Work:

- (1). All labor, travel, expenses, and parts for the repair and maintenance of the system are covered.
- (2). Updates to the hardware and software are covered.
- (3). Preventative maintenance according to manufacturer's specifications and at the recommended intervals and frequency is included.
- (4). Unlimited corrective maintenance is included.

(f). Guaranteed Uptime: This plan does not include any guarantee of uptime.

(g). Updates: Vendor will provide updates to the hardware and software.

(h). Services and parts not covered by contract: Contracting Officer (CO) authorization for any work or parts outside the scope of this contract must be received prior to performance of work or payment will not be authorized. Parts required that are not covered by contract will be purchased by the VA and installed under the terms of the contract.

(i). Repair Calls: The contractor shall only respond to service calls placed by the Contracting Officer's Representative (COR) or designee. Contractor shall respond with a phone call to the COR or designee within one hour after receipt of telephoned notification 24 hours per day. Contractor shall respond onsite to all repair calls within four hours after call is placed or by 8:00AM the next business day when calls are placed after 12:00PM, excluding emergency repairs that will require an onsite response within four hours.

(j). Qualifications: The contractor must meet The Joint Commission requirements for proving competency of service provider. Contractor personnel shall be OEM factory trained and authorized to work on equipment they are servicing. Contractor must provide documentation proving that they are qualified to work on the equipment listed. The contractor shall provide documentation of job title, job description, and qualifications of any and all that will or may provide service to the Medical Center. The CO may authenticate the training requirements, request training certificates or credentials from the contractor at any time for any personnel who are servicing or installing any VA equipment. The CO or COR specifically reserves the right to reject any of the contractor's personnel and refuse them permission to work on the VA equipment. If subcontractors are used, they must be approved in advance by the CO; the contractor shall submit any proposed change in subcontractor(s) to the CO for approval/disapproval. All service personnel will be aware of and compliant with Hospital policy and procedures pertaining to safety, fire, severe weather, and emergency procedures.

(k). Submittal Information:

- (1). Interested contractors who are responsible and capable of performing this type of work are strongly encouraged to respond by the date specified. At this time, no acquisition strategy has been decided.
- (2). Contractors having the skills and capabilities necessary to perform the stated requirements should submit a response of no more than 15 pages in length, single-spaced, with a 12-point font minimum. The Government will not review any other data

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or attachments that are in excess of the 15 pages. Companies shall provide clear and unambiguous evidence to substantiate their capability to fulfill these requirements.

(I). Interested parties shall furnish the following information:

1. Company name and address.
2. Company point of contact name, telephone number, and email address.
3. Company business size and status (i.e. Large Business, Small Business, Service Disabled Veteran Owned Small business, Woman Owned Small Business, etc.), the number of years in business, and affiliate information.
4. If the company holds a Federal Supply Schedule (FSS) Contract list the GSA Contract Number and relevant SINS.
5. Capabilities/Qualifications: A written response providing clear and unambiguous evidence to substantiate the capacity to fulfill this requirement. Description of the capabilities, qualifications, and skills the company possesses to perform services described in the scope of the work.

It is requested that the above information be provided no later than **10:00 p.m. ET Thursday, March 5, 2014**. Responses should be emailed to larry.buell@va.gov. All email correspondence for this project must reference the RFI Number and Project Title in the subject line of the email: **VA258-14-I-0620, GAMBRO Phoenix Dialysis Equipment - Maintenance & Repair Services."**

DISCLAIMER:

This RFI has been issued solely for information and planning purposes and does not constitute a solicitation. All information received in response to this RFI that is marked proprietary will be handled accordingly. In accordance with FAR 15.201(e), responses to this notice are not offers and cannot be accepted by the Government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI."

No responses were received and no potential contractors chose to identify themselves in the "Interested Vendors List".

No replacement or new requirements for the Gambro equipment is presently budgeted for or forecast.

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

The anticipated five year price (base and four option year extensions) for the services is \$280,600.00. The Contracting Officer will determine that the anticipated price(s) will be fair and reasonable by requiring the contractor to provide a written quote and additional information (other than cost or pricing data), which will include commercial price lists and prices for similar or the same services provided to other customers, to assist the Contracting Officer in determining if the contractor's proposed prices are fair and reasonable for the services being provided. The final

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price(s) will be negotiated. The Contracting Officer anticipates that the final prices(s) will be fair and reasonable.

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

Sources capable of providing Gambro OEM service and parts were sought. Reviewed AbilityOne and UNICOR capabilities; GSA Advantage and schedules library; reviewed existing FBO postings; published a Sources Sought on FBO; reviewed FBO notices declaring sole sources agreements with Gambro, utilized on-line search engine Google.com in an effort to locate existing contractors capable of performing the services; reviewed Gambro WEB site to review maintenance agreement terms and conditions, searched the WEB for pricing information and economic forecasts, searched System for Awards Management (SAM); and reviewed previous acquisitions for similar equipment.

Previous contracts for maintenance and repair (both VHA and other agencies) on this type of Gambro equipment revealed that they were procured utilizing other than full and open competition justifications under the authority of FAR 6.302-1. No vendors capable of providing the required services with the propriety equipment diagnostic software, OEM parts and within the required repair response time were identified except Gambro. No other vendors were identified, no responses were received and no potential contractors chose to identify themselves.

As described in Section 5 above, market research, in accordance with FAR Part 10, was conducted by posting a Sources Sought in FBO soliciting inquiries from interested parties.

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

Failure to properly and timely maintain the installed Gambro Hemodialysis equipment will endanger the health of beneficiaries being served by the Department of Veterans Affairs. These services are considered to be critical to the health of patients receiving hemodialysis. The health of the veteran beneficiary is of paramount importance in this acquisition and any factors which may influence the quality of care to the beneficiary is a critical consideration. The VA Medical Centers must be able to provide critical healthcare to veteran beneficiaries in the safest possible manner.

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

No responses have been received and no potential contractors have chosen to identify themselves.

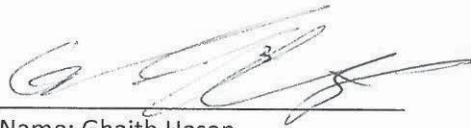
11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

Unless the manufacturer chooses to license its software and authorize local service providers to maintain test and calibrate its equipment sometime in the future, the only alternative that may be available to us is to replace the existing Gambro brand equipment with a more generic brand that may have a wider installed base and which does not have proprietary software. However, considerations other than sole source must be considered when contemplating replacement,

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specifically the anticipated remaining life span of the presently installed equipment, need for sufficient budget to acquire replacement capital items, the need to provide the most reliable and best equipment for the price, and the availability of quality maintenance and repair services. Right now the facility is satisfied with the quality and operation of the installed equipment, its maintenance and repair, and they do not have sufficient budget to replace the equipment.

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.



Name: Ghaith Hasan
Title: Biomedical Engineer
Facility: Saint Louis Health Care System

4-4-2014

Date: 4/4/2014

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.

Larry A Buell,
CPPO

Digitally signed by Larry A Buell, CPPO
DN: cn=Larry A Buell, CPPO, o=Dept. of Veterans
Affairs, ou=Network Contracting Office (NCO) 15,
email=larry.buell@va.gov, c=US
Date: 2014.04.04 09:24:54 -05'00'

Name: Larry A Buell
Title: Contract Specialist

Date

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Facility: General Services,
Network Contracting Office (NCO) 15

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

loyd.jackson@va.gov

Digitally signed by loyd.jackson@va.gov
DN: cn=loyd.jackson@va.gov
Date: 2014.04.04 13:58:29 -05'00'

Name: Christine L Scena
Network Contract Manager
Network Contracting Office (NCO) 15

Date

QA Reviewed

**william.stro
bel@va.gov**

Digitally signed by
william.strobel@va.gov
DN: cn=william.strobel@va.gov
Date: 2014.04.04 10:33:06 -05'00'