

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)**

Acquisition Plan Action ID: 36C250-18-AP-1631

1. **Contracting Activity:** Department of Veterans Affairs, VISN 10, VA Ann Arbor Healthcare System
2237: 506-18-3-118-0248
2. **Nature and/or Description of the Action Being Processed:**
The VA Ann Arbor Healthcare System requests a firm-fixed price purchase order for Fresenius 2008T Hemodialysis Machine w/Clinical Data Exchange (CDX) w/bibag & Crit-Line Clip (CLIC); QTY: 16 EA. This procurement will be conducted using the procedures at FAR 13.5, Simplified Acquisition Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format FAR 6.303-2.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
Fresenius 2008T Hemodialysis Machine w/Clinical Data Exchange (CDX) w/bibag & Crit-Line Clip (CLIC); QTY: 16 EA.

The estimated cost of this procurement is [REDACTED] The estimated delivery date is 60 days ARO.

4. **Statutory Authority Permitting Other than Full and Open Competition:**
 - () (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;

(X) FAR13.5 Simplified Procedures for Certain Commercial Items: *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).*
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 VA currently has a national contract in place for hemodialysis machines with Baxter Healthcare Corp. Normally, this would be a required source of supply for these machines. The Ann Arbor VA has

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
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an approved waiver to purchase hemodialysis machines manufactured by Fresenius. The basis for purchasing Fresenius 2008T brand-name hemodialysis machines are the following:

The unique features of the Fresenius 2008T allow the dialysis care team to take better care of patients in a more efficient manner and offer offers tools not available on any other system:

Integrated blood plasma monitoring: The Fresenius 2008T utilizes the CRIT-LINE CLIC system to continuously track hematocrit, oxygen saturation, & intravascular blood volume throughout the treatment. This system allows the user to accurately dialyze patients by clearly identifying and alerting staff:

- a. When a patient has reached their dry weight (ideal body weight).
- b. When they are about to crash (hypotensive episode).
- c. The system allows control of the ultrafiltration (fluid removal from the patient) based on data received through the CRIT-LINE system.
- d. There is continuous, prominent display of CRIT-LINE data onto the main hemodialysis machine screen, which forces staff to interact with and use the system for each treatment and increases patient safety.
- e. The machine will alert staff with an audible alarm when CRIT-LINE data exceed alarm limits.
- f. Data produced by CRIT-LINE is available for REMOTE real-time display, as well as transmission into CPRS, via EHR software.

Access flow measurement: Early detection of vascular access dysfunction and timely intervention prior to total graft failure, has been shown to enhance patient outcomes and help ensure the delivery of prescribed hemodialysis therapy. As a standard feature on the 2008T hemodialysis system, Online Clearance with Access Flow provides on-screen, step-by-step instructions for monthly (or more frequently based on patient's data) access flow measurement used in conjunction with the Fresenius Twister® reverse-flow bloodline.

Trending of access flow permits intervention at patient-specific limits before access failure. The staff are well educated on this process and provide testing monthly on all Vascular access. The Baxter machines do not allow for the same monitoring. The Baxter Diascan system measures effective Ionic Dialysance which is expressed as a percentage and is indicative of access function. However, per Dr. [REDACTED] AAVA Nephrologist, The Baxter statement about Diascan being comparable to the Fresenius Access Flow is misleading and deceptive. Dr. [REDACTED] reports Diascan does nothing like monitoring flow. The Nephrologists at the AAVA concur that Access flow monitoring is an effective and useful tool that is vital to patient care.

The Baxter machine process for treatment termination requires disconnection of the Arterial line, therefore, creating an open vs. closed circuit for blood return and increasing the risk of infection and blood loss.

Dialysis software system: Having the capability to perform bedside charting at the dialysis machine is critical to ensure any treatment changes are identified in a timely fashion.

The software system supplied on the national contract (Exalis) is not compatible with the existing Fresenius 2008 dialysis machines. In addition, the national contract with Baxter does not offer an external computer system.

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >SAT

The Fresenius 2008T Dialysis machine has a built-in computer, which can be used to install an integrated EHR (Electronic Health Record.)

Since the Baxter machine does not have an integrated computer, a separate computer would need to be obtained to access the EHR. Having a separate computer for the HER would:

- a. Add to the overall cost.
- b. Take up vital and unavailable space at the bedside.
- c. Would be an additional device requiring disinfection after each treatment.
- d. Would not be able to be used in an acute setting (ICU, ED, or floor patients).
- e. Potentially increase the risk of staff or patient injuries as it is another barrier between the patient and the staff.

Currently the VA has an active solicitation for a Baxter dialysis EHR software solution, but it is short-sighted and does not account for these computer systems needed at each machine. This may leave Baxter users without an option for bedside charting which is unacceptable in today's technologically savvy world.

Integrated computer system with built-in keyboard and touchpad: The Fresenius 2008T offers an integrated, separate computer system known as the Clinical Data eXchange (CDX), that is built into the existing framework of the machine:

- a. The CDX system allows installation and use of any dialysis EHR software to track dialysis treatments and vital signs, perform bedside charting (safety checks, administering meds, foot checks, rounding, pre/post assessment, reviewing historical data) without requiring a separate external computer workstation at each bed.
- b. The convenience offered by this is unparalleled in that the caregivers have immediate access to the EHR through the main screen of the dialysis machine at the press of a button. No other dialysis manufacturer offers this system.
- c. There is currently a national integrated product team (IPT) making efforts to create a mandatory contract for dialysis EHR software. Because the Fresenius 2008T dialysis machine already has a built-in computer designed solely for EHR software, AAVA and other locations with the 2008T machines will be better prepared to integrate the awarded software system into their existing dialysis program, and will be able to immediately utilize the bedside charting function without additional expense. Once the national contract is awarded, any VA location that does not have the Fresenius 2008T will have to purchase additional medical-grade computers for each dialysis bed, in order to take full advantage of the bedside charting function. If AAVA is forced to purchase the dialysis machine listed on the national contract, the added cost of these separate bedside computers needs to be factored as an additional cost. Depending on how these computer systems are mounted/installed the costs could add \$72,000 to \$144,000 to the overall cost. This cost is based on obtaining a chairside function that is included on the Fresenius T machine.

Duplication of training requirements, SOP's, competencies: If the National Contract machines are selected, it would require a new set of Standard Operating Procedures, Policies and competencies be rewritten which would add additional burden to the medical center. It would also require additional training of all of the current dialysis staff. This will add additional burden to staff and could potentially result in a delay of patient care.

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >SAT

Duplication of repair parts: Maintenance and repair parts are not shareable between dialysis machine types. Having a different manufacture of dialysis machines would require that the medical center purchase and maintain a different cache of spare parts for the different manufacture of dialysis machine.

Added burden on biomed staff: Having Baxter dialysis machines increases the burden on biomedical staff, who already perform all maintenance on the existing dialysis machines, and have a unique set of tools and spare parts dedicated to this effort.

Hemodialysis patient-aligned care team (PACT): Hemodialysis patients typically require dialysis 3 times per week and need continuous, high-quality care from the entire dialysis PACT. PACT's are completely dependent on hemodialysis equipment in order to sustain the lives of patients. The hemodialysis PACT at AAVA performs greater than 5000 dialysis treatments per year and requires state-of-the-art equipment with all available clinical tools to ensure safe, accurate, & efficient care.

Impact on the environment: The Baxter Bicart cartridges are not recyclable. The Fresenius Bibag bicarb bags are self-emptied by the machine and recyclable therefore reducing/eliminating waste stream products.

In summary, the Fresenius 2008T dialysis machine offers a proprietary, integrated blood plasma monitoring system known as CRITLINE. The CRITLINE system has been used for decades to monitor percent change in intravascular blood volume, hematocrit, and oxygen saturation. This provides useful, meaningful, real-time data to the dialysis care team that is used to improve outcomes of individual dialysis treatments, and deliver accurate, efficient dialysis. There is much evidence-based research available which identifies the value of using the CRITLINE system.

In addition, the ability to perform Access Flow Monitoring and provide timely interventions vs total access failures provides a priceless service to our veteran population. It decreases admission rates, related cost and increases patient's overall satisfaction.

The Fresenius 2008T dialysis machine offers a unique set of features designed to ensure safe, effective delivery of care, much like other available systems on the market. There are no "bells and whistles" that AAVA is asking for, nor do the manufacturers offer this.

As we have identified in the summary, the Fresenius 2008T dialysis machine offers a built-in computer, known as the CDX, which is separate from the firmware used to operate the dialysis machine. The CDX system offers unmatched convenience to the caregivers by allowing them to access and update the dialysis EHR at the patient bedside without installing additional equipment. The CDX is capable of running both Windows and Linux-based operating systems, and is compatible with any EHR that would be loaded into these operating systems. This system is a meaningful, useful system that provides added-value to the PACT and far exceeds the capabilities of other systems. The Baxter Phoenix machine does not offer this, and the national contract with Baxter does not offer an external computer system. For dialysis care teams, being able to do bedside charting at the dialysis machine is paramount importance.

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >SAT

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

A sources sought notice was published to FedBizOpps on 08/17/2018 under 36C25018Q9723 seeking any sources able to supply the Fresenius 2008T hemodialysis machine. Only one response was received – Veterans Healthcare Supply Solutions, an SDVOSB. Fresenius was also contacted directly to determine their interest in quoting this requirement directly. Fresenius sales rep stated they would quote if solicitation was published as unrestricted.

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

The Contracting Officer will determine the proposed prices fair and reasonable prior to contract award. The Contracting Officer is anticipating using comparison of competitive quotes received to determine the prices fair and reasonable as well as previous prices paid for past VA orders.

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

VIP was searched using NAICS 334510 and keyword "Fresenius" with zero results. Fresenius has an FSS contract (V797D-70253) but it does not cover hemodialysis machines. Sources sought posted to FBO resulted in one SDVOSB response (Veterans Healthcare Supply Solutions). Based on the results of market research, the Rule of Two cannot be satisfied. Fresenius sales rep also contacted directly, who expressed interest in quoting on this requirement.

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

Waiver to purchase hemodialysis machines from other than the VA national contract VA119-16-D-0028 was approved by Mr. Ricky Lemmon on 07/02/2018.

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

Veterans Healthcare Supply Solutions, Inc.
13949 Alvarez Road, Suite 300
Jacksonville, FL 32218
Phone: (904) 638-5519


Fresenius Kabi, LLC
3 Corporate Drive
Lake Zurich, IL 60047

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:

Prior to any future acquisition for this equipment/services, market research will be conducted to identify potential sources. Should the market research result in other sources which can satisfy the requirements, competition will be conducted.

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.

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >SAT



Mark Dotson
Chief Supply Chain Officer
VA Ann Arbor Healthcare System

8/24/18

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.

Charles P. Lakin
Contracting Officer
Network Contracting Office 10

Date

- b. One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K): I certify the justification meets requirements for other than full and open competition.

James J. Hallock
Branch Chief – Supplies Team
Network Contracting Office 10

Date