

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

1. Contracting Activity

Department of Veterans Affairs, VISN 11, Richard L Roudebush VA Medical Center (RLRVAMC) located at 1481 West Tenth Street, Indianapolis, IN 46202-2803. The Requesting Activity, Indianapolis Logistics, has submitted VA Form 2237# 583-15-2-075-0147 in the amount of \$206,272.00 for this request.

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

A sole-source standing order for a single year with Baxter Healthcare Corporation, One Baxter Parkway, Deerfield, IL 60015, for the monthly delivery of hemodialysis supplies used to treat patients requiring dialysis at the RLRVAMC. The resulting purchase order will be firm, fixed price with fixed quantities of monthly deliveries.

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

This acquisition will be for dialyzers used in hemodialysis machines when providing dialysis on RLRVAMC patients. The dialyzer is the heart of the dialysis machine which filters the blood as it passes through the machine. Therefore, the dialyzer is a critical component of the dialysis machine and the dialysis process as it comes into contact with bodily fluids re-inserted to the patient's body.

Based on market research, the total expected cost of the standing order is \$163,112.88.

Specifically for this request, the RLRVAMC will be purchasing the following dialyzers:

Part #	Manufacturer	Brief Description	Quantity	Price (EA)	Ext Total
5M2132	Baxter Healthcare	DIALYZER,HEMODIALYSIS CELLULOID,EXELTRA 210,CELLULOSE TRIACETATE, HIGH FLUX,PRIMING VOLUME 125 ML,DISPOSABLE,STERILE	222 Cases- 24 per Case	\$407.88	\$90,549.36
5M2121	Baxter Healthcare	DIALYZER,HEMODIALYSIS CELLULOID,FILTER,EXELTRA 190,CELLULOSE TRIACETATE,HIGH FLUX,HIGH KOA VALUE PER SURFACE AREA,OUTSTANDING BIOCOMPATIBILITY PROFILE,STERILE	180 Cases- 24 per Case	\$346.00	\$62,280.00
5M2120	Baxter Healthcare	DIALYZER,HEMODIALYSIS CELLULOID,EXELTRA 170,CELLULOSE	32 Cases- 24 per Case	\$321.36	\$10,283.52

		TRIACETATE, PRIMING VOLUME 70 ML,U/F COEFFICIENT 24.5 ML/HR,DISPOSABLE			
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4. **Statutory Authority Permitting Other than Full and Open Competition**

The statutory authority permitting an exception to fair opportunity is Section 41 U.S.C. 4106(c) as implemented by the Federal Acquisition Regulation (FAR) Subpart 16.505 Subpart 16.505(b)(2)(i):

- (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 specific products listed in the table in Section 3 have been determined by the RLRVAMC clinical team to be the only products that all current RLRVAMC patients who receive dialysis treatment can use. The reason is the Exeltra High-Flux, Single-Use Dialyzers manufactured by Baxter Healthcare are the only dialyzer currently available in the market place that has a cellulose-based triacetate membrane. These dialyzers differ from other dialyzers available in the marketplace in that other dialyzers utilize a polymer-based membrane which may trigger allergic reactions in patients. In the past, the RLRVAMC has used Rexeed brand dialyzers. These dialyzers contained a polysulfone membrane which caused dialyzer reactions in RLRVAMC patients. The cellulose based dialyzer manufactured by Baxter and requested through this justification, is a semisynthetic option which have caused no allergic reactions from any of the current patients receiving treatment from the RLRVAMC hemodialysis group. As Baxter is the only manufacturer of dialyzers containing cellulose triacetate membranes, Baxter Healthcare is the only contractor qualified to meet the requirements of the Government.

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

Market research was conducted, details of which are in the market research section of this document. This effort did not yield any additional sources that can meet the Government's requirements. There is no competition anticipated for this acquisition. In accordance with FAR 5.301 and 16.505(b)(2), this action will be synopsisized at award on the Federal Business Opportunities Page (FBO) and the justification will be made publicly available.

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

The Contracting Officer has determined through market research and reviewing previous purchase orders that the cost of this acquisition will be fair and reasonable. Previous acquisitions, such as Purchase Order

VA251-14-P-1718 purchased the following with the previously determined fair and reasonable pricing, nearly the same per-unit pricing as indicated above in Section 3.

Part #	Quantity	Price (EA)
5M2132	11 Cases	\$407.88
5M2121	7 Cases	\$346.08
5M2120	4 Cases	\$321.36

Additional research consisted partially of Google searching the part numbers included in the table above. No usable returns were found for Part #'s 5M2121 or 5M2120. A return for Part #5M2132 came back on MedSurplusOnline.com (not registered in SAM.gov and therefore ineligible for award) at \$9.99 per unit. A case from Baxter Healthcare contains 24 units, therefore purchasing the supplies from MedsurplusOnline.com would result in nearly 58% savings. While the Contracting Officer did not feel comfortable soliciting from online retailers not registered in SAM.gov for such critical components of the dialysis process, the Contracting Officer will utilize this information in attempting to receiving better pricing from Baxter Healthcare.

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

The Contracting Officer researched dialyzers utilizing the General Services Administration (GSA) Advantage website with no results. The Contracting Officer contacted Baxter Healthcare, who currently has four (4) awarded VA contracts under schedule 651B and none of the dialyzers were on any of these contracts. The Contracting Officer also input the specific part numbers being acquired and received no responses from retailers or distributors of ths products. The Contracting Officer then searched for dialyzer manufacturers through a general Google search and found that companies such as Fresenius Medical Care, Baxter Healthcare, and Gambro AB all manufacture dialyzers that could be used by the VA. However, based upon the technical expertise and medical findings of the RLRVAMC clinical staff, the dialyzers manufactured by other companies would not be suitable for the use of the RLRVAMC as the dialyzers researched by the Contracting Officer all had some form of polymer based membrane, including the Ployflux by Gambro, which contain both a polymer blend of polyarylethersulfone, polyvinylpyrrolidone and polyamide membrane, the Evodial brand by Gambro which includes a polyacrylonitrile membrane, and the Fresenius brand dialyzers that contain Fresenius Polysulfone, "a special plastic with exceptional filtering and hemocompatibility characteristics."

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

No additional facts other than those above are included as part of this justification.

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

No sources have expressed interest in this acquisition as the Government has not made public the request based on the information in Paragraph 5 that no other sources would meet the Government's requirements.

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

No actions are being taken to remove or overcome any barriers to competition. Barriers to competition include substantial previous investment in training, personnel, and equipment to support the use of the

supplies being acquired through this acquisition. Until the marketplace produces additional dialyzers that are not documented to produce allergic reactions in RLRVAMC patients, the barriers to competition will remain as the risk to the VA are significant.

12. Technical and Requirements Certification:

I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.



Shawn Sickles
Supply Technician
Richard L Roudebush VA Medical Center

1/20/15
Date

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ROSE 495306

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495306
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a.gov, cn=NATALIE N. ROSE 495306
Date: 2015.01.16 14:58:41 -0500

Natalie Rose
Registered Nurse
Richard L Roudebush VA Medical Center

Date

13. Contracting Officer's Certification

I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Jared A. Tritle 718134

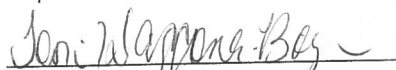
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Date: 2015.01.20 07:33:26 -0500

Jared Tritle
Contract Specialist
Network 11 Contracting Office

Date

14. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP

Director of Contracting /Designee (Required \$150K and above): I certify the justification meets requirements for other than full and open competition.



Toni Waggoner-Boykin
Designee for Director of Network 11 Contracting Office
Supervisory Contract Specialist
VISN 11 Southern Tier Supplies & Services

22 Jan 15
Date