

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

****NOTE FOR USER: TEXT IN RED AND BLUE (PERTAINS TO LEASING ACTIONS) ARE INSTRUCTIONS AND SAMPLE LANGUAGE ONLY AND SHOULD BE REMOVED FROM THE TEMPLATE BEFORE SUBMITTING FOR APPROVAL.**

1. **Contracting Activity:** Department of Veterans Affairs, VISN 04, Pittsburgh Acquisitions, NC04, for the VA Wilkes Barre Medical Center. 2273# 693-15-2-140-0021.
2. **Nature and/or Description of the Action Being Processed:** "Brand Name Only" and Only One Responsible Source" Sole Source Justification, for Gambro/Baxter Healthcare Hemodialysis Products/Supplies. This will be an unrestricted acquisition, resulting in award of a new Base and Two Option Year "Firm Fixed Price" Contract, with Fixed Yearly Quantities.

FAR13.5 Test Program: *This procurement for a Base and Two Option Year Contract, is accordance with FAR 13.5 Test Program 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 of FAR 6.303-2.*

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This acquisition is for the procurement of Baxter Healthcare Hemodialysis Supplies, needed for the VA Wilkes Barre Medical Center (VHAWB), to be used with existing VHAWB owned Gambro Phoenix Dialysis Machines, that is used for end stage renal disease in patient care requiring dialysis. The Government requires a Base (6 Month) and Two Option Years "Firm Fixed Price" Contract. Contract Items; Quantity (Qty); and Pricing is as follows:

Line Item 1: Baxter Healthcare Item# 110643 – Mo. Qty - 9, Annual Qty - 108

Line Item 2: Baxter Healthcare Item# 109733 – Mo. Qty - 22, Annual Qty – 264

Line Item 3: Baxter Healthcare Item# 101025 – Mo. Qty 14, Annual Qty - 168

Estimated Period of Performance:

Base Year: 3/2/2015-9/30/2015

Option Year One: 10/1/2015-9/30/2016

Option Year Two: 10/1/2016-9/30/2017

4. **Statutory Authority Permitting Other than Full and Open Competition:** *41 USC §253(c)(1), as implemented by FAR 6.302-1.*

(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;

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

- () (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;

FAR13.5 Test Program: *The authority for applying the Commercial Test Program of FAR 13.5 is (Section 4202 of the Clinger-Cohen Act of 1996) 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.** It is essential to the VA Wilkes Barre Medical Center (VA), to purchase the Gambro (Baxter Healthcare) Hemodialysis products listed under Section 3 above, to be used with the VA's Gambro Phoenix Machines, for the following reasons, thereby precluding consideration of a product manufactured by another company.

#110634 – Polyflux Revaclear Dialyzer: According to a Gambro Renal Representative, these Dialyzers are the only ones sold in the United States that are Steam Sterilized. In addition, these are the only Dialyzers that do not require a "refresh" or dumping of the saline prime volume in the blood circuit prior to treatment initiation, saving significant saline volume.

#109733 - BICART 720G With Caps: According to Gambro Renal Representative, this is the only on-line bicarbonate cartridge that has been tested and validated in the lab to meet the performance specifications of the Gambro Phoenix Dialysis System, and is the only such product indicated for use in the Phoenix Operator's Manual.

#101025 – Per Gambro Renal Account Executive and Renal Representative, this is a Cartridge Blood Set that is a dedicated disposable, and that is proprietary, and for these reasons, no other manufacturer's Blood Set (Blood Tubing) made for hemodialysis machines will fit or work on the Gambro Phoenix Machine.

It is also essential that the Government purchase the above Gambro Hemodialysis Supplies, from Baxter Healthcare Corporation, since they own Gambro, and since the Supervisor of Government Contracts for Baxter Healthcare, has informed the Government in writing, that Baxter Healthcare sells these specific supplies directly to the Department of Veterans Affairs, and does not authorize resellers or distributors to resell/distribute these specific items to the Department of Veterans Affairs, and that Baxter Healthcare does not provide firm fixed prices to any resellers or distributors for a three year term, which the Government requires for this acquisition.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A Combined Synopsis/Solicitation will be posted to Fedbizopps for 5 days.

Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: Fair and Reasonable Price will be determined by competition, and in the event

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

only one Quote is received, by comparing the quoted price, to the price previously paid by the VA Wilkes Barre Office, for the same items.

7. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** The Contracting Officer obtained a written confirmation from the Governments Contracts Supervisor for Baxter Healthcare Corporation, that there only resellers of Hemodialysis Supplies were Cardinal Health; Owens and Minor; Medline; Professional Hospital Supply. However, the Governments Contracts Supervisor for Baxter Healthcare Corporation confirmed that they do not authorize resellers or distributors to resell/distribute these specific Hemodialysis Supplies being purchased, to the Department of Veterans Affairs.
8. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** It is essential to purchase the Gambro Hemodialysis products listed under #3 above, to ensure patient care, and to avoid substantial duplication of cost to the Government, that is not expected to be recovered through competition, and to avoid unacceptable delays in fulfilling its requirements.
9. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** NA
10. **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:** NA .
11. **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.

Vera Levchuk

Name: Vera Levchuk
Title: Physician (Nephrology)
Facility: Wilkes Barre, PA Medical Center

2/18/2015

Date

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

- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Name: Ronald Mazzei
Title: Contract Specialist
Facility: H.J. Heinz, Pittsburgh, PA

Date

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

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

Name: Michael J. Lamb
Title: Branch Chief, NC04
Facility: H.J. Heinz, Pittsburgh, PA

Date