

JUSTIFICATION FOR SINGLE SOURCE AWARDS IAW FAR 13.106-1
 (OVER MICRO-PURCHASE THRESHOLD(\$3K) BUT NOT EXCEEDING THE SAT (\$150K))

IAW [FAR13.104](#), COs must promote competition to the maximum extent practicable to obtain supplies and services from the source whose offer is the most advantageous to the Government, considering the administrative cost of the purchase. When competition is not practicable, IAW [FAR13.106-1\(b\)](#), COs solicit from a single source for purchases not exceeding the simplified acquisition threshold. COs may solicit from one source if the CO determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization). IAW [FAR13.106-3\(b\)\(3\)](#), COs are required to include additional statements **explaining the absence of competition** (see [13.106-1](#) for brand name purchases) if only one source is solicited and the acquisition does not exceed the simplified acquisition threshold (does not apply to an acquisition of utility services available from only one source) or supporting the award decision if other than price-related factors were considered in selecting the supplier. This template when completed can be used to document single source awards IAW [FAR13.106-3\(b\)\(3\)](#). Note: Statements such as "only known source" or "only source which can meet the required delivery date" are inadequate to support a sole source purchase.

1. PURCHASE REQUEST OR REQUISITION NUMBER: 541-16-3-250-0594 / 541-20F-16-00001	1A. PROJECT/TASK NUMBER N/A	1B. ESTIMATED AMOUNT: \$75,000.00
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2. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES REQUIRED AND THE INTENDED USE:
 Continuous Venous-Hemofiltration (CVVH) is used to provide renal replacement therapy in critically ill patients who have acute kidney injury and are not able to tolerate conventional hemodialysis.

The need for CVVH remains high, with post-operative Acute Kidney Injury, and patients with multisystem illnesses in the MICU/CCU critical care units. The number of units needed is insufficient to meet peak patient demand time while providing back up in case of failure of one of the existing units. Due to the critical need of this treatment, repair time for failed units is not an option as treatment delay directly impacts patient mortality.

In the past, a rental company was used to access a CVVH machine when both VA units were in use or under repair. However, this service has become more erratic and unreliable due to demand for CVVH machines. Given the critically ill nature of patients who require CVVH, lack of access to the machine is not desirable.

3. UNIQUE CHARACTERISTICS THAT LIMIT AVAILABILITY TO ONLY ONE SOURCE, WITH THE REASON NO OTHER SUPPLIES OR SERVICES CAN BE USED:
 Similar and more rigorous treatments such as full hemodialysis exist however as this treatment is for acute patient care in the ICU, post-operative or for advanced heart failure and not chronic patient care as in dialysis other products are not appropriate for the intended use.

The PRISMAFLEX System delivers all modes of continuous renal replacement therapy (CRRT) and therapeutic plasma exchange (TPE) without additional equipment.

The PRISMAFLEX System can be used for:

- CVVHDF – Continuous Venous-Hemodiafiltration
- CVVHD – Continuous Venous-Hemodialysis
- CVVH – Continuous Venous-Hemofiltration
- SCUF – Slow Continuous Ultrafiltration
- TPE – Therapeutic Plasma Exchange

4. REASON THAT SUGGESTED SOURCE IS THE ONLY SOURCE, WHICH CAN PROVIDE THE SUPPLIES OR SERVICES:

Nephrology currently has other Prismaflex CVVH units in service at the Louis Stokes Cleveland DVAMC. Prismaflex CVVH machine is able to meet all criteria necessary to perform the functions needed to treat critically ill patients who have acute kidney injury.

The Prismaflex CVVH machine is able to meet all criteria necessary to perform the function described above. Baxter is the only manufacturer of this equipment. A similar product is available however it uses different methodology, conventional hemodialysis, than the Prismaflex CVVH to accomplish replacement therapy, critically ill patients who have acute kidney injury and are not able to tolerate conventional hemodialysis.

In addition the facility is adding unit to increase capacity and this requirement should be considered a follow-on to the original equipment acquisition.

5. DESCRIPTION OF MARKET RESEARCH CONDUCTED AND RESULTS OR STATEMENT WHY IT WAS NOT CONDUCTED:

Thomas Knauss MD of the Nephrology Section, the Technical expert, used his professional knowledge of the industry to conclude that all other product currently on the market perform hemodialysis were as the equipment require by the government performs hemofiltration. The contract specialist queried the internet using google, searched GSA using GSA Advantage, and searched the NAC contracts using the Med Surg Search Tool. Baxter Healthcare Corporation is the only known vendor/manufacturer.

6. Contracting Officer's Certification: *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.*

Signature:

Date: 07/29/2016

Name: Christopher A. Callihan

Title: Contracting Officer

Title: Contracting Officer NCO: 10