

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)

Acquisition Plan Action ID: 36C249-19-AP-2233

1. **Contracting Activity:** Department of Veterans Affairs, VHA, NCO 9, 1639 Medical Center Parkway Suite 400, Murfreesboro, TN 37129. Purchase Request number 626-20-1-200-0003.
2. **Nature and/or Description of the Action Being Processed:**
The Nashville VA Medical Center requires Therakos Cellex Photopheresis Procedural kits and lights for their Therakos Cellex Photopheresis System for the period of 10/1/2019-09/30/2020. The estimated value is \$526,604.86.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
The Nashville VA Medical Center requires Therakos Cellex Photopheresis procedural kits and light assemblies for blood treatment in patients suffering from cancer. The procedural kits will be used throughout FY20.
4. **Statutory Authority Permitting Other than Full and Open Competition:**
A Sources Sought notice was published to Federal Business Opportunities (FBO) on 06/17/2019 under 36C24919Q0331. Zero vendors responded to the sources sought notice as potential suppliers of the required supplies. A previous award was made to Therakos, Inc., the manufacturer of the required supplies, during FY19 under award VA249-19-P-0063 in the amount of \$485,470. Additionally, a search was conducted in VIP under NAICS 339113 key word "photopheresis". Zero vendors were returned.

(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;

FAR13.5 Simplified Procedures for Certain Commercial Items:

This requirement meets the criteria for using simplified procedures under FAR 13.5 Simplified Procedures for Certain Commercial Items, as it is exclusively for the procurement of commercial supplies, exceeds the simplified acquisition threshold, but does not exceed \$7M.

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**
Therakos, Inc. is the Original Equipment Manufacturer (OEM) of the Cellex Photopheresis System. As the OEM, Therakos is the only vendor that can provide the replacement parts to ensure that the equipment continues to operate as required. The Nashville VA currently uses the Therakos Cellex Photopheresis System, with which no other procedural kits will work.

Contractor: Therakos Inc., a Mallinckrodt Company
Service Program/Supplies: TVHS/Therakos Cellex Photopheresis System Supplies

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

A Sources Sought Notice was posted to FBO on June 17, 2019 and closed on June 21, 2019. The notice detailed the requirement for 72 cases of Therakos Cellex Photopheresis procedural kits with product code CLXUSA, 4 Light assemblies with product code CLXLGT, and 6 cartons UVADEX Sterile Solution with product code 21612 for the Nashville VAMC. Following the sources sought closing, no responses were received.

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

Based on market research and historical pricing established with the prior acquisition of the exact items under VA249-19-P-0063, with the exception of sterile solution, therefore the anticipated cost to the Government 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:

Market research was initiated with the search for Service Disabled Veteran-Owned Small Businesses and Veteran-Owned Small Businesses through Vendor Information Pages at <https://www.vip.vetbiz.va.gov/>, which resulted in no available SDVOSB/VOSB vendors. Research continued with the posting of a sources sought on 17 June 2019 for one week, which resulted in the zero submissions. Lastly, a search of the Dynamic Small Business Administration search engine at http://dsbs.sba.gov/dsbs/search/dsp_dsbs.cfm resulted in the identification of no additional vendors.

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

Therakos provided a sole source letter explaining that the Cellex Photopheresis system and products connected to its operation and maintenance are proprietary to Therakos, Inc and there are no authorized vendors or distributors except the OEM.

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

Sources sought notice posted to FBO for the period of June 17, 2019 to June 21, 2019 returned zero interested vendors.

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:

The Department of Veterans Affairs will continue to seek vendors capable of providing these supplies in future procurements. At the present time, based on available market research, there are no other vendors capable of providing the required supplies.

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.

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[REDACTED]

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.

[REDACTED]

- 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.

[REDACTED]