

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA244-16-AP-1564

1. **Contracting Activity:** Department of Veterans Affairs, VISN 04, VA Pittsburgh Medical Center Network Contracting Office 04 Pittsburgh, 1010 Delafield Road, Pittsburgh PA 15215
2. **Nature and/or Description of the Action Being Processed:** The services being procured are for the recovery and transportation of organs (livers) from deceased organ donors for the purposes of transplantation to veteran patients. This procurement will include costs for removal of the deceased patient's organ and transportation to the Pittsburgh VA Medical Facility. This is a six-month follow-on Requirements contract with fixed pricing and estimated quantities.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** These services are for deceased donor organ management, recovery, and delivery. This procurement will be a Requirements contract with fixed pricing and estimated quantities for a six-month period. The estimated cost under the contract for six months is \$815,760.00. The contract will have three line items one for local transplants, a second line item Fly-Out transplants, and a third for Import transplants. It is estimated that over the period of the contract there will be an estimated total of 24 transplants of the combined line items. The additional line items are required for import and fly-out transplants when the local Organ Procurement Organization (OPO), Center for Recovery and Education (CORE), has to import organs from another OPO's Donor Service Areas (DSA). Date of award for this contract is April 1, 2015 and will expire on September 30, 2015. This procedure will be in accordance with the United Network for Organ Sharing (UNOS) regulations for allocation of livers. Based upon review of several years of historical data for VAPHS, this importation fee is utilized approximately 12 times per year for liver imports.

The organs will be recovered at the donor hospital and delivered to a VA Pittsburgh Healthcare System (VAPHS), University Drive C, Pittsburgh, Pennsylvania, 15240 for the purposes of implantation into a veteran patient with end stage organ disease.

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;
 - (X) (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):** It is imperative to continuously maintain a contract for organ transportation. The current contract for these services was scheduled to expire on 31 March 2015 and with the obvious need to continue to provide organs for veteran patient transplants a contract must be established under urgent and compelling urgency. No other sources exist for organ procurement. "The Center for Organ Recovery & Education (CORE) is one of 58 federally-designated not-for-profit organ procurement organizations (OPO) in the United States. Each OPO must have a written agreement with all hospitals that participate in Donation after Circulatory Death (DCD) recovery. CORE is responsible for facilitating the computerized matching of donated organs and placement of corneas. CORE Pittsburgh is federally designated to serve the Pittsburgh region. According to the Organ Procurement and Transplantation Network (OPTN) Policies, the administration of organ allocation and appropriate geographic representation within the OPTN policy structure, the membership is divided into eleven (11) geographic regions. Members belong to the region in which they are located. VA Pittsburgh belongs to Region 2: Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, West Virginia, and the part of Northern Virginia in the Donation Service Area served by the Washington Regional Transplant Community (DCTC) OPO. Code of Federal Regulations (CFR) 42.121.9 states that in order to receive organs for transplantation: (a) a transplant program in a hospital shall be a member of the Organ Procurement and Transplantation Network (OPTN) and shall abide by these rules: 1) Be a transplant program approved by the Secretary for reimbursement under Medicare; or 2) Be an organ transplant program which has adequate resources to provide transplant services to its patients and agrees promptly to notify the OPTN and patients awaiting transplants if it becomes inactive and which: (i) Has letters of agreement or contracts with an Organ Procurement Organization (OPO); (ii) Has on site a transplant surgeon qualified in accordance with policies developed under §121.4; (iii) Has on site a transplant physician qualified in accordance with policies developed under §121.4; (iv) Has available operating and recovery room resources, intensive care resources and surgical beds and transplant program personnel; (v) Shows evidence of collaborative involvement with experts in the fields of radiology, infectious disease, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine, histocompatibility, and immunogenetics and as appropriate, hepatology, pediatrics, nephrology with dialysis capability, and pulmonary medicine with respiratory therapy support; (vi) Has immediate access to microbiology, clinical chemistry, histocompatibility testing, radiology, and blood banking services, as well as the capacity to monitor treatment with immunosuppressive drugs; and (vii) makes available psychiatric and social support services for transplant candidates, transplant recipients, and their families; or (3) Be a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital. (b) To apply to be a designated transplant program, transplant programs shall provide to the OPTN such documents as the OPTN may require which show that they may meet the requirements of §121.9 (a) (1), (2), (3). (c) The OPTN shall within 90 days accept or reject applications to be a designated transplant program. (d) Applicants rejected for designation may appeal to the Secretary. Appeals shall be submitted in writing within 30 days of rejection of the application. The Secretary may (1) Deny the appeal or (2) Direct the OPTN to take action consistent with the Secretary's response to the appeal. (CFR 42 §121.9)

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** N/A CORE is the locally designate not-for-profit OPO. No other potential source exists.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated costs under this contract action are considered fair and reasonable. When comparing costs to the Portland Oregon's VAMC costs for liver transplants, Pittsburgh's costs are lower but comparable.

	Pittsburgh, PA	Portland, OR
Local:	\$33,990.00	\$36,000.00
Fly out:	\$49,440.00	\$51,000.00
Import:	\$49,440.00	\$51,000.00

United Network for Organ Sharing (UNOS) and Centers for Medicare and Medicaid Services (CMS) allows for OPO's to have different costs depending on their average travel and hospital recovery costs.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted in accordance with FAR Part 10, was conducted by publishing Intent to Sole Source on FedBizOpps.gov. There were no responses. In addition to the published Intent to Sole Source, research was conducted that disclosed the Center for Organ Recovery and Education (CORE) is federally designated and has a written agreement with VA Pittsburgh Healthcare System for Organ recovery.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** N/A
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** N/A
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 planned to be taken. As stated above CORE is the local federally designated OPO and no other source is available to execute this procurement through.
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.

CAROL A MILLER 449856

Digitally signed by CAROL A MILLER 449856
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Carol Miller
 Management Analyst
 Pittsburgh VAMC

Date

13. **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.

Shawn E.
Smith 346238

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a.gov, cn=Shawn E. Smith 346238
Date: 2016.02.03 06:28:44 -05'00'

Shawn E Smith
Supervisory Contract Specialist
NCO 04 Pittsburgh

Date

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

Benjamin P. Iachini 644827

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Benjamin Iachini
NCO 04 Director of Contracting
NCO 04 Pittsburgh

02/19/2016

Date

- c. **SAO HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$12.5 million) or approve (\$650K to 12.5 million) for other than full and open competition.

Randy L. Hays 534204

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0.9.2342.19200300.100.1.1=randy.hays@va.gov, cn=Randy L. Hays 534204
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Director, SAO East (or Designee)
SAO East Head of Contracting Activity (HCA)

Date

**Note: Determination is being approved after contract award in accordance with FAR 6.302-2 (d)(5)