

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)

For

Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: [REDACTED]

1. **Contracting Activity:** Department of Veterans Affairs, VISN 19, Denver VA Medical Center, Eastern Colorado Health Care System (ECHCS), Network Contracting Office 19.
2. **Nature and/or Description of the Action Being Processed:** Sole Source Justification and Approval for creating a Not to Exceed (NTE) Option Contract for the acquisition of Abbott vascular and coronary catheters for the cardiac and electrophysiology labs at the Denver VA Medical Center (VAMC).
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Abbott vascular and coronary catheters that are required for used as a life support device that can be inserted quickly to support high risk cardiac interventions to preserve life and reduce risk to the patient from Fiscal Year (FY) 2017-2018. Total estimated value of the contract is [REDACTED].
4. **Statutory Authority Permitting Other than Full and Open Competition:** *41 USC §3304(a)(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;
 - () (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):** Requirement is for Abbott wires, balloons, Emboshield, and access closure devices. The wires and balloons are compatible with the products currently in use and part of systems. The Emboshield is a specific requirement for Carotid procedures. There is no suture based closure device on the market and is critical to pre-close in procedures such as Endovascular Aneurysm Repair Surgery (EVARs).
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** No other vendors on the market today have the Abbott products requested which is specific to certain specialized procedures: Chronic Total Occlusions of Coronary arteries, Carotid Artery stenting and Endovascular Aortic Aneurysm Repairs.

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7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Based on comparison to a recently awarded contract and comparison to manufacturer pricelist, it is anticipated that the proposed pricing will be fair and reasonable and in the best interest of the government.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** NAC, GSA, SAM, FPDS were surveyed and no other source was found for the catheters and supplies listed above that will work with procedures in place. The manufacturer was also queried and no authorized distributor was identified.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The products listed are all currently in use parts of clinical systems that have been reviewed and evaluated by the Director of the Interventional Cardiology program. To change them would be disruptive requiring re-evaluation of current procedures and changing out of many of our products, some of which are proprietary systems. This would negatively impact patient care.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Abbott Laboratories, 3200 Lakeside Dr., Santa Clara, California 95054
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:**
Based on the professional medical judgment of the cardiac interventionalists at Denver VA Medical Center. An alternative product would not meet all of the specifications necessary to treat veterans congruent with their clinical needs. In the future, new technology will be considered by other competitors and continuous market research is being conducted to overcome barrier while still meeting the needs of the patients.
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.
- [Redacted Signature] _____
Date
- Admin Officer/COR
Medicine Service/Cardiology Section
Denver VAMC (554)
13. **Approvals in accordance with the VHAPM, Volume 6, Chapter VI: 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 Signature] _____
Date
- Branch Chief, Supply 1 East
NCO 19

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- b. Director of Contracting /Designee (Required over\$150K but not exceeding \$700K): I certify the justification meets requirements for other than full and open competition.

[Redacted Signature]

[Redacted Title]
Chief Division II
NCO 19

Date