

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA259-17-AP-8684

1. **Contracting Activity:** Department of Veterans Affairs, Program Contracting Activity Central (PCAC), in support of VA Eastern Colorado Health Care System located at 1700 N. Wheeling Street, Aurora, CO 80045

2. **Nature and/or Description of the Action Being Processed:**

FAR13.5 Simplified Procedures for Certain Commercial Items: This is for a Brand Name Justification in accordance with FAR 13.5 Simplified Procedures 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:**

Brand Name: CareFusion Alaris Infusion Pump Software
Brand Name: CareFusion Alaris PC unit
Brand Name: CareFusion Alaris PC unit software
Brand Name: CareFusion Volume IV Pump
Brand Name: CareFusion Alaris Software Management

Estimated Value: \$1,062,591.52 [Base Period]
\$1,273,651.52 [Base Period and Four (4) Option Periods]

VAECHCS requires the delivery and upgrade of the Alaris software system that operates throughout the VAECHCS. This acquisition is an upgrade to the existing CareFusion Alaris system as well as a replacement of the current aging Alaris PC and Volume IV hardware. All existing software licenses will be reutilized.

4. **Statutory Authority Permitting Other than Full and Open Competition:**

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 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):**

The CareFusion Alaris system is the existing infusion delivery system for the ECHCS. The system includes the drug management library, the Alaris PC unit, the Volume IV unit, ETCO2, Syringe, and PCA. This requirement replaces and refreshes the drug management library software, upgrades all Alaris PC units to the newst version and newest hardware with reuse license, upgrades Volume IV pump hardware with

reuse license. All ETCO2, Syringe, and PCA modules are reused and will not be required for this procurement.

The CareFusion Alaris system is the only infusion system that can integrate the ETCO2 and PCA modules as CareFusion holds the patents on the proprietary integrated infusion pump container and fluid infusion system. The integration is a patient safety feature for the PCA pump to shut down if the ETCO2 device is in the alarm mode. The VA National Patient Safety Center (NPSC) recognizes this integration enhances the safety of patients while using the PCA pump. In order for ECHCS to reuse ETCO2 or PCA, the Alaris PC unit must be used. The Alaris PC unit is the main controller that ensures the ETCO2 and the PCA modules operate in accordance with clinical specification. There is no other existing product on the market that can control the Alaris ETCO2, PCA, or Syringe pump unit. CareFusion is the sole manufacturer of the Alaris Infusion System and holds the patent on the integrated infusion pump container.

The cost savings to the Government for reusing ETCO2, PCA, Syringe, the Volume IV license, and Alaris PC license is estimated at \$591,928.00.

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

Preliminary Market Research was conducted by the requiring activity through the professional medical device evaluation firm, ECRI. According to ECRI, there is no other PCA pump that can integrate with the ETCO2 device. Further, the Denver Biomedical Engineer stated their market research indicated there were no authorized dealers for CareFusion.

The Contracting Officer (CO) posted a notice of intent to sole source to FedBizOpps asking any vendor that believes they are capable to submit a response. Additionally, a search in VetBiz of NASICS 339113 and FSC code 6515 yielded 74 results. An email was sent to all 74 vendors asking for a response if they believe they are willing and capable of providing the items detailed in the Performance Work Statement (PWS) and are an authorized dealer/distributor of the Original Equipment Manufacturer (OEM) for all items.

Two (2) responses from SDVOSB vendors were received, TrillaMed and Veterans Healthcare Supply Solutions (VHSS). One (1) vendor, VHSS, provided an authorized dealer letter from CareFusion, the OEM. The CO contacted CareFusion to determine if these vendors were authorized dealers and were able to provide the equipment and services detailed in the PWS. A call was held with the OEM. TrillaMed is not an authorized dealer of CareFusion; however, VHSS is. Further, the OEM sent their list of three (3) SDVOSB authorized dealers.

VENDOR	DUNS	CVE VERIFIED SDVOSB	CAPABLE
Beacon Point Associates, LLC	078717364	YES	YES
Four Points Technology, LLC	089896737	YES	YES
Veterans Healthcare Supply Solutions, Inc.	964899483	YES	YES

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

The anticipated cost to the Government has been determined fair and reasonable by previously conducted market research by NCO 19 in addition to comparing pricing with the pricing of the existing GSA contract held by CareFusion for the exact Alaris software and server systems. Further, an informal quote was received by the facility from the OEM. Pricing received from the SDVOSB authorized dealers

will be compared to the OEM price. A determination the price is fair and reasonable will be performed before award.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

Preliminary Market Research was conducted by the requiring activity through the professional medical device evaluation firm, ECRI. According to ECRI, there is no other PCA pump that can integrate with the ETCO2 device.

The Contracting Officer (CO) posted a notice of intent to sole source to FedBizOpps asking any vendor that believes they are capable to submit a response. Additionally, a search in VetBiz of NASICS 339113 and FSC code 6515 yielded 74 results. An email was sent to all 74 vendors asking for a response if they believe they are willing and capable of providing the items detailed in the Performance Work Statement (PWS) and are an authorized dealer/distributor of the Original Equipment Manufacturer (OEM) for all items.

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

CareFusion is the sole manufacturer of the Alaris Infusion System and is the sole patent holder of the proprietary integrated infusion pump container and the fluid infusion system. There is no other existing product on the market that can control the Alaris ETCO2, PCA, or Syringe pump unit.

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

As of this date, there have been no other sources that have expressed interest in this acquisition in writing or any other form.

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:

To remove or overcome any barriers to competition before future acquisitions for the same supplies and services are conducted, the VA will ensure extensive market research is performed in a timely manner to evaluate vendor capabilities and determine whether the market allows for authorized distribution of the same system or offers similar systems that can potentially meet the Government's requirements.

- 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.

/original signed/

[Redacted Signature]

Date

- 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.

/original signed/

[Redacted Signature]

Date

- b. **Director of Contracting**: I certify the justification meets requirements for other than full and open competition and recommend approval.

/original signed/

[Redacted Signature]

Date

- c. **VHA 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 approve (\$700K to \$68 million) for other than full and open competition.

/original signed/

[Redacted Signature]

Date