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: [redacted]

   VA ECHCS requires the delivery and upgrade of the Alaris software system that operates throughout the VA ECHCS. 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. The VA ECHCS currently owns 237 Alaris PC units, 25 Alaris CareFusion Large Volume pumps, 25 syringe modules, 35 Patient Controlled Analgesia (PCA) modules, and 45 EtCO2 modules. All existing 237 software licenses for the 237 Alaris PC units will be reutilized. The VA ECHCS will purchase an additional three (3) software licenses, 358 large volume pumps; will not purchase any additional PCA, end tital (EtCO2), or syringe modules; and will trade in 237 currently owned Alaris CareFusion PC units.

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 ECHCS is pursuing an upgrade of the CareFusion Alaris infusion therapy system. Infusion therapy involves the intravenous administration of medication. It is prescribed when a patient's condition is so severe that it cannot be treated effectively by oral medicaions. The CareFusion Alaris infusion therapy

system includes the following items: drug management library software, infusion device maintenance software, Alaris PC unit, Alaris high volume IV unit, Alaris ETCO2 unit, Alaris Syringe unit, and PCA unit. This requirement is for the upgrade of the drug management library software, upgrade of Alaris PC units, and upgrade of Alaris high volume IV units. The licenses for the existing Alaris PC units and Alaris high volume IV units will be reused. All existing Alaris ETCO2 units, Alaris Syringe units, Alaris PCA units and respective licenses will also be reused. The Government reviewed the facts supporting this requirement as outlined below before determining reuse was in the best interests of the Government.

According to the Agency for Healthcare Research and Quality at the Department of Health and Human Services, the leading cause of patient harm is medication errors and account for almost 20% of medical injuries. Administration is the stage of the medication use process most vulnerable to error, and the intravenous (IV) route of drug administration often results in the most serious outcomes of medication errors. IV infusion errors that involve high-risk medications delivered directly into the patient's bloodstream have been identified as having the greatest potential for patient harm.[1]

The CareFusion Alaris infusion therapy system is the primary infusion therapy system in use at the ECHCS; the sole exception being that there are two (2) Iradimed MRI-safe pumps in the MRI clinic. Iradimed is an FDA cleared MRI-compatible infusion pump system with a non-magnetic motor and non-ferrous components that enables patients who cannot disconnect from IV medication to undergo important MRI scanning while continuing to receive safe delivery of IV medications. Uniformity of infusion therapy systems, and the components of those systems, are essential for patient safety, specifically the safety of veterans seeking treatment. The VA National Patient Safety Center (NPSC) recognizes that uniformity of infusion therapy systems significantly increases patient safety and specificially the compatability of Drug Error Reduction Software (DERS) between the different components of the infusion therapy system. The VA NPSC received over 750,000 saftety reports over 11 years including 12,000 root cause analyses (RCAs). There were 12,000 RCAs, of which 129 involve infusion pumps. Of the 129 RCAs that involve infusion pumps, 60 were on general purpose infusion pumps, 69 were on PCA pumps, and 129 RCAs account for over 13% of medical device related RCAs for just the two types of pumps. As a result, 60% of the actions taken by the RCA teams were to standardize on devices as well as protocols, clinical guidelines, and order sets. 625 of the PCA pump related RCAs were candidates where an integrated EtCO2 monitoring system would have averted the adverse events.[2]

Additionally, a joint Association for the Advancement of Medical Instrumentation (AAMI)/Food and Drug Administration (FDA) Infusion Devices Summit conducted October 5-6, 2010 at FDA headquarters generated 13 top priorities to prevent adverse events related to infusion devices. These top priorities include: incompatibility across devices and with systems (cleared products that support data transfer); standardization of terminology used in the infusion related systems (same wording, same spelling, etc. across the process and devices, containers, etc); lack of knowledge/familiarity with the device; lack of standardization that supports data aggregation; lack of formulary and standards – standardization of concentrations and transparency (e.g. sharing between facilities) of drug librarities; and dealing with the complexity of multiple infusions, including secondaries, disposables, etc.

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[1] Maddox, Ray, et al. "Intravenous Infusion Safety Initiative: Collaboration, Evidence-Based Best Practices, and "Smart" Technology Help Avert High Risk Drug Events and Improve Patient Outcomes," *Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 4: Technology and Medication Safety),* Agency for Healthcare Research and Quality, August 2008, available at https://www.ncbi.nlm.nih.gov/books/NBK43752/.

[2] VA National Patient Safety Center via VA generated patient safety and root cause analysis reports gathered from the VA NPSC SPOT system.

As a result, the Infusion and Patient Controlled Analgesia (IV/PCA) Integrated Product Team (IPT) that met May 19-21, 2009 at the National Acquisition Center (NAC) in Hines, Illinois identified the following as minimum recommendations for any infusion system purchased: Single platform and single user device interface; Dose Error Reduction System (DERS); Electronic drug libray; QI data extraction capabilities; and wireless networking consolidation of infustion data into the patient electronic record [requiring FIPS-2 certification].

To further increase the patient safety factor associated with the ECHCS infusion therapy system, the large volume IV pump needs to be compatible with the Alaris PC unit. According to a 2015 British Journal of Healthcare Management article[3], user error is one of the most common issues with infusion devices and can have catastrophic consequences. To reduce the risk to patients from user errors, DERS is recommended to be used. The Alaris drug management software provides the DERS for the Alaris infusion therapy system. By separating the high volume pumps from the Alaris infusion therapy system, the DERS used would be differing between the two systems and provides an increase chance for error.

With unique and seperate infusion systems, the nursing and clinical staff would need to program two infusion devices and the DERS systems would not interact. This could increase the chance of negative drug interactions due to the DERS not capturing all the drugs or doses being administered to a patient through one software. An additional critical patient safety feature includes the shut down of the PCA pump if the ETCO2 device is in the alarm mode.

Standardization of infusion pumps was a recommendation brought forward through the 2010 British Journal of Nursing article titled, "A Team Approach to Identify and Manage Risk in Infusion Therapy" by Paul T. Lee (Lee, 2010)[4]. For the evaluation of two large acute care hospitals, there were over 30 different infusion devices being used, and many different consumable sets for each of these devices. Patients were being swapped to different therapy devices, with different infusion sets, which inevitably increases the chance for user errors. The hospital systems had significant risk reduction by establishing a standardized infusion therapy system and reduced unnecessary duplication through multiple devices.

One infusion therapy system would also improve patient safety by limiting the training required for nurses, physicians, other medical practitioners, and users of the system. One system at a medical facility greatly increases the understanding users of the system will have as opposed to having to maintain proficiency on multiple systems that logically increases the risks to patients.

All infusion pump systems utilized by the VA must have National Institiute of Standards and Technology (NIST) FIPS-2 validated cryptographic modules. The current Alaris sytem is NIST FIPS-2 validated. The used Alaris pumps would not function without an Alaris PC unit to control setup for clinical use and there is no other product on the market that can control the Alaris ETCO2, PCA, or Syringe pumps as CareFusion holds the patents on the proprietary integrated infusion pump container and fluid infusion system.

Fielding multiple infusion therapy systems at the VA ECHCS increases the risk to veteran patients at the point of care and is a leading cause of patient harm. Maintaining uniformity in the infusion therapy system at the VA ECHCS is essential to the VA's requirement for upgrades to its infusion therapy system.

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[3] Blandford, Ann, et al., "Infusion Device Standardisation and Dose Error Reduction Software," *British Journal of Healthcare Management,* Volume 21, Issue 2, February 9, 2015.

[4] Paul Lee, "A Team Approach to Identify and Manage Risk in Infusion Therapy," *British Journal of Nursing,* Volume 19 Issue Sup1 (2010): online https://doi.org/10.12968/bjon.2010.19.Sup1.47080

If the VA ECHCS were to procure a brand new system, it would be required to purchase 25 additional large volume infusion pump units not covered under this requirement at a cost of [redacted]. As the facility is currently using the Alaris infusion therapy system, these 25 units currently in place could be reused. Additionally, the VA ECHCS would be required to purchase an entirely new DERS with 240 new software licenses. As the facility currently owns Alaris CareFusion Patient Controlled Analgesia (PCA) modules, EtCO2 modules, and syringe modules that will be used with the equipment being purchased, the VA ECHCS recognizes a savings of [redacted] in not having to purchase PCA, EtCO2, and syringe modules compatible with an entirely new system.

Based on an analysis of the cost of a brand new infusion therapy system versus purchasing only the Alaris CareFusion equipment, software, and services not currently owned by the facility, the estimated savings are [redacted] or over [redacted] the current independent government cost estimate. The estimated cost of an entirely new and workable system is approximately [redacted]. The savings and estimated cost of a new system do not take into account the added cost of purchasing and maintaining spare equipment for two or more infusion therapy systems that would be required in order to keep an adequate number of working systems available for patient use and also do not include delivery, installation, operations and maintenance, and training. In accordance with the authority prescribed in Federal Acquisition Regulation (FAR) 6.302-1(a)(2)(ii)(A), award to another source would result in substantial duplication of costs to the Government that is not expected to be recovered through competition.

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

See section 8 below for detailed efforts to ensure offers will be solicited from as many potential sources as deemed practicable.

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

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

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

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

On Tuesday September 12, 2017, notification was received that ICU Medical, Inc. filed a protest of Sources Sought Notice VA701-17-N-052 with Deputy Assistant Secretary for Acquisition and Logistics, Mr. Jan Frye.

During discussion of the Request for Information (RFI) protest with the Office of Acquisitions and Logistics (OAL), it was realized a Small Business Administration (SBA) Nonmanufacturer Rule (NMR) waiver would be required to proceed with award resulting from the solicitation that was set-aside for SDVOSBs. As a waiver cannot be granted after quotes on a solicitation have been received, the CO cancelled the solicitation and resolicited ensuring compliance with the NMR.

After the protest was decided, the CO performed a review of pricing received in response to the original solicitation. The only technically acceptable quote received was more than [redacted] over the estimated total price; the markup being nearly [redacted]. Thus, the CO did not determine the price fair and reasonable and in the best interest of the Government.

Previous market research efforts did not determine a reasonable expectation that two (2) or more quotes could be received from any other small business subcategory. This requirement will be solicited using full and open competition.

9. <u>Any Other Facts Supporting the Use of Other than Full and Open Competition</u>:

CareFusion is the sole manufacturer of the Alrais 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. <u>Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:</u>

- Beacon Point Associates, LLC
- Four Points Technology, LLC
- Veterans Healthcare Supply Solutions, Inc.
- BD (Becton, Dickison and Company)/CareFusion
- ICU Medical, Inc.

11. <u>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</u>:

To remove or overcome any barriers to competition before future acquisitsions for the same supplies and services are conducted, at the system's end of life, the VA will ensure extensive market research is performed in a timely manner to evaluate vendor capabilities with the intent of opening competition to all brands of IV infusion pump therapy systems that can potentially meet the Government's requirements. The estimated lifecycle of infusion therapy systems is approximately eight (8) years.

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] [redacted]

[redacted] Date

Biomedical Engineer, Facilities Management Service
VA Eastern Colorado Health Care System

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] [redacted]

[redacted] Date

Contracting Officer
Program Contracting Activity Central (PCAC)

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

[redacted] [redacted]

[redacted] Date

Director of Contracting
Program Contracting Activity Central (PCAC)

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.

[redacted] [redacted]

[redacted] Date

VHA Head of Contracting Activity (HCA)