

**LIMITED SOURCES JUSTIFICATION**

**ORDER >SAT**

**FAR PART 8.405-6**

**Acquisition Plan Action ID: 36C249-19-AP-1647**

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office 9 (NCO-9), 1639 Medical Center Parkway, Suite 400, Murfreesboro, TN 37129.  
2237 Number: 626-20-1-701-0001
2. **Description of Action:** This acquisition is conducted under the authority of the Multiple-Award Schedule Program (41 U.S.C. 251 and 40 U.S.C. 501). Network Contracting Office 9 (NCO-9) of the Department of Veterans Affairs (VA) has a new requirement to lease the CareFusion Pyxis® Point of Care Decentralized Automated Dispensing Cabinet Medication Distribution System (CareFusion Pyxis®) for the Tennessee Valley Healthcare System (TVHS). Blanket Purchase Agreement: ☒ FSS Contract Number: 36F79718D0454 under schedule number 65IIA and Category A-92.

Name of Proposed Contractor: **CareFusion Solutions, LLC.**  
Street Address: **3750 Torrey View Court**  
City, State, Zip: **San Diego, CA 92130**  
Phone: **(858) 617-4824**

**3. Description of Supplies or Services:**

The estimated value of the proposed action is: Base Year: \$1,600,000  
Option Year 1: \$1,760,000  
Option Year 2: \$1,936,000  
Total Est Value: \$5,296,000

This acquisition is for the lease of CareFusion Pyxis® Point of Care Decentralized Automated Dispensing Cabinet Medication Distribution System (CareFusion Pyxis®) along with software and system maintenance support. CareFusion Pyxis® systems are currently used to support all inpatient Bar Code Medication Administration (BCMA) and all outpatient clinics. The systems function both locally and at remote Community-Based Outpatient Clinics (CBOC) by way of one main server located at the Nashville Veterans Affairs Medical Center (VAMC). Unit Dose medication packaging is used for patients that are admitted or treated in clinic, for medication and drug accountability/security and to minimize medication diversion. The CareFusion Pyxis® system is a living process, conforming to the Government's needs by expanding to accommodate new activations or added services, and through reduction as necessary during remodeling or a shifting of services. All items required for this

procurement are found on VA NAC FSS contract 36F79718D0454, with no Open Market items being leased.

**4. IDENTIFY THE AUTHORITY AND SUPPORTING RATIONALE (see 8.405-6(a)(1)(i)(A), (B), and (C) or 8.405-6(b)), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE. (CHECK ALL THAT APPLY AND COMPLETE)**

☐ An urgent and compelling need exists and following the ordering procedures would result in unacceptable delays.

☒ Only one source can provide the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized.

TVHS is a 1A dual site, transplant, BMT, high acuity care AND Long Term Care (LTC) AND Psychiatric Care center and is unlike every other facility within VISN-9. The demands on a TVHS distributive ADC system are much more diverse than at any other VISN-9 facility. Likewise, capabilities often presented with vendor products, including products related to the CareFusion/Pyxis system, undergo trials at small, single site, low acuity locations, which do not implement the full range of transaction management, diversion oversight, and personnel training accomplished at TVHS. For example, Kansas City VAMC, which has been used as a test site, has never implemented "profiling", a highly valuable diversion control process; a process nearly universally implemented throughout TVHS. TVHS has expanded profiling across diverse users and is working closely with users within Nursing, Physician, and Pharmacy departments to identify issues needing correction, that will otherwise go undetected. Subjecting TVHS patients and users to a system untested at the same level diversity and standards of implementation would carelessly expose Veterans to currently unresolved issues identified in other systems and decrease medication safety. The personnel expertise, product capabilities, and user training are currently unique to this vendor.

☐ In the interest of economy and efficiency, the new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

☒ Items peculiar to one manufacturer:

☐ A patent, copyright or proprietary data limits competition. The proprietary data is: (If FAR 8.405-6(a)(2)iii before posting. Do not include specific proprietary data. Only mention the type of equipment, procedure, etc. to show that proprietary supplies or services are being procured.)

☐ These are "direct replacements" parts/components for existing equipment.

- ☒ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

This acquisition requires compatibility with the existing CareFusion Pyxis® Enterprise Server ADC system currently supporting the communication of platforms within the medication use process, particularly with the TVHS Bulk to Unit Dose Auto Re-packager units located at the main pharmacies on the Nashville and Murfreesboro, TN campuses. The network infrastructure is currently configured to support CareFusion Pyxis®. Allowing another contractor to re-configure the network to accommodate a new system is lengthy and will likely present a cost constraint to the Government, as these costs often cannot be estimated, since most are typically incurred during the post-award phase. The current software and other ancillary network items used with CareFusion Pyxis® equipment has already endured this process and will incur minimal additional resources when adding ADC devices at currently unsupported locations, as opposed to a complete system replacement.

Under this procurement, additional CareFusion Pyxis® devices will be placed at locations where none exist, while providing sustainment of existing operational devices currently installed at other locations. Insufficient numbers of ADC devices throughout TVHS represent substantial vulnerabilities during the care of patients, ranging from prescription mislabeling, over-medication, under-medication and others. At this time, it would not be advantageous for the government to pursue a competitive award for this system. Replacing the CareFusion Pyxis® system with a competitive system will require a duplication of effort in the procurement of a replacement server to support the new system and entail replacement of devices currently embedded within the medication use process.

Additionally, any disruption to patient care would be an unacceptable consequence of changing vendors on a scope and scale of this nature. TVHS has been utilizing CareFusion Pyxis® for over 10 years. Changing vendors will require a minimum of 12 months of system evaluation, system testing, and new vendor system configuration, during such time, the CareFusion Pyxis® will still be required during the system transition period to maintain operational continuity. This extends to the full range of user training, platform testing, and product swapping. Due to the increased cost to the Government for vendor changeovers, VA ITOPS and VA Pharmacy ADPACs have generally agreed that such vendor changes should only occur with end of life-cycle equipment or with technology upgrades. TVHS recently installed the newest CareFusion Pyxis Enterprise Server ADC system in FY19 and could not efficiently change vendors until the expiration of the existing supporting contract. Converting from one system to an entirely new system will require countless man-hours and other resources, which would be cost-ineffective and negatively impact patient care.

**(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.404(d) TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:**

The proposed prices for this requirement will be established against the existing FSS orders with CareFusion Solution (3624919N0042 and 3624919N0043) and using their current FSS contract list or discounted pricing/rates. There are no open market items being procured under this requirement and therefore, in accordance with FAR 8.404(d), GSA has already determined the prices under schedule contracts to be fair and reasonable. For the reasons identified above, the CO determines that establishing a sole source BPA award with additional option periods for this requirement represents the best value to the government.

**(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:**

TVHS Department of pharmacy continuously conducts market research on packaging and dispensing hardware and software including stock management solutions. Auto repackaging and automated dispensing cabinets technology are more mature than stock accountability solutions and are dominated by two vendors, CareFusion and Omnicell. TVHS Pharmacy is in constant contact with both vendors assessing improvements and innovation for a best fit at TVHS. TVHS Pharmacy has met with the competing vendor, Omnicell, more than five times throughout 2017 and 2018 on their full line of products. As a result, Omnicell was determined equivalent or superior on stock accountability software with hardware equivalence (not yet ready to purchase) and Sterile Products compounding software and hardware superiority (IVX system being requested on separate contract) but inferior on the Automated Dispensing Cabinet. Overall, CareFusion/Pyxis products are considered superior.

**(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:**

Without the use of automated re-packagers for barcoded labeling of bulk to unit dose repackaging, the VA will lose the safety, cost, and time efficiencies of these products. TVHS's current vendor of a competing re-packager has proven the sub-optimal nature of a non-natively communicated re-packager to automated dispensing cabinet medication distribution. Selecting a different vendor for the automated repackagers separate from the already installed automated dispensing cabinets will prevent the TVHS Pharmacy services department from providing the best possible medication use environment, which will subsequently affect the level of care our Veterans currently receive and deserve.

**(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:**

Actions required to remove or otherwise overcome barriers created using the current system would cause significant disruptions to patient care and present overwhelming technical challenges and cost related risks to the government. Therefore, no plans are being considered to replace the current system.

**(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

[REDACTED]

8/5/2019

Date

[REDACTED]

**(10) APPROVALS IN ACCORDANCE WITH THE VHAPM Part 806.3 OFOC SOP:** *This part if filled out by Contracting Staff as part of the Justification*

**a. CONTRACTING OFFICER'S CERTIFICATION (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

[REDACTED]

8/5/2019

Date

[REDACTED]

**b. One Level Above the Contracting Officer (Required over the SAT but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

[REDACTED]

Date

[REDACTED]

**HIGHER LEVEL APPROVAL (Required for orders over \$700,000):**

[REDACTED] [REDACTED]  
[REDACTED] [REDACTED]  
[REDACTED] \_\_\_\_\_ Date  
[REDACTED]

c. **VHA SAO HCA REVIEW AND APPROVAL (over \$700,000 to \$68 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

[REDACTED]  
[REDACTED]  
[REDACTED] \_\_\_\_\_ Date  
[REDACTED]  
[REDACTED]