

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Limited Sources Justification Format >\$150K

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA242-17-AP-3687 – 2237: 630-17-2-3086-0051

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source: Provide original manufacturer's name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, ALSO provide dealer information.)

Manufacturer/Contractor: Carefusion

Manufacturer/Contractor POC & phone number: [REDACTED]

Mfgr/Contractor Address: 3750 Torrey View Court San Diego CA 92130

Dealer/Rep address/phone number: [REDACTED]

☒ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs
New York Harbor Healthcare System
St. Albans & Brooklyn
800 Poly Place
Brooklyn, NY 11209
2

VISN:

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

The VA New York Harbor Health Care System is looking to upgrade the current Pyxis medication automation system for the Brooklyn and St. Albans Campus. Pharmacy service requires a platform solution proven technology with actionable intelligence to prevent medication errors, which will help free up clinician time to focus on patient care, increase the predictability of medication availability and reduce inefficiencies in the medication use process.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

The VA New York Harbor Health Care System is looking to upgrade the current medication automation system for the Brooklyn and St. Albans Campus location with required software, installation and training from CareFusion. This Acquisition will upgrade the existing Pyxis MedStation® 3500 system and CII Safe® system. The acquisition consists of replacing existing system with a modern system and adding new components throughout the VA New York Harbor Health System at the Brooklyn and St. Albans Campus.

The Pharmacy Service needs a platform solution that will:

- Streamline the medication management in OR and procedural areas
- Speed the access to medications and supplies when and where needed
- Provide simple, safer clinical workflows centered on the patient

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- Increase medication security and safety
- Give pharmacy visibility to medication inventory and utilization
- Leverage integration with our current healthcare information technology systems
- Simplify system support, and reduce IT footprint
- Centralize medication management across the health system
- Meet the current VA IT security requirements.

A platform approach for hospitals and health systems should feature the following core capabilities, such as secure, quick access and electronic documentation for controlled substances and waste. The system should be able to automate charge and cost capture and facilitates administration verification and medication tracking. The system should be simple, provide safer patient-centric workflows, enhanced security and innovative capabilities that can be leveraged or integrate with current health systems. Additional benefits would be:

- Anesthesia providers can decrease manual documentation
- Pharmacy can manage just one synchronized formulary
- IT can manage user sign-on privileges
- Staff can access reports from any web browser

(b) ESTIMATED DOLLAR VALUE: [REDACTED]

(c) REQUIRED DELIVERY DATE: 180 days ARO

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

CareFusion is the only company that upgrades its products. Switching to a different vendor would entail not only the cost a new machine, but also the purchase of all additional supplies needed to run the machine and require significant amount of training and retraining. Switching to another vendor is cost prohibitive and would derail the entire project.

The Pyxis[®] ES platform begins a new generation of Pyxis[®] systems designed to address current and future trends in healthcare. It includes capabilities that help make the medication management process simpler, safer and more secure. It offers innovative communication and workflow optimization tools to help enhance nursing and pharmacy's ability to work more efficiently and effectively as individuals and as a collaborative team in their efforts to deliver safe, high-quality patient care.

Key features of the Pyxis MedStation[®] ES system that would help achieve the VA Brooklyn and St. Albans procurement goals are as follows:

Enterprise-wide integration exceeds the needs of advanced healthcare enterprise information technology departments. Providing true integration with hospital information systems, enterprise-wide integration helps support every stage of growth along a health system's long term strategic plan.

- Manage one user database – Sophisticated Active Directory capabilities allow centralized user management for the entire health system or single hospital.

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Pharmacy no longer needs to manage lost passwords, employee terminations, or new hires in the Pyxis[®] Enterprise Server. Pharmacy is able to focus on managing user privileges within the Pyxis[®] Enterprise Server.

- Manage one formulary through true integration with the Pharmacy Information System (PIS).
- Manage less hardware with flexible and scalable deployment options – Software-only and VMware ready configurations, as well as server farm integration, are standard capabilities.
- Web-based accessibility to the system allows management of the system from any hospital computer.

Simple, safe workflows focused on the patient helps guide pharmacy and nursing to the information they need, helping increase clinical and operational efficiencies and simplifying the caregiving process.

- The Pyxis MedStation[®] ES system workflows were completely redesigned to be completely patient-centric, moving away from a task-based workflow to one that starts with the patient. The result is safer and more efficient workflows for the clinical team.
- Fewer steps to accomplish tasks. The new remove workflow is quicker than ever – 4 steps in 5 seconds and the nurse has the medication for the patient at the time due.
- New safety enhancements make it easy for the users to identify or help avoid potential errors. For example, patients with the same last name are easily identified in the system that enables clinicians to see they are on the correct patient profile.
- The new workflows allow the nurse to access patient and medication information without leaving the workflow. Keeping information in one place helps nurses get the information they need, more easily than ever before.

CUBIE[®] pockets from CareFusion increase medication security by restricting access to only one medication at a time during the remove and refill process by having a locked lid only releasing when that specific drug is requested; higher security. CUBIE[®] drawers provide the highest security, flexibility, and capacity.

The CUBIE[®] Drawers and pockets are a competitive differentiator. No other competitor offers a drawer type that provides a high level of security, single med access to only one medication during the remove and refill process and can be quickly and easily reconfigured by customers to accommodate changing needs. Customers utilize CUBIE[®] technology to increase efficiencies and cost savings by facilitating rapid pocket/drawer configurations without having to replace the drawer. The pockets are available in various sizes and can be exchanged to accommodate most storage needs and seasonal formulary changes.

CareFusion Coordination Engine is a flexible, enterprise level, integration tool used to provide customers with interoperability between CareFusion products and the customers' Health Information System.

CareFusion Coordination Engine utilizes state of the art technology providing integration with many hospital systems such as, but not limited to, Patient Information for perpetual census, Pharmacy, Materials Management and outside vendors for restocking, Operating

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Room Information Systems for all facets of procedure management, and Financial systems for patient charging. Some standard integration options:

- Admissions, Discharge, and Transfer (ADT)
- Usage (for Patient charges and/or Costing)
- Patient Medication Profile (Pyxis MedStation[®] only)
- Floor Stock (Pyxis MedStation[®] only)
- Electronic Medication Charting (Pyxis MedStation[®] only)
- Purchase Requisition/Restock Orders
- ORIS/Procedure Management (Pyxis SupplyStation[®] only)
- Item Maintenance (Pyxis SupplyStation[®] only)
- Inventory Management (Pyxis SupplyStation[®] only)

CareFusion prefers HL7 messaging and supports version 2.2-2.7.

CareFusion's new IT friendly, scalable platform product strategy will help support the entire continuum of care, CareFusion Coordination Engine is the engine that brings CareFusion's solutions together. Currently supporting all Pyxis[®], Respiratory and Pharmogistics[®] products, Carefusion is currently expanding development to support a single scalable solution for all CareFusion products, including Alaris[®] systems. This means collecting data and information from the entire spectrum of patient care. This means data and information from the entire spectrum of patient care. Easy access to vital information supports your efforts to drive better patient outcomes, achieve meaningful use goals, increase security and lower cost.

CareFusion's Pyxis C^{||}Safe[®] system narcotic vaults are physically designed to improve security and come with a variety of diversion reports to assist the hospital in tracking and monitoring trends across the hospital. The Pyxis C^{||}Safe[®] system helps support compliance with strict state and federal guidelines. The system enables clinicians to gain real-time audit capabilities, helping control diversion and ensure staff compliance with government regulations.

One of the key benefits of CareFusion's Pyxis C^{||}Safe[®] system is the ability to manage the outdating and expirations of controlled substances. The Outdate tracking feature allows users to quickly understand what medications are set to expire and give them the option of moving them to a pending destruction bin.

CareFusion has installed more than 250,000 Automated Dispensing Machines (ADM) and related peripherals within the United States, and has extensive experience with customer installations of all sizes and complexities. CareFusion is the most experienced ADM vendor in the United States, with more than 1,000 field-based implementation, software integration, clinical training and field service professionals placed regionally throughout the country.

The CareFusion Team develops an implementation plan to meet the needs and expectations of the Client goals and expectations. CareFusion takes into consideration products purchased, client's timeline expectations, availability of client resources,

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construction considerations, workflow and change management, training, etc. when developing these plans. CareFusion designs each implementation plan to meet each individual customer's needs.

Each implementation team consists of a project manager, clinical consultant (nurse and/or pharmacist), technical consultant, workflow consultant and implementation analyst. Project managers oversee the project team to help ensure speed to impact and project success. Clinical consultants work with the hospital team to assist each account's development of a unique data set drug library and clinical practice. Technical consultants work with the client to design the most effective architecture for their system; workflow consultants assist in the design of future state workflow and the client's configuration of the system to support the workflow. Implementation analysts configure and deploy the devices as well as provide education on use of the system.

In addition, the VA Clinical staff is already familiar with the CareFusion user interface and would not require extensive retraining as would be required for a different system.

CareFusion is the only company that offers true Customer Support available 24/7/365 through CareFusion Pyxis® Technical Support Centers (TSC) to respond immediately to any support issue. A CareFusion Customer Support Representative will work with customers to perform initial troubleshooting. In most cases, problems are resolved over the phone.

CareFusion is the only company in the industry that can provide a true, comprehensive end-to-end medication management system offering the single most comprehensive and integrated collection of medical device technologies in the industry, while leveraging a single, common interface engine and standardized reporting solution in Knowledge Portal. Truly designed for health system performance, CareFusion medication management solutions combine our industry leading Alaris® intelligent infusion system and Viasys® respiratory solutions with our Pyxis Pharmogistics® pharmacy automation and inventory management solution, Pyxis® IV system*, Pyxis MedStation® ES system, Pyxis® Anesthesia ES system, Pyxis® SMART Remote Manager, and Pyxis CII Safe® to enable enterprise-wide medication management.

The CareFusion Pyxis® medication automation system is currently in use in VA New York Harbor Healthcare System at the New York, Brooklyn and St. Albanses campus in New York. At the Brooklyn Campus the CareFusion Pyxis® medication automation system is being used in all med/surg nursing units, critical care, ER and OR Core locations. At St. Albans location the Carefusion Pyxis medication automation system is being used in the following locations: 4 South, A5-3, WHEN and Domiciliary.

The CareFusion Pyxis® medication automation system is also interfaced with the VHA system for patient records allowing clinicians to efficiently record medications that have been administered to patients.

The VA Clinical Staff are already familiar with the CareFusion Pyxis® systems user interface and would not require extensive retraining as would be required for a different system.

☐ 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.)

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N/A

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

☒ 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.

The VA New York Harbor Health Care System is looking to upgrade the current medication automation system for the Brooklyn and St. Albans location with required software, installation and training from CareFusion. This Acquisition will upgrade the existing Pyxis MedStation® 3500 system and CII Safe® system. The acquisition consists of replacing existing system with a modern system and adding new components throughout the VA New York Harbor Health System at the Brooklyn and St. Albans Campus.

☐ 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.
N/A

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

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

There is no other Pyxis like products that can be used to upgrade the systems already in place. Therefore upgrading the existing equipment would save the government money over procuring a new system. The quote from Carefusion will be compared to the IGCE to determine fair and reasonable pricing. Additional discounts will be requested prior to award IAW FAR 8.405-4

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

Market research was conducted on VIP/Vet Biz to determine if any SDVOSB and VOSB contractors were capable of providing Pyxis upgrades, software and training. A keyword search of Pyxis and CareFusion was completed and resulted in no matches. The CO then posted an RFI to SEWP and two (2) SDVOSB contractors responded. Additionally, please see attached sole source letter from CareFusion confirming that they are the only company capable of providing the Pyxis upgrade and equipment. Only CareFusion (via its authorized distributors) is able to provide the upgrades to existing Pyxis equipment and all software associated with Pyxis is proprietary to CareFusion. Upon solicitation phase, SEWP has now pulled the medstations off of the price lists, so SEWP is no longer an option. Due to the dollar amount on this and the manufacturer being large, this cannot be set aside. Therefore it is in the best interest of the government to purchase this off of Carefusions NAC contract V797P-4012b on 65-II.

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(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

The NYH VA Clinical staff is already familiar with the CareFusion user interface and would not require extensive retraining as would be required for a different system. It is imperative for the OEM to provide any new equipment and upgrades to existing Pyxis equipment as it must be compatible with CareFusion equipment and software currently in use at these facilities

(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:



This is an upgrade of equipment already in use therefore the contracting officer does not believe that, in this instance, any barriers exist that would make this procurement action non-competitive in the future. If purchases are made in the future, the requesting service and Contracting Officer will conduct market research to determine if new products are available that could meet the VA's need and result in a competitive procurement

(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.)*

		5/1/2017
SIGNATURE		DATE
		
NAME	TITLE	SERVICE LINE/SECTION
NY Harbor Healthcare System		
FACILITY		

(10) 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.

	06/15/2017
CONTRACTING OFFICER/DESIGNEE'S SIGNATURE	DATE
	NCO 2
NAME AND TITLE	FACILITY

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b. **Director of Contracting/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

[REDACTED]

SIGNATURE

DATE

[REDACTED]

NAME

[REDACTED]