

DEPARTMENT OF VETERANS AFFAIRS

SOLE SOURCE JUSTIFICATION UNDER SIMPLIFIED PROCEDURES FOR CERTAIN COMMERCIAL ITEMS IN ACCORDANCE WITH FAR 13.5

Acquisition Plan Action ID: 36C249-22-AP-3260

1. **Contracting Activity:**

Network Contracting Office 9 (NCO 9)
Department of Veterans Affairs, Robley Rex VA Medical Center, 800 Zorn Ave., Louisville KY 40206
2237 No.: 603-23-1-984-0008

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

This proposed brand name action is for the procurement of purchased Pyxis® Automated Dispensing Cabinets (ADCs) in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Document 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. This requirement will be solicited unrestricted as a brand name RFQ posted to Contract Opportunities, and will be awarded as a new, firm-fixed-price contract.

The ADC, a computerized point-of-use medication management system, is designed to replace non-automated floor stock storage, offer better control of medications that are available in the patient care area, and allow for tracking of pharmaceutical distribution. Point-of-use ADCs minimize patient exposure to medication administration errors while concurrently ensuring immediate availability of necessary medication therapies for all patients. The Institute for Safe Medication Practices (ISMP) has recognized ADC distributive medication systems in health care systems as a Best Practice and recommends ADC use in all areas. Barcode medication accountability, congruent with ADCs, are imperative for patient safety.

3. **Description of Supplies/Services Required to Meet the Agency’s Needs:**

The Robley Rex VA Medical Center has a need to procure 148 Pyxis® Automated Dispensing Cabinets, to include ancillary equipment and technical support. This Brand Name Justification is for award of a base contract for the procurement of the ADCs, ancillary equipment, and technical support, and four (4) additional option periods to allow for ongoing technical support. The total estimated value of the procurement is [REDACTED].

LI	Description	QTY	Unit	Unit Price	Total
0001	Pyxis® ADC Purchase – Base Period 11/01/2022 – 10/31/2023	1	LT	[REDACTED]	[REDACTED]
1001	Technical/IT Support – Option Period 1 11/01/2023 – 10/31/2024	12	MO	[REDACTED]	[REDACTED]
2001	Technical/IT Support – Option Period 2 11/01/2024 – 10/31/2025	12	MO	[REDACTED]	[REDACTED]
3001	Technical/IT Support – Option Period 3 11/01/2025 – 10/31/2026	12	MO	[REDACTED]	[REDACTED]
4001	Technical/IT Support – Option Period 4 11/01/2026 – 10/31/2027	12	MO	[REDACTED]	[REDACTED]
				Total	[REDACTED]

4. Statutory Authority Permitting Restricted Competition:

FAR 13.5 Simplified Procedures for Certain Commercial Items. The statutory authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. § 1901 and is implemented by FAR 13.106-1(b)(2) for restricting competition on this procurement. **Competition is restricted on this procurement for the reason below:**

- Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements
- Unusual and Compelling Urgency
- Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services
- International Agreement
- Authorized or Required by Statute
- National Security
- Public Interest

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 current, leased ADCs are at or near end of life. The Robley Rex VA Medical Center Pharmacy Service is requesting that all existing leased ADCs be returned to Carefusion and the purchase of a new brand-name system will include upgraded cabinets to replace all existing Pyxis® equipment capable to expand with the number of patient care areas, ensuring adequate and secure drug storage within Robley Rex VA Medical Center, the operating rooms, and the remote VA Clinics. The current leased automated dispensing cabinets will be replaced at each VA clinic (Scott, Carroll, Grayson, Stonybrook, Newburg, Greenwood, New Albany, Ft. Knox), Substance Abuse Residential Rehabilitation Treatment Program (SARRTP), Medical Procedures Unit (MPU), Cardiac Cath Lab, Emergency Department, Urgent Care, Medicine Clinic, Operating Rooms, Acute Stroke Unit (ASU), Operating Holding Room, Dental Clinic, Pain Clinic, Radiology, Oncology Clinic, Nuclear Medicine, Procedural Areas, Med/Surg floors, and Intensive Care Unit (ICU). The system will also include upgraded Pyxis CII Safe machines for securely storing controlled substances within the pharmacies. This machine will continue to serve as the main 'hub' for storing controlled substances that will be deployed out to the various automated dispensing cabinets within the Medical Center. Pyxis® Anesthesia ES Systems will also be upgraded in each Operating Room with Codonics printers.

Salient characteristics include secure narcotic storage, barcode automation, scanning and labeling, uninterrupted power supply, compatibility and integration with Veterans Health Information Systems and Technology Architecture (VistA), integrated inventory management, and user access management. The system must also provide an automated medication management system for refrigerated medications that provides controlled point-of-use access, electronically tracks and records transaction data and generates reports necessary for inventory management and regulatory compliance. Furthermore, the ADCs must be compatible with procured Pyxis® Carousel and Pyxis® Logistics Software that is utilized in support of the Medical Center. [REDACTED] Automated Dispensing Cabinets are not compatible with the Pyxis® Carousel and Pyxis® Logistics Software and would not properly interface with the network and would void any existing warranties on purchased Pyxis® equipment and software.

The Robley Rex VA Medical Center also requires removal and return of current leased Pyxis® equipment, which can only be accomplished by the equipment's manufacturer or authorized

distributors. The replacement of Pyxis® equipment with congruent - brand name equipment ensures compatibility of form, fit, and function of the equipment, and proper interfacing with existing Pyxis®-brand infrastructure. Given the proprietary nature of VA information systems along with local nuances associated with Veterans Health Information Systems and Technology Architecture (VistA), ADC systems are not plug and play solutions. Procuring the exact brand name equipment will mean no interruption to patient care as the programs are already compatible with the current servers and network interface. Additionally, it will be a smooth transaction of removing old, leased equipment, and replacing with new purchase equipment, item for item.

Accordingly, [REDACTED] is the only firm capable of removing leased equipment and replacing it with new, purchased brand name equipment described in Section 3 above without the Veterans Health Administration experiencing unacceptable delays in fulfilling its requirements.

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

A Notice of Intent to Sole Source (Special Notice No. 36C24922Q0673) was posted on Contract Opportunities on 08-22-2022, informing the public of NCO 9's intent to award a sole source Purchase Order to Carefusion for purchased Pyxis® Automated Dispensing Cabinets, as there appears to be no vendors available in the marketplace that can meet the needs of the Robley Rex VA Medical Center. [REDACTED] response was received from interested vendor [REDACTED]

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

The Contracting Officer will conduct pricing analysis in order to determine price fair and reasonable, by comparing quoted rates to the Independent Government Cost Estimate (IGCE), review of historical pricing of the equipment awarded to other VISNs, and current market rates.

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

In accordance with 13 CFR § 121.406, the Nonmanufacturer Rule is analyzed for this requirement. The SBA Nonmanufacturer Rule Waiver List was checked to determine if the NAICS was listed. Although NAICS 339112 is listed on the Waiver List, it is only for CPAP Device Manufacturing. The Waiver List was further reviewed to determine if Automated Dispensing Medication Systems were included under a different NAICS code, but nothing was found.

Correspondence was received from [REDACTED] confirming that they have [REDACTED] for their equipment; [REDACTED] and [REDACTED] are [REDACTED]

[REDACTED] However, based on the review of the Nonmanufacturer Rule for this procurement, no small businesses would meet the "four-prong test" to qualify as a Nonmanufacturer in accordance with 13 CFR § 121.406(b)(1)(i), (ii), (iii), and (iv). [REDACTED] is not a small business, and this requirement is over the Simplified Acquisition Threshold (SAT). Therefore, in accordance with the Nonmanufacturer Rule Decision Tree, this award cannot be set aside or sole sourced to an SDVOSB.

As described in Section 6 above, market research, in accordance with FAR Part 10, was conducted by synopsis of the proposed acquisition, advising industry of the pending acquisition and soliciting inquiries from interested parties.

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

As the Robley Rex VA Medical Center inpatient pharmacy is installing a purchased Pyxis® carousel (an automated, vertical, rotating, dispensing machine) and purchased Pyxis® Logistics software, for compatibility and functionality, it is in the best interest of the government to solicit this requirement as a Brand Name RFQ, posted unrestricted, while still allowing for competition amongst the OEM and its distributors.

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

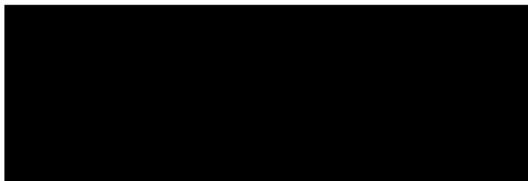


11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

The current Robley Rex VA Medical Center is projected [redacted] Network Contracting Office 9 will work closely with the Robley Rex VA Medical Center to ensure [redacted] will be competed as brand name or equal requirement, allowing competition to the maximum extent practicable.

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.



Chief, Pharmacy Service
Robley Rex VA Medical Center

13. Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):

- a. **Contracting Officer's Certification:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Contracting Officer
Network Contracting Office 9

- b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$750K):** I certify the justification meets requirements for other than full and open competition.



Branch Chief, Supply East
Network Contracting Office 9

- c. **Division Chief:** I certify the justification meets requirements for other than full and open competition.



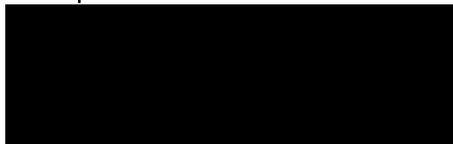
Division Chief / Supplies, Services, and Prosthetics
Network Contracting Office 9

- d. **Director of Contracting Concurrence:** I concur / non-concur that the justification meets requirements for other than full and open competition.



Director of Contracting
Network Contracting Office 9

- e. **VHA RPO 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 belief and approve (\$750K to \$7.5 million (or \$15.0 million for acquisitions described in FAR 13.500(c)) for other than full and open competition.



Executive Director
Regional Procurement Office Central (VHA)