

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA263-18-AP-2568

1. **Contracting Activity:** US Department of Veterans Affairs, Network Contracting Office 23 (NCO 23), 4801 Veterans Drive, St. Cloud Minnesota 56303-2099.

2237#: 618-18-2-109-0232

2. **Nature and/or Description of the Action Being Processed:** A sole source justification to award an open market rental contract to lease Pyxis cabinets for the use in the outpatient and inpatient areas throughout the Minneapolis VA facility to help properly store, track, and dispense medications throughout the facility. In addition to leasing the system, 24/7 software and hardware service support is also required.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Minneapolis VA Health Care System (HCS) requires an open market purchase order for the Pyxis Medstation medication dispensing system and supporting equipment located throughout the Minneapolis VA facility. The complete list of Pyxis leased equipment is listed below. Support service for all of this equipment is also included.

The required period of performance is March 1, 2018 – February 28, 2019.

QTY	Description
21	MedStation 4000 Profile- 6 drawer main with 5 cubies
5	MedStation 4000 Profile - 6 drawer main with 4 cubies
2	MedStation 4000 Profile - 6 drawer main with 3 cubies
1	MedStation 4000 Profile - 6 drawer main with 1 cubies
2	MedStation 4000 Non-Profile - 6 drawer main with 3 cubie
4	MedStation 4000 Profile - 2 drawer main with 1 cubie
6	MedStation 4000 Non-Profile - 2 drawer main with 0 cubie
12	MedStation 4000 Non-Profile – 2 drawer main with 1 cubie
1	MedStation 4000 - Profile Console with 1 printer, monitor and UPS
1	MedStation 4000 - Pyxis Workstation with 1 printer, monitor and UPS
2	MedStation 4000 - Single Column Auxiliary with 4 doors and zero drawers
3	MedStation 4000 – Double Column Auxiliary with 8 doors and zero drawers
1	Double Column Narcotics Vault Auxiliary with 8 doors and zero drawers
1	Smart Remote Manager
1	CII Safe Control Station Dbl Column Integrated Main w/7 doors, 1 rapid access drawer
1	CCE Server

1 Virtual Test System, PC with peripherals

Pending install:

- 1 MedStation 4000 Profile - 2 drawer main with 1 cubie
- 4 MedStation 4000 Non-Profile – 2 drawer main with 2 cubie
- 3 MedStation 4000 Profile- 6 drawer main with 5 cubies
- 9 MedStation 4000 - Single Column Auxillary with 4 doors and zero drawers
- 4 Smart Remote Manager
- 2 Additional cubie drawer, including 1 set of 2-1/2 height drawers with pockets

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

- (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- (2) Unusual and Compelling Urgency per FAR 6.302-2;
- (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- (4) International Agreement per FAR 6.302-4
- (5) Authorized or Required by Statute FAR 6.302-5;
- (6) National Security per FAR 6.302-6;
- (7) Public Interest per FAR 6.302-7;

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

Pyxis (Carefusion) is the only source for these cabinets for the following reasons:

-This highly specialized system equipment is deployed throughout the Minneapolis VAHCS in inpatient units, ambulatory care units, emergency room, and operating room areas. CareFusion is the sole manufacturer and exclusive provider of lease & service support for Pyxis products in the United States. Only CareFusion and their Field Service Technician Affiliates have the capabilities and authorization required to perform installation and maintenance services for Pyxis products. Performance of those services by a third party voids their warranty for the serviced products.

-The Minneapolis VA HCS has standardized other equipment to the Pyxis platform throughout the hospital. This requires one server to run all medication cabinets and the other equipment. The cost of switching the entire Minneapolis VAHCS medication dispensing cabinets over to a new system would be very costly, and in addition, the new system would not be compatible with other programs and would cause additional costs for other equipment as well.

-Due to extensive planning, workload, and disruption of workflow expected over the next two years in the Minneapolis VA inpatient pharmacy related to construction remodeling and workflow adjustments required for USP800, the Minneapolis VAHCS pharmacy department does not have the ability to support any additional adjustments to policy/procedure, bargaining

obligations, drug file/database set up, testing, or any training related to these medication dispensing machines which would be required above and beyond even the maximum support a vendor could provide in project management & education support for any change to our current system. There are new USP800 regulations that are set to become official on Dec. 1, 2019. These regulations are related to handling of hazardous drugs in healthcare settings which includes how medications are handled within our inpatient pharmacy. In order to meet the new regulations, our inpatient pharmacy will require significant remodeling and significant workflow adjustments surrounding our sterile compounding processes. Once this physical remodel has been completed and we have completed our needed upgrading to our sterile compounding processes, we expect to turn our attention to a thorough review of our inpatient and in-clinic automated medication dispensing cabinet system to include a careful assessment of leasing vs purchasing of any systems that would meet our needs.

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

Consideration was given to whether a change to a new medication dispensing system could be supported by the Minneapolis VAHCS pharmacy. It was determined that a change away from Pyxis cannot be supported after FTEE review and review of extensive projects required in a short time frame to become compliant with USP regulations. Given that the Minneapolis VAHCS requires the Pyxis system, BD/CareFusion is the sole manufacturer and service provider.

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

Once pricing is received, the Contracting Officer will review proposed open market prices for this order against comparable PO/DOs. The Minneapolis VA Pharmacy considered lease vs. buy for this procurement. The Minneapolis VA has been expanding the use of equipment into new areas and during that expansion, they wanted flexibility to allow for quick adjustments to increase or decrease the equipment needs. The Minneapolis VA Pharmacy feels that leasing allows for more agile flexibility. At this current time, with known upgrading/updating in both the dispensing cabinets and the software/platform capabilities, the Minneapolis VA feels it would be best to consider purchase once they are able to support an upgrade into a new operating platform. Historically, the Minneapolis VA has not purchased this equipment and instead has only pursued the lease option, due to the changing technology in the ADMs, changes to the interfacing systems and changes/expanding use with the Minneapolis facility.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: Market Research was conducted between August 2017 and November 2017 using the search term "Automated Medication Dispensing System" and reviewed vendor catalogs for multi-drawer secure medication dispensing cabinets with ability to interface with electronic medication order systems. Also, reviewed contractors listed under FCS Group 65-II (Medical Equipment and Supplies, A-92 (Medication and Supply Packaging and Dispensing Equipment). There are few options for a comprehensive inpatient and outpatient systems. A few could interface with Vista. At this time, it is deemed more cost effective to continue leasing the Pyxis MedStation equipment rather than purchase this equipment and paying for upgrades and replacement as we are assessing the impact of use of the machines in additional areas. The impact to Veteran care is deemed too great to introduce an entirely new system. A VIP query was performed using the term 'Medication Dispensing' and NAICS code 532490 to determine if there

were two or more qualified SDVOSB/VOSBs that could fulfill this requirement and none were found. CareFusion does not have any authorized SDVOSB/VOSB distributors for the items requested on this procurement as CareFusion does not provide leases through SDVOSB/VOSB firms. CareFusion's FSS contract expired June 30, 2017 and while they are attempting to renegotiate a new FSS contract, it is not in place at this time. Sole sourcing to CareFusion is in the best interest of the Government to continue the lease of these medication dispensing units.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None

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

CareFusion Solutions Inc
3750 Torrey View Court
San Diego CA 92130-2635

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:**

MVAHCS has utilized the Pyxis MedStation system over the last 15 years. Until the MVAHCS decides to completely revamp its medication dispensing system, there are no actions planned to remove barriers to competition. Due to the highly specialized and integrated nature of the Pyxis MedStation System a sole source contract is required to continue uninterrupted service and care to Veterans.

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.

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.

- b. One Level Above the Contracting Officer (Required over \$150K but not exceeding \$700K): I certify the justification meets requirements for other than full and open competition.

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- 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 belief and recommend approval (if over \$68 million) or approve (\$700K to \$68 million) for other than full and open competition.

Date

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