

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA69D-17-AP-6413

1. **Contracting Activity:** Department of Veterans Affairs, VISN 12, William Middleton VA Medical Center, Great Lakes Acquisition Center, Request Number 607-17-4-969-0328.

2. **Nature and/or Description of the Action Being Processed:**
This action is a Brand Name Only Justification and Approval. An unrestricted solicitation will be posted to fbo.gov for Brand Name Only CareFusion equipment and installation services which will result in a new Firm Fixed Price contract. This procurement is 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:**
The supplies required to meet the agency's needs are a pharmacy dispensing system (carousel, packager, dispensing cabinets, and analytic software) used to assist in the timely delivery of medications from initiation of order from provider to delivery to patient. This purchase and subsequent installation of dispensing system cabinets will mainly replace existing outdated cabinets and will be installed at Madison, WI VA Medical Center locations. The estimated award date is 6/1/2018 with an estimated delivery date of 03/01/2019. The estimated value of the acquisition is \$1,973,403.

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

FAR 13.5 Simplified Procedures for Certain Commercial Items. The authority for applying Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented 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 following is a description of the essential features of the equipment, software, and system as a whole that are required to meet the minimum need of the VA. In 2012 the Madison, WI VAMC purchased approximately 700 Becton, Dickinson and Company (BD) Alaris smart pumps with a total value at the time of approximately \$1.2M. The VA requires the ability to integrate real time data from these existing and currently in-use (BD) IV Alaris smart pumps into one centralized workflow dashboard that incorporates real time automated dispensing cabinet data as well as IV workflow data. The system shall provide inpatient medical/surgical floors with two full cabinet dispensing stations that support a decentralized drug distribution model with a total width no greater than 80" and 28" depth and that also allows for a half-height refrigerator at each dispensing station within that space (to allow for identical/mirrored dispensing stations) due to space limitations of the existing areas. The VA requires the ability to change and/or rearrange the size of lidded pockets within a drawer. Lidded storage is required over non-lidded for security and inventory management purposes. It is necessary that the provider of the equipment has successfully completed VA

Pharmacy Automated Dispensing Equipment (PADE) interface testing. The VA requires the ability to stock controlled substances from the packager directly into the unit dose dispensing module of an automated dispensing cabinet thereby eliminating the need for extra counting of controlled substances which can lead to inefficient workflow and increased risk for controlled substance discrepancies. The VA requires the ability to queue medications needed from nursing medication queuing software including the ability to directly send notification to central pharmacy for medications that are not in the automated dispensing cabinet. In addition, the VA requires the ability to transport a locked pocket, and the ability to pour medications into a bin that subsequently unit dose packages the medication when a canister is not available. Only the required CareFusion equipment can fully meet the minimum needs of the VA.

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

A Sources Sought notice (VA69D-17-N-1546) was posted to fbo.gov. The notice included the main types of equipment the VA requires for this dispensing system which include medication packaging system for the central pharmacy, central pharmacy and carousel, automated dispensing cabinets, printers for dispensing cabinets that can print patient specific medication at the cabinet, and analytic software and integration. Also listed in the notice were the salient features that are required to meet the minimum need of the VA (see Section 5).

Arxium responded to the Sources Sought notice but it was determined they cannot fully meet the need of the Government. CareFusion and Four Points also responded to the Sources Sought notice. CareFusion is the manufacturer of the suggested equipment and is known to be capable of meeting the minimum need of the Government and, as CareFusion had stated earlier in the Market Research process, Four Points is authorized as a distributor of their equipment/software.

It has been determined that because there are multiple providers of the only known equipment and software (CareFusion and authorized distributors) capable of meeting the need of the Government, it is in the best interest of the Government to post an Unrestricted Brand Name Only solicitation to fbo.gov.

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

Market research indicates the anticipated pricing for med-stations, which constitutes the majority of the anticipated award amount, is comparable with the pricing of similar equipment offered on established FSS contracts. FAR Part 8.404(d) states that GSA has already determined the prices of supplies under schedule contract to be fair and reasonable. Because of this it is reasonable to determine that since the anticipated open market pricing is comparable to established FSS pricing, the open market pricing will also be able to be determined fair and reasonable. Furthermore, there are multiple known providers of the same equipment (manufacturer and authorized distributors) and a Brand Name Only solicitation will be issued to maximize the competition amongst these sources.

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

The NAICS is 339112. The FSC is 6515. The size standard is 1,000 employees. The manufacturer of the required equipment is CareFusion (BD) and they are a large business. CareFusion has stated they have two VIP verified SDVOSBs authorized as distributors (Four Points and Microtechnologies).

Facility technical expert and end user market research has revealed that the main providers of this type of equipment and software integration, in addition to CareFusion, is Omnicell and Arxium – both large businesses.

The Madison, WI VAMC Pharmacy and Nursing staff conducted extensive market research over the course of the past three years. This market research included contacting manufacturers to review equipment information, as well as including multiple vendors (including Omnicell, Carefusion, and Arxium) at product meetings and demonstrations. The following is a list of dates and a description of the major events and efforts of the market research conducted by the facility technical experts and end users:

- February 25th, 2014: MedSelect/Amerisource Bergen, Pyxis/Carefusion, Omnicell each given one hour presentation during all day meeting kick off to Automated Drug Distribution (ADD) committee.
- March 5th, 2014: Start of weekly 1 hour meetings for ADD committee.
- May 7th - 9th, 2014: Site visit at Jesse Brown VAMC (Med Pass/ICU/med surg units) and Hines VA to evaluate Pyxis/Omnicell installed at those VA.
- May 20th, 2014: Omnicell 2-day site visit at Madison VA to assess and evaluate need.
- June 17th, 2014: MedSelect/Amerisource Bergen site visit.
- July 9th, 2014: All day ADD meeting - both Pyxis/Carefusion and Omnicell on site to present solution.
- July 30th & August 4th, 2014: Omnicell & Pyxis demos open to Nursing/Pharmacy staff.
- August 1st, 2014: VISN 12 capital equipment proposal submitted.
- July, 2015: Omnicell semi tour return visit opened to all Nursing.
- August, 2015: Pyxis/Carefusion- return visit/presentation to Nursing leadership/Pharmacy/ADD committee.
- September, 2015: Omnicell/Pyxis refreshed quotes.
- November, 2016: Updates by Omnicell.
- January, 2016: Updates by Carefusion, now under the auspices of BD which acquired Carefusion, including the Alaris IV Pumps.
- February, 2017: Possible funding available, notification to Committee Members.
- February, 2017: Revisit by Carefusion to outline new modifications and improvements to Pyxis system.
- April, 2017: Revisit by Omnicell.

In addition to the efforts listed above, there has been extensive research done over the past 3 years for this project involving the inpatient and procedural areas, clinics, CBOCS, and central pharmacy needs to fully automate drug distribution. This included research on market leading vendors using ASHP, VA, and private sector Pharmacy and Nursing information. VA information was obtained on how well vendors were functioning within Vista/CPRS IT infrastructure by soliciting information from other VA sites with leading vendors installed. Site visits to other VA hospitals (Jesse Brown and Hines). Multiple follow up phone calls and emails (including with multiple other VA facilities) were also completed to analyze the major vendors' ADD systems.

To supplement the above facility technical expert and end user market research a Sources Sought notice describing the minimum requirements needed to meet the need of the VA was posted to fbo.gov on 08/09/2017 and requested that responses be received by 10:00am CST on 08/16/2017. Arxium, Four Points, and CareFusion responded to the Sources Sought notice stating they could meet the need of the Government. Arxium, a large business, stated they could offer their own products. Four Points, a verified SDVOSB, stated they were an authorized distributor of the

CareFusion products (and CareFusion confirmed they were authorized to distribute). CareFusion, a large business, stated they could offer their own products. The CO conducted online searches of established FSS contracts (GSA Advantage and VA NAC FSS) and historical data via the Federal Procurement Data System (FPDS) using keywords “automated medication dispensing cabinet” and found similar equipment available from vendors including Arxium, Omnicell, and Parata Systems.

The VA has determined, based on the facility technical experts’ extensive market research and knowledge of the industry, that only the products from CareFusion can fully meet their minimum need. They have also stated via email, although Arxium stated in their response to the Sources Sought that they can meet the need of the Madison VAMC, Arxium in fact cannot meet the minimum need. Again, this is based on the facility technical experts’ knowledge of the industry and their extensive market research.

Based on the cumulative market research of the Contracting Officer, technical experts, and end users it has been determined that the Rule of Two cannot be met and only the equipment manufactured by CareFusion will fully meet the need of the Government. Since it appears multiple contractors can offer this equipment (manufacturer and authorized distributor(s)) an unrestricted Brand Name Only RFQ acquisition strategy is in the best interest of the Government.

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, Four Points, Omnicell, MedSelect, and Arxium.

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:

If subsequent acquisitions for automated medication dispensing cabinets and/or systems are required the VA will conduct market research at that time and proceed, as it applies to the FAR, VAAR, and any other pertinent regulations and/or policies, and in a manner that is determined to be in the best interest of the Government.

