DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)
"Brand Name Only"

Acquisition Plan Action ID 36C258-19-AP-0961

1. **Contracting Activity:** Department of Veterans Affairs, VISN 22, New Mexico Medical Center, Contracting Office NCO 22-Gilbert, 2237: 501-19-3-119-02142.

2. **Nature and/or Description of the Action Being Processed:** This procurement for Becton Dickinson Carefusion Alaris PC units, Pump modules, Syringe modules, EtCO2 modules, and server implementation to be awarded as a new contract is intended to be Brand Name Only for any vendor that can provide the brand name products requested. This will include the Point-of-care software for the PC Units, pump modules, syringe modules, EtCo2 modules, system manager license, server license, equipment check in services, remote professional services and implementation.
FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is a Brand Name Only for Becton Dickinson Carefusion Alaris PC units, pump modules, syringe modules, EtCo2 modules, and server implementation 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:**

Becton Dickinson Carefusion Alaris PC units, pump modules, syringe modules, EtCo2 modules, and server implementation must include the following:

8015- Alaris PC unit	QTY:250
8100- Alaris Pump module	QTY:400
8110-Alaris Syringe module	QTY:5
8300-Alaria EtCO2 module	QTY:20
Guardrails® Point-of-Care Software for Alaris PC units	QTY:1
Guardrails® Point-of-Care Software for Pump modules	QTY:2
Guardrails® Point-of-Care Software for Syringe modules	QTY:5
Guardrails® Point-of-Care Software for EtCO2 modules	QTY:14
Remote Professional Services	QTY:1
Equipment Check-in Services	QTY:1
Onsite Biomed Skills Lab (workshop)	QTY:1
Alaris® Systems Manager License (Perpetual)	QTY:1
Alaris® Systems Manager Implementation	QTY:1
Dell Server License (perpetual)	QTY:1
Dell Server Implementation	QTY:1

The latest version of the Alaris Guardrail must be approved on the VA Office of Information and Technology (OI&T) Technical Reference Model (TRM) portal and allow user access through the VA OI&T workstation computer. Functional with

Windows 10 workstation.

The Contractor must complete the VA 6550 Pre-Procurement Assessment form for each software type. The software must be upgraded with the noted functionalities.

All reports, data, documents, content, and plans created or otherwise generated from the software delivered hereunder must be the property of the VA.

CareFusion Alaris Guardrails Editor must have:
- Used for editing drug formulary/library
- Provide access controlled by usernames to limit access to approved pharmacy staff only to edit drug listings.
- Have the capability to pull current library and previous library into a table format or to be exported into a spreadsheet format.
- Allow for date and time stamp of the drug library to note when put into clinical use.
- Capability to provide wireless updates through the OI&T Wireless network. This push mustt be Federal Information Processing Standard (FIPS) 140-2 compliant in terms of encryption and security for the data transfer.

CareFusion Alaris Guardrails CQI Reporter must have:
- Provide report generation and quality improvement measurements.
- Allow for access control for nursing, pharmacy, and biomedical engineering staff for report generation.
- Capability to provide pre-generated reports that include: error codes, alarms activated, pump programming.
- Ability to produce self-generated reports with fields determined by department users
- Capability of running reports in table, graph, or chart format or have the capability to be exported in a data type to allow for table, graph, or chart generation.

CareFusion Alaris System Maintenance must have:
- To be used by biomedical engineering staff for maintenance of infusion pumps and devices.
- Must have configurable profiles for quick upload of technical information to the device.
- Must have step-by-step procedures and testing of devices and prompt staff for data values and information to complete the Preventative Maintenance (PM) report.
- Software must be able to connect to the device to interrogate for alarms, error logs, or other information related to PM.

The Contractor must provide an Implementation Plan and schedule and implementation meeting within two (2) weeks of order shipment. The Contractor must identify specific deployment tasks and milestones in the Implementation Plan.

The Contractor must provide and maintain an accurate, detailed Inventory List of the

Contractor installed equipment and software including serial numbers, Government provided Equipment Entry (EE) Tag Numbers, version release, and licenses.

The Contractor must perform all installation and configuration necessary to complete the requirements detailed in this PWS. The Contractor must also perform technical service checks to ensure the product is fully operational in accordance with the manufacturer's operating standards.

The system must have the following requirements and functionality:

The BD alaris system must be a modular infusion system for all infusions and monitoring. Must contain a Point of Care Unit, Pump Module, PCA Module, Syringe Module and EtCO2 Module. A system that would have only ONE connection to Cerner for bi-directional interoperability. This infusion system that requires only 1 wireless connection for all infusion modalities and EtCO2 on one platform. Must have one battery on the PCU.no batteries on any pumps or monitors.

The BD Alaris pump module provides a large infusion pump that continuously or intermittently delivers fluids, medications, blood, and blood poducts to patients. Must have the ability to attach up to (4) infusion modules to a single BD Alaris PC Unit. Has 4 channel capability for both LVP and Syringe pump infusions – with only 1 power cord per 4 channel system.

The BD Alaris PC Unit has a common user interface for IV administration by standardizing the pump module and syringe module to one platform. There is only 1 drug library/dataset necessary to generate and maintain that includes LVP, PCA, Syringe and EtCO2 Modules on one platform. Has only 1 CQI dataset for LVP, PCA, Syringe and EtCO2 Modules on one platform.

The BD Alaris Syringe module provides flow rates from 0.01 to 999mL/hr and instrument accuracy of +/-2% depending on the syringe variation. The module accepts syringe sizes from 1 to 60mL with automatically detecting the size. Unique pressure-sensing disc which helps shorten time to alarm, monitor in-line pressure and decrease inadvertent bolus occlusion release.

The EtCO2 module provides easy to use plug and play technology. Accuracy with small sampling size (50mL/min) that measures accurate EtCO2, respiratory rate, fractional inspired carbon dioxide, and no breath indication for all patients. Includes smart alarm for respiratory algorithm to reduce insignificant respiratory rate alarms. Custom profiles that add alarm limit flexibility. Can be used as a stand alone monitor. PCA Pause capability with EtCO2 to stop PCA infusion if patient's respiratory rate falls below VA ABQ's defined guidelines. Must have single source for monitoring ALL IV administrations with EtCO2.

<u>Anesthesia Mode – requirement for Anesthesia</u>
- Silence key presses and Alarms for "quiet" in the OR
- Device has time delay option if you chose to set-up multiple infusions before a case
- Access to all Guardrails Drugs in database, smart alarms will ask you to bypass guardrails once
- Your most common used drugs are brought to top of screen

BD Alaris Guardrails software drug error reduction system with 2 safety limits for intermittent infusions- total dose and duration. Supports a drug library with up to 10,000 entries with hard and soft limits on each infusion parameter. Must have retrospective reporting, providing executive overviews of key performance indicators, benchmarking and real-time reporting for all infusions to drive safety and reduce the cost of care.

Training Requirements must include system administrator training for the VA Biomedical Engineering Staff. Onsite pump controller user level training. Training shall be held as small group instruction and include, at a minimum, end user roles and responsibilities and instruction on how to safely operate the system. The Contractor shall deliver a compilation of the manufacturer recommended maintenance schedule(s) and operation manual(s) packaged in binders to the onsite point of contact upon completion of delivery.

The total acquisition will be for $1,355,687.37 for the equipment, software, server, license, training, and implementation. Equipment Delivery date will be 60 days after receipt of order.

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

(X) (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;

FAR13.5 Simplified Procedures for Certain Commercial Items: *The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by 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 Alaris software is compatible with the following devices currently in service at the
facility to include:

- Alaris 8015 PC units
- Alaris 8100 Pump modules
- Alaris 8110 Syringe modules
- Alaris 8300 EtCO2 modules

The NMVAHCS has an existing contract **V797D-30183 VA258-15-F-2832** Carefusion Optimization Services software for Guardrails with Optimization System. This contract has 2 remaining years for the Software management services for the infusion system.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**
Efforts are limited by the requirement to only use Alaris Equipment which is compatible with the Carefusion Optimization Services software. This limits the pool of vendors to authorized distributors of the Alaris equipment.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:**
Fair and Reasonable Pricing will be based on competition between authorized distributors for the BD Carfusion system

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

Market research is limited due to the sole source documentation along with our standardization initiative within the facility.
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9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:**

The NMVAHCS has an existing contract V797D-30183 VA258-15-F-2832 Carefusion Optimization Services software for Guardrails with Optimization System. This contract has 2 remaining years for the Software management services for the infusion system.

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

4 Points and Beacon Point

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**: *This is being contemplated as a Brand Name Only not a sole source to garner competition for those authorized distributors for the BD Carefusion Products*

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.

_Shaun Carabajal_____   _____09-05-2019_____
Shaun Carabajal   Date
Program Specialist-Equipment Integration
NMVAHCS

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.

    _____
    Tina Kennedy
    Contracting Officer

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

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Lori Faber
Division Chief
Facility

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