

JUSTIFICATION
FOR AN EXCEPTION TO FAIR OPPORTUNITY

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Technology Acquisition Center
23 Christopher Way
Eatontown, NJ 07724
2. Description of Action: The proposed action is to include specifications for limited competition for a firm-fixed-price delivery order to be issued under the National Aeronautics and Space Administration (NASA) Solutions for Enterprise-Wide Procurement (SEWP) V Government Wide Acquisition Contract (GWAC).
3. Description of the Supplies or Services: VA Veterans Health Administration Office of Informatics and Analytics, Bar Code Resource Office, has a requirement for renewal of VA's enterprise licenses and maintenance and support services for the following CareFusion Corporation (CareFusion) Pyxis® software products: Med Administration Verification VA (wMA), Pyxis® Nursing Data Collection (NDC) VA, and Pyxis® Transfusion Verification (TV). This software employs bar code scanning technology by expanding Bar Code Medication Administration (BCMA) functionality that allows clinicians to collect vital signs data with a handheld device and matches the blood product with the correct patient. In doing this, the products must mimic VA's workflows, utilize point-of-care technology, support the full breadth of requirements for clinical processes and documentation requirements required by VA, and be Federal Information Processing Standards (FIPS) compliant. This software enhances the quality of care, improves quality control, and decreases the number of adverse events due to patient misidentification. The enterprise license renewal includes maintenance such as software downloads, upgrades, bug-fixes, minor-release upgrades, and troubleshooting. This maintenance support from the OSD will ensure these items remain operational. The twenty sites to be covered are as follows: C.W. Bill Young VA Medical Center (VAMC) (Bay Pines, FL); Boise VAMC (Boise, ID); Sam Rayburn Memorial Veterans Center (Bonham, TX); VA Boston Healthcare System (Brockton, MA); Dallas VAMC (Dallas, TX); Danville VAMC (Danville, IL); Carl Vinson VAMC (Dublin, GA); Iowa City VAMC (Iowa City, IA); Kerrville VA Hospital (Kerrville, TX); Little Rock VAMC (North Little Rock, AR); VA Loma Linda Healthcare System (Loma Linda, CA); Marion VAMC (Marion, IN); Omaha VAMC (Omaha, NE); VA Pittsburgh Healthcare System (University Drive Campus) (Pittsburgh, PA); VA Pittsburgh Healthcare System (H. J. Heinz Campus) (Pittsburgh, PA); Audie L. Murphy Memorial VA Hospital (San Antonio, TX); VA Caribbean Healthcare System VA Hospital (San Juan, PR); Colmery-O'Neil VAMC (Topeka, KS); Washington DC VAMC (Washington, DC); and VA Boston healthcare System West Roxbury Campus (West Roxbury, MA). The period of performance is for a 6-month base period, with three 6-month option periods.
4. Statutory Authority: The statutory authority permitting an exception to fair opportunity is Section 41 U.S.C. 4106(c)(2) as implemented by the Federal Acquisition Regulation (FAR) 16.505(b)(2)(i)(B), entitled "Only one awardee is capable of providing

the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.”

5. Rationale Supporting Use of Authority Cited Above: Based on market research, as described in section 8 of this justification, it was determined that limited competition is viable among authorized resellers for CareFusion Pyxis® software licenses and maintenance support from the OSD. CareFusion TV software is currently in production testing, and the wMA and NDC applications are currently in production at 20 sites. The renewal of these licenses and maintenance will provide VA the ability to continue to use the aforementioned CareFusion Pyxis® products and receive the requisite software maintenance.

Specifically, CareFusion Pyxis® products are the only products that can satisfy VA's functional requirement to follow clinical workflows specific to VA and applications already in use by VA. CareFusion Pyxis® applications were specifically designed to mimic these workflows. For example, the wMA application is designed to mimic the exact workflow already used for VA's BCMA application, and the NDC application is designed to mimic the exact workflow of the VA's Vitals Graphical User Interface (GUI) 5.0 application. Additionally, only CareFusion Pyxis® applications use point-of-care technology, a VA functional requirement. This means that these applications use the VA's wireless network to allow clinical staff to positively identify patients at the bedside or chairside and subsequently match the patient to orders the clinician prepares. Also, no other product supports the full breadth of requirements for clinical processes and documentation requirements required by VA. For example, other applications are only used to document vital signs, blood product transfusion, or medication administration, but cannot perform all three together in one solution like the CareFusion Pyxis® products, which is a VA functional requirement. This will allow all features to work on the same device, rather than multiple devices. Finally, due to the sensitive nature of the healthcare information being transmitted, all information must be transmitted securely using encryption that meets FIPS 140-2. Only CareFusion Pyxis® applications meet the FIPS requirement.

Furthermore, the required software being maintained contains CareFusion Pyxis®'s proprietary code and any form of maintenance, such as bug fixes or enhancements, cannot be performed by any software developer other than CareFusion Pyxis®, or a vendor with the authorization from CareFusion Pyxis® to resell these services. Only CareFusion Pyxis® has access to this proprietary code, and therefore CareFusion, or an authorized reseller, are the only sources that can provide the required maintenance.

Should the Government procure any other maintenance from an OSD other than CareFusion, the Government would have to procure another software suite and applications to replace the CareFusion Pyxis® applications. As stated above, there is no other product that would satisfy all of the Government's requirements.

VA has invested multiple years in the development and support of the GUI, Electronic Digital Assistant (EDA) and Veterans Health Information Systems and Technology Architecture (VistA) interfaces specifically for the CareFusion Pyxis® products. Should

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another solution be procured, these interfaces would have to be completely re-developed and deployed, as there would be interoperability and compatibility issues. Furthermore, the CareFusion Pyxis® suite of applications provide the same functionality as the VA-developed applications, but are specifically designed to work on EDA devices running the Windows Mobile operating system. In addition to the applications themselves, information from the applications is passed through and in some cases stored (at least temporarily) on servers specifically configured to convert the data coming from the EDA's into a format that can be communicated to, and stored in, VA's VistA database. Since emerging, point-of-care technologies are focused on the Android and Apple IOS platforms as opposed to Windows Mobile operating system, all the EDAs currently in the field would also need to be replaced if a different solution were procured.

Failure to procure CareFusion maintenance as described above would result in the current version of software being outdated and unable to be updated or fixed through pushes/patches from CareFusion or an authorized reseller. As previously noted, the CareFusion Pyxis® applications mimic the workflow of VA-developed applications. When updates are made to VA-developed applications, CareFusion Pyxis® simultaneously produces updates to its applications to ensure the two applications retain synchronized functionality. Without these updates, the software becomes unreliable and may negatively impact patient safety due to differences in functionality between the vendor and VA-developed applications. For example, the upcoming software patch to BCMA contains new functions to support transdermal medication administration (including a reminder to remove the medication at a specific time). If CareFusion Pyxis® does not create a patch to the wMA product to mimic this functionality the nurse may not receive the warning in the wMA application resulting in an overdose.

Accordingly, the Government must procure the required licenses and maintenance and support services from CareFusion Pyxis® or its authorized resellers as described above.

6. Efforts to Obtain Competition: Market research was conducted, details of which are in section 8 of this justification. This effort did not yield any additional sources that can meet the Government's requirements. It was determined, however, that three authorized resellers on the NASA SEWP V GWAC provide the required software license renewals, which includes the requisite services including maintenance from the OSD. In accordance with FAR 5.301 and 16.505(b)(2)(ii)(D), this action will be synopsisized on the Federal Business Opportunities Page and this Justification will be made publicly available within 14 days of award.

7. Actions to Increase Competition: The Government will continue to conduct market research to ascertain if there are changes in the marketplace that would enable future actions to be competed.

8. Market Research: In February 2015, the Government technical experts conducted market research, reviewing software product offerings from Omnicell Nursing, Cardinal Health, McKesson, Hospira, and Cepheid. The Government technical experts

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determined that none of the above sources meet the Governments requirements as discussed in section 5. Therefore, only CareFusion software and maintenance from the OSD through an authorized reseller will satisfy the Governments requirements as discussed in section 5.

Further market research was conducted in April 2015 through use of the Quick Request for Information Tool on the NASA SEWP website, and it was determined that there are three Government resellers of the required CareFusion software license renewals and maintenance from the OSD which hold current NASA SEWP V contracts.

9. Other Facts: None.