

LIMITED-SOURCES JUSTIFICATION

**ORDER >\$3,000
FAR PART 8.405-6**

2237 Transaction # or Vista Equipment Transaction #: 600-13-1-9634-0004; 605-13-1-3950-0001; 605-13-1-3959-0001; 664-13-1-9072-0005; 691-13-1-2018-0001

Restricted to the following source:

Manufacturer/Contractor: Phillips Healthcare

Manufacturer/Contractor POC & phone number: Jeff Stayberg (714) 926-6087

Mfg/Contractor Address: 3000 Minuteman Road, Andover, MA 01810-1099

Dealer/Rep address/phone number: N/A

The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs VISN 22

Network Contracting Office 22

4811 Airport Plaza Drive Suite 600

Long Beach CA, 90815

VISN:

Desert Pacific Healthcare Network 22

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

This acquisition shall be conducted under the authority of the Multiple-Award Schedule Program under Federal Acquisition Regulation (Hereafter referenced as FAR) 8.401 and FAR 8.405-6(a)(1). Awarded Contractor shall provide and implement a current generation Vertical Patient Monitoring and Telemetry System for four Department of Veterans Affairs (Hereafter referenced as VA), Veterans Integrated Service Network (Hereafter referenced as VISN) 22 Healthcare Facilities. This action shall provide a Firm Fixed Price Blanket Purchase Agreement (Hereafter referenced as BPA) with a listing for replacement parts, additional monitors as needed (future clinics/departments/expansion), service/repair agreements and additional miscellaneous items as needed to ensure standardization for the VISN. The first delivery order against the awarded BPA shall be the initial implementation of the Vertical Patient Monitoring and Telemetry System across the four facilities.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

Acquisition of new physiologic monitoring medical equipment to reduce variation by upgrading or replacing current systems including acquisition of monitors to serve as Clinical Information System (Hereafter referenced as CIS)/ Anesthesia Record Keeping (Hereafter referenced as ARK)/ Computer Personal Records System (Hereafter referenced as CPRS) charting points for electronic medical records (Hereafter referenced as EMR), and upgrade of bedside, central, and telemetry monitoring system infrastructure in the following VISN 22 Medical Centers: Greater Los Angeles, CA; Long Beach, CA; San Diego, CA; Loma Linda, CA. The VA Southern Nevada facility shall also participate in this BPA for future requirements to maintain standardization. These new systems shall provide state-of-the-art physiological monitoring functions configured to VISN 22 requirements and VISN 22's unique computer information systems profile. The system shall provide integration to the CIS, the ARK, CPRS and other medical informatics systems ensuring work flow efficiency and improved patient safety. This system shall meet goals of VA directives to include standardization for Sterile Processing Department (Hereafter referenced as SPD) requirements, standardization of Information Technology (Hereafter referenced as IT) equipment, continuous real time charting capabilities for critical care areas, integrated PC functionality without the need of Citrix based solutions for critical care areas (due to space limitations), and a 1.4 GHz Wireless Medical Telemetry System (Hereafter referenced as WMTS) that shall also include continuous charting during Patient Transport procedures. The primary goal of this system is to further advance quality patient care and safety.

- (b) ESTIMATED DOLLAR VALUE: \$22,399,849.11 (Initial Delivery Order) \$27,392,907.61 (Total BPA)
(c) REQUIRED DELIVERY/INSTALLATION DATE: April 1, 2013 (Est. Award); 120 days from the date of award.

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

- FAR 8.405-6(a)(1)(i)(B) – Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized;

Philips Healthcare provides a Vertical Integrated Patient Monitoring System (Hereafter referenced as VIPMS) that shall meet all requirements of VISN 22 monitoring by allowing clinicians to remotely monitor patients in a real time setting, chart directly from the bedside, directly connect to the existing and future VISN information systems, comply with VA/VISN Standardization requirements, comply with VA SPD requirements, provide continuous transmission of data to patient EMRs through the use of a 1.4 GHZ WMTS (excluding low acuity vital signs monitors) utilizing Health Level 7 (Hereafter referenced as HL7) frameworks and substantially increase patient safety and care with a limited system footprint. The VISN is currently implementing the Philips CIS IntelliSpace Critical Care and Anesthesia (Only the Critical Care portion of this system has been purchased at this time, the anesthesia portion shall be procured at a later date) system formerly known as the Intellivue Clinical Information Portfolio. The CIS allows the direct charting of patient information into VISN information systems and EMR, eliminating traditional paper based charting. The CIS requires the use of computer based terminals to input information into the system and also directly records information from patient monitoring systems on a real time basis from both wired and wireless physiological monitoring devices. The VIPMS provides transmission of data on a continuous basis to ensure accurate patient data and meets CIS requirements to maintain a complete EMR. In addition, the VIPMS utilizes Integrated Personal Computers (Hereafter referenced as IPC) within their patient monitors to allow charting of patient EMRs at the primary source of origination. In addition, the VA Southern Nevada Healthcare Facility located in Las Vegas, Nevada has already procured and implemented the latest generation Philips Patient Monitoring Solution in June of 2011 – June of 2012 under competitive negotiations through Full and Open Market Competition (Contractors within FSS schedules were not available at the time). This VIPMS also includes unique Central Stations, non-critical-care Vital Signs Monitors and Transport Monitors which all relay information directly to the facility CIS all of which advance significant, unique patient safety and care requirements.

Philips Healthcare provides a unique and highly specialized IPC monitor system. The use of this IPC eliminates the need of a secondary computer terminal/workstation to transmit/modify data in a patient's EMR. All other contractors can only provide a secondary terminal/workstation. Secondary computer terminals/workstations require either extensive networked individual computers or a more streamlined Citrix server based solution utilizing thin clients. Both workstation based solutions from other vendors require significant space (space for a workstation by each patient monitor), infrastructure modifications to provide network access and additional layers of data interface requirements. Several facilities within the VISN are constrained by limitations of space due to significant increases in patient populations, lack of additional facilities and inability to easily modify existing structures due to age and building code requirements. Space requirements are also affected by Underwriters Laboratories Section 544 (Industry Safety Standard for Medical Devices) which requires that electrical medical devices be shielded from electrocution risks when present within fifteen feet of a patient. A secondary computer terminal/workstation will require significant additional costs to meet this safety requirement whereas the Philips IPC monitor already meets this requirement. It is highly likely that certain areas of the facilities will not be able to accommodate other contractor solutions. No other contractor within the

Patient Monitoring marketplace can provide an integrated PC that meets the standards of this paragraph or provide such minimally invasive installation concerning space limitations and meet CIS operation requirements.

The patient monitors shall send vital patient information directly to the CIS as HL7 data as charted information and eventually store this data in the patient's EMR. The Phillips solution interfaces directly with the CIS database in order to provide this information instead of introducing redundant integration points such as additional servers required by the procurement of another contractor's system. All other contractors require additional hardware/software to convert data into HL7 and CIS/EMR compatible data. Other contractor systems increase the risk of system failure due to the introduction of numerous third party equipment and software requirements, whereas the Phillips solution allows a seamless interface between the CIS, EMR and the critical care patient monitoring system; and allows easier mitigation of problems of incompatible equipment/software common to mixed third party equipment/software systems associated with highly specialized medical equipment acquisitions. Direct interface of data to the CIS will increase the likelihood that all data is appropriately captured by the CIS and EMR resulting in accurate patient care. Loss of data during transmission may lead to mistakes that may cause significant harm or bodily damage to patients, such as the loss of a patient's allergies record due to incompatibility between a third party contractor and the CIS.

The Phillips solution provides clinical staff with remote access accounts which can view patient vitals overviews from any patient care department or office. This allows an overview of the patient's real time waveform data as if the clinician were viewing the waveform directly from central station saving crucial time in the critical care environment. In addition to viewing the waveform data in real time remotely, this type of data can be captured directly into the Phillips CIS via HL7 without delay unlike all other vendors in the market. Also unlike other vendors in the market, Phillips provides a system which will allow clinical staff to annotate and database waveform data without the use of any third party solution. Annotation and data basing of waveforms significantly increases clinical capability to track, monitor and increase care for patients through custom notations as applicable to individual patients. The only commercial off the shelf third party solution known to exist in the marketplace with this capability is provided by Excel Medical. However, this Excel system will require an additional separate workstation, server system, additional training and potentially significant IT related incompatibility issues. Excel Medical can only provide Electrocardiography (Hereafter referenced as ECG) waveforms at this time, whereas the Phillips solution will include ECG and Blood Pressure waveforms with customizable alarms to enhance patient safety. Acquisition of another contractor would require the additional procurement of not only the Excel Medical system, but equipment to run this software further affecting the already limited space requirements of the VISN and only provides half of the Phillips waveform functionality. Phillips solution allows customers to purchase additional licenses for the central station monitors which allow the support staff to reload software onto another computer that meets the operating requirements to support the software without the need to procure additional third party backup equipment. As opposed to other solutions which are proprietary, additional backup equipment is required and in-house support staff must rely on the original equipment manufacturer/third party contractor to provide all repair service to this type of equipment. The introduction of additional third party contractors typically leads to additional administrative burden, incompatibility issues, and situations where a current contractor and third party contractor blame each other for failure of the device and attempt to shift blame from one party to the other.

Phillips Healthcare already provides 1.4 GHz WMTS networks for the bedside, central monitors and database servers at three VISN 22 sites at Las Vegas, San Diego and Loma Linda. This project includes upgrades to VISN 22's existing Phillips Healthcare infrastructure and current monitoring system to bring the technology up to date at two sites that have this infrastructure in place (Loma Linda and San Diego). In order to achieve the ongoing VA goal to reduce variation, all VISN 22 sites shall implement the same devices and infrastructure. Phillips is the only vendor that provides a complete 1.4 GHz WMTS that can be utilized by both Patient Telemetry and Patient Transport. All other vendors utilize 802.11 frequency solutions either in Telemetry or Transport or both. 802.11 solutions are less secure, subject to controversy according to surveys of medical professionals across the country and subject to potential interference due to the number of devices on that frequency. The 1.4 GHz bandwidth is almost exclusively dedicated to the use of Medical Devices and provides far stronger security

measures than other bandwidths. A few contractors are capable of providing a system that will utilize a 608-614 MHz frequency bandwidth, however this bandwidth is subject to wide speculation across the industry to reallocation by the Federal Communications Commission (Hereafter referenced as FCC) due to requirements set forth in "The Middle Class Tax Relief and Job Creation Act of 2012". Clinical/IT staff across the VISN anticipates the removal of Medical Devices from this bandwidth due to FCC actions. The 1.4 GHz band is ideal for this VISN's future, security and reliability. Only Phillips is the only that provides a complete 1.4 GHz WMTS network that is utilized by both Telemetry and Patient Transport in the current industry.

The Phillips WMTS infrastructure supports Patient Telemetry, Patient Transport, connection to Patient Monitors and connection to the Central Station which will act as the gateway to the CIS and patient EMR. Patient Telemetry involves the use of small devices that can be worn around a patient's neck in a mobile environment within the confines of the WMTS network. The Phillips WMTS network utilizes frequency hopping which will establish multiple connections within the network simultaneously as a patient moves from one area to the next under different wireless access points and does not release connections until fully connected to the next access point. Frequency hopping significantly decreases the chance of loss in data transmission. Most other vendors utilize non frequency hopping systems which sever connection from one access point and jumps to the next access point during patient movement. One other vendor can provide frequency hopping capabilities, but only under the 608 MHz. If any interference occurs during the jump, loss of data transmission will occur and connection to the CIS will be broken until reinstated by medical personnel. The CIS can only chart with real time data, otherwise manual entry of data will be required which shall lead to the introduction of human error during manual entry, ultimately defeating the purpose of the CIS and EMR project. The Phillips Telemetry pack and WMTS doubles as a two way/bidirectional frequency system which allows the telemetry pack to communicate with the Central Monitoring Station. The two way/bidirectional nature of the system allows real time location of patients and will help prevent patient wandering out of confined areas through the use of automated system alarms and tracking features. This significant safety feature is unique to the Phillips system, and all other vendors in the industry are unable to provide a comparable solution under the 1.4 GHz frequency.

The 1.4 GHz WMTS also supports the Patient Transport System. Patients transported by clinical staff will continually transmit data to the CIS without any break in connection thus preserving the real time data transmission requirement of the CIS. During transport, the patient is placed on a transport bed/system; a wireless transport module connected to the bedside monitor is detached and reattached to the patient transport bed/system without disconnection of any patient cables. During transport to another section of the hospital such as the OR, the transport module will continually transmit data to the CIS without interruption. In the past, there have been cases of patient emergencies such as cardiac arrests in transport which led to significant medical attention and care provided within a hallway. That specific care was not automatically recorded due to the lack of a data transmission solution, which introduces the possibility of significant human error in data input immediately following an intense situation. All other vendors cannot maintain continuous data transmission wirelessly during transport. One other contractor can provide a module that will transport with the patient, however it is not wireless. Another contractor is able to provide a separate instrument that is wireless, but only on the 802.11 band and connection is broken when the patient enters transport as all patient cables must be swapped to the new transport monitor. Only Phillips can provide continuous transmission of data to the CIS and EMR within the industry to meet the real time requirements of the CIS.

The Central Station acts as the primary point of transmission of data to the CIS connected to all other monitors either through the WMTS or wired local area network. The Phillips Central Station is capable of displaying thirty-two (32) patient vitals on one screen while all other vendors can only display up to a maximum of sixteen (16) patient vitals on a single screen regardless of size. In addition, the Phillips solution is able to display patient locations across both Telemetry and Transport networks under the 1.4 GHz WMTS unlike all other vendors in the industry within the FSS.

Low acuity Vital Signs monitors provide physiological monitoring on a spot check basis and transmit data to a patient's EMR utilizing a hospital's existing 802.11 wireless network unlike the critical care area Patient

Monitors. Low acuity monitors typically track limited values such as Non Invasive Blood Pressure (Hereafter referenced as NIBP), Oxygen Saturation (Hereafter referenced as SpO2), temperature, and other limited physiological parameters. Phillips monitors possess several unique qualities in the marketplace such as embedded HL7 Interfaces and critical care compatible patient cables for NIBP and SpO2 (Other vendors do provide this capability, however only fully vertical system providers such as GE and Nihon have this option). Embedded HL7 Interfaces eliminate the need of additional hardware/software to convert patient data into the HL7 format for transmission to the CPRS and a patient's EMR. If data is not properly converted to the HL7 format, the data will be rejected by these computer systems resulting in inaccurate patient records. All other contractors in the marketplace provide a separate HL7 interface which will indirectly transmit the data to the CPRS and a patient's EMR. The addition of more hardware/software will result in additional costs of maintenance/service including manpower requirements and will be subject to additional risk of failure.

All Patient Monitoring Systems include numerous parts that are considered Reusable Medical Equipment (Hereafter referenced as RME), primarily the cables that will connect to the patient to transmit data. All reusable medical equipment must undergo proper sterilization after each use and before connection to a new patient. Failure to properly sterilize cables significantly increase risk of infection. Risks include the transmission of diseases such as Staphylococcus (Staph Infections) which may lead to death or serious bodily injury for VISN patients. In response to previous outbreaks of diseases, such as the HIV outbreaks in VA facilities located in Florida, Tennessee, and Georgia due to improper cleaning of medical scopes which are considered RME; the VA issued directives concerning the proper usage, standardization and cleaning of RME. The HIV outbreaks occurred due to the usage of VA owned medical scopes manufactured by several different companies. The presence of numerous contractor products led to numerous cleaning procedures which in turn led to human error and significant harm to our veteran patients. VA released VHA Directive 2009-004 and VHA Directive 2009-031, which both require standardization of equipment at the facility level but also ensure standardization (to the maximum extent practicable) across all facilities within a VISN per Directive 2009-031 under the VISN Director and the SPD Management Board responsibilities. RME considerations concerning vital signs monitors are significantly reduced by reduction of equipment produced by multiple manufacturers. Patient cables for NIBP and SpO2 are used across both Phillips platforms and are the exact same cables. These cables will require the exact same cleaning procedures which will lead to a significant reduction in error concerning the proper sterilization of this equipment which further promotes the VA directive goals of reducing the transmission of disease in the hospital environment. In addition, standardization of equipment across all facilities within a VISN shall promote a single VISN protocol regarding, infection control parameters, training, documentation, quality management and standard operating procedures under a one VISN standard connected to the CIS. If a patient visits another hospital, they will receive the same standard of care. If an employee transfers to another hospital within the VISN, that employee will be fully trained and ready to use the equipment within that hospital whether in a low or high acuity area. This will lead to significant reductions in error across the VISN and within each facility promoting safer and more effective patient care. In addition, the use of a single VISN protocol also promotes significant efficiency and cost savings allowing the VISN to focus on other areas of Patient Care instead of undue administrative burden.

Phillips Healthcare is the only source within the Federal Supply Schedule that can provide equipment that will seamlessly integrate with our current unique computer system profile, provide a full 1.4GHz WMTS network for both Patient Telemetry and Patient Transport, meet limited space requirements without costly infrastructure modifications, significantly reduce information technology conflicts due to the introduction of multiple third party equipment items, provide numerous patient safety features and standardize equipment, protocols, standard operating procedures and infection control under a one VISN standard. The unique and highly specialized nature of the Phillips system is the only solution that provides a complete vertical platform within the Federal Market and meets all of the VISN's minimum requirements and significantly promotes patient safety and effective care. Thus award should be made to Phillips Healthcare for their highly specialized and unique system which is the only solution that can provide the level of quality required to meet the needs of VISN 22.

(5) DETERMINATION BY THE ORDERING ACTIVITY CONTRACTING OFFICER THAT THE ORDER REPRESENTS THE BEST VALUE:

Per FAR 8.404(d), GSA has already determined the prices of supplies and fixed-price services, and rates for services offered at hourly rates under schedule contracts to be fair and reasonable. However the Government shall seek additional discounts before entering into a delivery order/BPA with the contractor. In addition, when compared to other comparable equipment, this contractor offers very competitive pricing. Estimates for equipment for GE and Nihon Kohden range from \$15-\$24 million dollars based upon past procurements, Federal Procurement Data System Next Generation award information. However, additional installation and infrastructure changes to our facilities will be necessary to accommodate their equipment and is currently estimated in the range of several million more dollars to complete implementation. These costs include the procurement of Citrix based solutions which in past procurements have ranged from \$100,000.00 - \$200,000.00 within this VISN dependent upon the size of the facility for initial equipment and installation. In addition, there will be extra costs related to the procurement of servers, computer workstations, network expansion and other items to implement the system with the current CIS. Finally, there is a large administrative burden to implementing systems other than the Philips system due to third party conflicts experienced across the VA. Third party conflicts are considered significantly expensive but difficult to estimate due to the volatility of individual facility experiences. A single lawsuit or dispute may disrupt installation, halt patient care, or eliminate features of other third party products such as the failure of the VA Flight System which attempted to integrate numerous third party systems and ultimately failed at an exorbitant cost.

(6) DESCRIPTION OF THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

Market research has been conducted to identify current FSS contract holders with the ability to meet the Government's requirements; Market research has also been conducted to identify specific factors of this type of procurement utilizing the internet and phone conversations with FSS contractors and technical experts. In addition, both the Technical Team and Contracting Officer have researched comparable items extensively within the industry to find acceptable solutions.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

None.

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:

Alternate sources have been given consideration. This procurement involves the implementation of the later generation technology in Patient Monitoring which has an anticipated lifecycle of five plus years. Future requirements for this service cannot be accurately predicated at this time. In addition, this procurement shall be in the form of a Blanket Purchase Agreement, should a future contractor pose better pricing, exceptional technology and compelling reasons to upgrade technology, the Government may always opt out the proposed BPA and create a new competition with contractors to fulfill a future need.

(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. (This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)

Pamela Christian

SIGNATURE

2-1-13

DATE

Pamela Christian

NAME

Biomedical Engineer

TITLE

Deputy Network Director

SERVICE LINE/SECTION

VISN 22

FACILITY

(10) APPROVALS IN ACCORDANCE WITH FAR 8.405-6(d):

a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

[Signature]

SIGNATURE

2-1-13

DATE

Deeptichandra Chakka

Contracting Officer

Network Contracting Office 22

FACILITY

c. NCM/PCM/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

[Signature]

SIGNATURE

2-1-2013

DATE

Kevin Blanchard

VISN 22-NCM/PCM

HIGHER LEVEL APPROVAL (Required For orders over \$500,000):

e. SAO: I certify the justification meets requirements for restricting consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

[Signature]

SIGNATURE

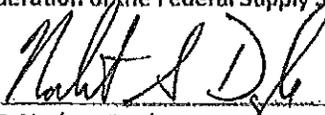
2-1-2013

DATE

Della Adams

DIRECTOR, SAO West

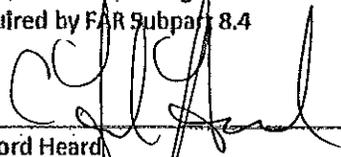
f. VHA HCA REVIEW AND APPROVAL (over \$500,000 to \$10 million): I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4



NAME: Norbert Doyle
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

DATE 3/21/13

g. VA Deputy Senior Procurement Executive Approval (\$10 million not to exceed \$50 million): I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4



C. Ford Heard
Deputy Senior Procurement Executive (DSPE)

DATE 4/2/13