

**Department of Veterans Affairs  
Justification and Approval  
For  
Other than Full and Open Competition**

This document constitutes justification and approval for other than full and open competition for the acquisition described herein, under the authority of FAR 6.302-1 "Only one responsible source and no other supplies or services will satisfy agency requirements." It is executed on behalf of the Department of Veterans Affairs, Veterans Health Administration, Service Area Office Central Region (SAOC), and Veterans Integrated Service Network (VISN) 12, to include the following stations: Chicago VAMC, FHCC VAMC, Hines VAMC, Madison VAMC and Milwaukee VAMC.

**1. Nature and/or description of the action being provided.**

This sole-source procurement is needed to provide VISN 12 a short-term solution to continue the supply of Custom Surgical Procedure Packs. This short-term solution is necessary to ensure availability and consistency of custom surgical procedure packs until such time as a regional long term contract is awarded. The proposed contracting action is for a firm fixed price IDIQ contract for six months to begin May 1, 2015 through November 30, 2015 with one (6) six month option period. The estimated value of the contract including the option period is estimated at \$2,494,055.00.

The intent of the proposed sole source contract is only to bridge the gap until a fully competitive long term contract can be put into place. The SAOC Central Region Custom Sterile Procedure Pack procurement is in the development and review process. Conversion to a regional custom sterile procedure pack contractor will require the new contractor to become intimately familiar with the requirements histories of supported VHA healthcare facilities in VISN 9, 10, 11, 12, 15, 16 and 23. The contractor will be required to become familiar with VA systems necessary to transmit and receive supply chain data, modify or create systems to meet these requirements, ordering initial stocks from VHA specified sources, positioning these stocks and developing a distribution system to meet VHA responsiveness requirement. In addition, VA personnel will need to be educated on the new custom sterile procedure pack contractor's processes and systems, and VA files annotated with appropriate changes. At a minimum these actions would require a creation of a complex implementation plan that would take 90 days or more to accomplish.

Award of this sole-source contract will provide continuous delivery of custom sterile procedure packs to VHA facilities, ensuring that quality direct patient care is provide to our Veterans.

A bridge contract must be in place that is capable of providing current supplies. Direct patient care would be jeopardized if the capability provided via the VISN 12 Custom Sterile Procedure Pack contractor were interrupted as VISN 12's supply chain would be unable to provide timely delivery of medical and surgical supplies.

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### **2. Description of the supplies/services required to meet the Agency's needs.**

Provide for a Custom Sterile Procedure Pack production and delivery of individualized custom procedure packs to be utilized by each of the requiring medical centers in VISN 12. The Custom Sterile Procedure Packs will include but not limited to; pack assembly/manufacture, sterilization, quality assurance, and packaging, contractor electronic communication ordering reporting, and delivery. Specific custom procedure packs to include list of component and configuration for each requested pack and estimated quantities for each medical center will be listed in the Schedule of Items. All aspects of pack assembly, packaging and sterilization must adhere to the quality control standards set by the FDA.

### **3. Identification of the statutory authority permitting other than full and open competition.**

The statutory authority permitting other than full and open competition is 41 U.S.C. 253 (c) (1) and FAR 6.302-1, which authorizes, under certain conditions, contracting without providing for full and open competition when the agency's need for the supplies or services can be provided from only one responsible source and no other supplies or services will satisfy agency requirements.

### **4. Demonstration that the proposed contractor's unique qualifications or the nature of the acquisition requires use of the authority cited.**

Custom Sterile Surgical Packs are critical to patient care and VHA medical centers and/or related facilities cannot operate without them. Cardinal Health is the only vendor with the resources capable of providing seamless, uninterrupted service that can meet the government's system-wide requirements, principally to ensure uninterrupted Custom Sterile Surgical packs without compromising direct patient care.

The tasks aforementioned not only require time and money but also a fair number of skilled personnel to set up accounts, train customers, forecast inventory, order and receive inventory and adjust delivery schedules. Historically these actions have taken an estimated 6-8 weeks implementation period. The lead time to award this contract is insufficient to allow a new vendor several months to build and distribute packs. The probability is very low that a new vendor would be able to successfully build these processes and relationships by May 1, 2015, and the likelihood of tremendous disruption and confusion in the field because they failed would be great.

Additionally, the startup cost for a new contractor to implement a new system to support VISN 12's needs is significant and they would be unlikely to do so with no guarantee of a long term business commitment. Furthermore, setting up a short term contract with anyone other than current Vendors would result in changing contractors twice. Engaging in these complex transaction activities in a relatively short period of time is not cost effective to VA or any potential offeror. This requires a cash investment, warehouse space and additional personnel. It

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would be challenging for a new vendor to make this financial commitment for a contract projected to last six months and no more than twelve months.

For the expressed reasons herein, the government's needs are best served by a short term sole-source contract with Cardinal Health to support Custom Sterile Surgical Packs. Cardinal Health is the only contractor capable of fulfilling the Government's short-term requirements without unacceptable disruption to operations and significant potential risks to patient care and patient safety. This contract will ensure continuous delivery of packs to participating medical facilities.

**5. Description of the efforts made to ensure that offers are solicited from as many potential sources as is practicable, including whether a notice was or will be publicized as required by Subpart 5.2 and, if not, which exception under 5.202 applies.**

In accordance with FAR Part 6, the contracting officer will post the approved Sole Source Justification and summary of the Custom Sterile Surgical Packs contract at Federal Business Opportunities ([www.fbo.gov](http://www.fbo.gov)) for informational purposes only. The contracting officer has determined that competitive short term procurement is impractical and not in the best interest of the Government.

**6. A determination by the contracting officer that the anticipated cost to the Government will be fair and reasonable.**

The Independent Government Estimates for this procurement is based on the historical data on usage during the previous year available and the information provided as part of the procurement package submitted to support the regional contract. In addition, it is noted that these products are available in the commercial market place which will serve as a basis for determining fair and reasonable pricing. The VA expects to award a fair and reasonable contract identical to, or closely based on, the current sole source contract on the resultant short-term Custom Sterile Surgical Pack contract.

**7. A description of the market research conducted, the results or a statement of the reason market research was not conducted.**

The Contracting Officer did market research in preparation for the regional procurement. VHA is familiar with the current competitive market. No other sources can satisfactorily meet the requirements of the Custom Sterile Surgical Packs contract in such a short period of time. This contract will commence performance on May 1, 2015. The compelling need to have a consistent, stable Custom Sterile Surgical Pack contract while the challenging and complex process of completing and operationalizing the next generation Custom Sterile Surgical Pack contract is completed dictates the need for continuation of services from the current vendors and drives the need for this sole source justification.

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8. List of sources, if any that expressed interest in the acquisition.

Not applicable for the reasons stated herein in this document.

9. Statement of actions the agency may take to remove or overcome any barriers to competition before any subsequent acquisition for the supplies or services required.

The period of performance will not exceed the time necessary for the agency to enter into another contract for the required goods through the use of competitive procedures. Acquisition for the long term regional contract will be based on full and open competition.

**TECHNICAL AND REQUIREMENTS CERTIFICATION**

I certify that the facts and representations under my cognizance which are included in this justification and, which form a basis for this justification are complete and accurate.

**Robby A. Schopen 240610**

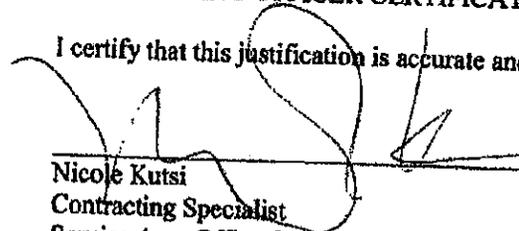
Digitally signed by Robby A. Schopen 240610  
DN: cn=Robby A. Schopen, o=USDA, ou=USDA, email=R.Schopen@aphis.usda.gov, c=US  
Reason: I signed in good faith because of the Government.  
Date: 2015.02.19 10:16:00 -0500

Robby Schopen  
VISN 12  
Chief Logistics Officer

Date

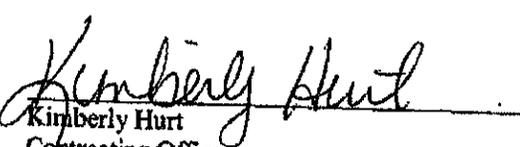
**CONTRACTING OFFICER CERTIFICATION**

I certify that this justification is accurate and complete to the best of my knowledge and belief.

  
\_\_\_\_\_  
Nicole Kutsi  
Contracting Specialist  
Service Area Office Central Region (SAOC)

2/19/2015  
Date

**CONCUR:**

  
\_\_\_\_\_  
Kimberly Hurt  
Contracting Officer

2/19/15  
Date

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Service Area Office Central Region (SAOC)

**NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition:

christine a hansen 417240

Digitally signed by christine a hansen 417240  
DN: cn=christine a hansen, o=VHA, ou=SAOC, email=christine.a.hansen@va.gov, c=US  
Reason: I agree to the signed service of this document.  
Date: 2015.03.11 15:41:06 -0500

Christine Hansen  
VISN 12  
Director of Contracting  
Great Lakes Acquisition Center

Date

**SAO (If over \$500K):** I certify the justification meets requirements for other than full and open competition:

  
Rick Lemmon  
Director  
Service Area Office, Central Region

Date

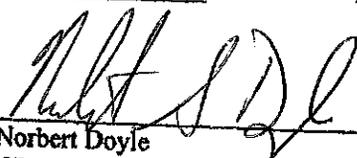
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**VHA HCA Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$10 million) or approve (\$500K to \$10 million) for other than full and open competition.

Approved

Disapproved:

Amount: \$3.8M

  
Mr. Norbert Doyle  
Chief Procurement and Logistics Officer  
VHA Head of Contracting Activity (HCA)

Date

3/16/15

VISN	BASE YEAR EST.	MONTHLY	BASE EST.	TOTAL	PERIOD 1 EST	
					MONTHLY	OPTION PERIOD 1
					TOTAL	EST TOTAL
12	\$	207,837.96	\$	1,247,027.78	\$ 207,837.96	\$ 1,247,027.78
<b>VISN TOTAL:</b>	<b>\$</b>	<b>207,837.96</b>	<b>\$</b>	<b>1,247,027.78</b>	<b>\$ 207,837.96</b>	<b>\$ 1,247,027.78</b>
<b>TOTAL ESTIMATE</b>				<b>\$</b>	<b>2,494,055.56</b>	

<b>POC NAME: Robby Schopen</b>	<b>Phone: 414-844-4831</b>
<b>Email: roby.schopen2@va.gov</b>	<b>Date: 2/18/2015</b>