

VA Internal Use Only

LIMITED SOURCE JUSTIFICATION Medical Surgical Prime Vendor – Next Generation (MSPV) Blanket Purchase Agreements (BPA) for Medical Supplies

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Strategic Acquisition Center
10300 Spotsylvania Avenue, Suite 400
Fredericksburg, VA 22408
2. Description of Action: The proposed action is for medical supplies, under the authority of Federal Acquisition Regulation (FAR) 8.405-6, "Limited Sources." The required items are supplied by Mimedx Group, Inc., Small Business, located at 1775 WEST OAK COMMONS COURT, NE, MARIETTA, GA 30062. These items will be procured via VA-Federal Supply (VA-FSS) Schedule V797D-40303 to populate the MSPV formulary with mandatory health care supplies. The MSPV formulary is a list of approved healthcare commodities including medical, surgical, dental, laboratory, facilities/cleaning products, and textiles. This LSJ will supply the MSPV formulary with medical instrument and accessories distributed by Mimedx Group, Inc. on a not-to-exceed 12-month period of performance until these items can be competed in accordance with FAR 8.405-3. As the identified required items are competed, they will no longer be acquired under the LSJ; thus, bringing the MSPV formulary in compliance with the FAR 8.405-3, "Blanket Purchase Agreements".
3. Acquisition History: VHA manages the largest integrated healthcare system in the United States. In 2013, the system consisted of 21 Veterans Integrated Services Networks with approximately 150 medical centers, 820 outpatient clinics, and various other facilities to include Community Living Centers, Veteran Centers and Domiciliaries. Together, these health care facilities, and the more than 53,000 independent licensed health care practitioners who work within them, provide comprehensive care to about 9.3 million enrolled Veterans. The MSPV Program is the primary means to obtain medical and surgical supply support for the VA healthcare system through contract support. VHA, in cooperation with VA's National Acquisition Center (NAC), initiated contract support for the MSPV program in 2005. The result was the first generation of seven prime vendor distributor contracts that not only support VHA, but also support the Department of Health and Human Services, Department of State, Indian Health Service, and the Federal Bureau of Prisons.

Since that time, VHA and NAC have successfully executed two long-term, multiple-award 5-year contracts in support of the MSPV program. In 2015, upon expiration of the second MSPV program, a set of bridge contracts were executed by the NAC extending the period of performance to April 19, 2016. Those bridge contracts were as follows: VA797N-15-C-0003, VA797N-15-C-0004, VA797N-15-C-0005, VA797N-15-C-0006, VA797N-15-C-0007, VA797N-15-C-0008, and VA797N-15-C-0009.

In preparation for the continuation of the MSPV Program, the Strategic Acquisition Center (SAC) assumed responsibility to award the new MSPV contracts in 2014. Due

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to a protest and continued technical evaluations, the SAC Contracting Officer determined that a second set of bridge contracts would be required to ensure continuity of services and the continuance of healthcare support throughout the VA community beyond the bridge contracts' expiration on April 19, 2016. In February 2016, the SAC awarded the second set of bridge contracts. They are as follows: VA119-16-D-0007, VA119-16-D-0008, VA119-16-D-0009, VA119-16-D-0010, VA119-16-D-0011, VA119-16-D-0012, and VA119-16-D-0013. The period of performance for the second SAC bridge contracts began April 20, 2016, and will expire no later than April 19, 2017.

Leveraging the NAC's lessons learned, VHA and SAC developed a procurement strategy for a complete VA-wide MSPV formulary of approved supplies by April 2016. To execute this plan, VHA and SAC formed a team in February 2015, to initiate development of the MSPV formulary. The goal of this team was to solicit and award approximately 7,000 individual line-items, identified as an optimal initial level, for the pending MSPV formulary. The team developed a streamlined approach to solicit and award these items, which involved VHA providing salient characteristics for all 7,000 line-items, and SAC awarding competitive BPAs based on those salient characteristics.

Between April 2015 and January 2016, VHA forwarded to SAC approximately 4,400 individual procurement packages consisting of both single and multiple line-items, of which approximately 3,500 were solicited and 900 returned to VHA for inclusion in future grouping efforts. Although SAC issued multiple Requests for Quotations (RFQs), vendor response rates averaged less than 30 percent. Due to lack of response, SAC and VHA sought input from industry via a series of MSPV Industry Days. When queried, industry partners indicated two main problems: (1) VHA's salient characteristics were flawed and/or insufficient. They did not appear to be based on clinical input, and often cited unnecessary manufacturer-specific features. This prohibited timely and quality responses, or no responses at all in many cases; (2) Industry also indicated the administrative burden of providing quotes for single-item BPA awards was not cost effective enough for them to provide quotes.

In order to obtain a better success rate, and work on completing new MSPV contracts, two possible strategies were identified: (1) VHA created supply-line commodity teams, and began seeking clinical input for the development of salient characteristics. Additionally, logical commodity groupings were developed; and (2) moving forward, VHA's Program Management Office was to group line-items by supply-line categories, or by United Nations Standard Products and Services Codes. Supply-line categories were found to be the most favored by industry. In an effort to validate this, a Request for Information (RFI) was issued to industry in February 2016. The RFI results confirmed the supply-line category approach as the most appropriate method to solicit BPAs for item inclusion in the approved formulary.

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On February 24, 2016, awards were made to four MSPV distributors, with an estimated performance starting 120 days after notice to proceed. The period of performance under these contracts are scheduled to begin on October 20, 2016. It was anticipated the distributors would have a full-line of 7,000 competitively awarded BPA formulary line-items to populate their electronic catalogs (e-catalog). Due to lack of vendor response, the formulary fell short of the necessary items required to complete the Prime Vendor's e-catalog. In an attempt to resolve the shortfall identified above, numerous changes in VA's strategy for populating the formulary were considered. This directly resulted in the need to establish additional MSPV bridge distribution contracts to ensure continuation of service. The MSPV bridge contracts were awarded with a start date of April 20, 2016. This included a 3-month base period of performance, and three 3-month option periods. The final period of performance expiration date is not-to-exceed 12 months.

4. Description of Supplies/Services: The MSPV formulary will consist of two tiers: 1) the 1,600 line items previously competed by the SAC and NAC, which is being automatically populated into the MSPV formulary and estimated to be ready for use by October 20, 2016; and 2) the additional GSA items identified by VHA to be procured under this LSJ. This group includes 9 types of medical supplies distributed by Mimedx Group, Inc. Examples of items covered under this category include various types of medical and surgical instruments and supplies. The full list of items covered under this LSJ is as follows:

Part Number	Item Description	Estimated Quantity
AI-5050	ALLOGRAFT,AMNIOTIC MEMBRANE,AMNIOFIX,0.5 ML,FOR TENDON & SOFT TISSUE INJURIES,INJECTABLE/POWDER FORM	95
GS-5160	ALLOGRAFT,AMNIOTIC MEMBRANE,EPIFIX,16 MM DISK,USED IN TREATMENT OF WOUNDS/ULCERS/BURNS/MOHS/SCAR REVISION	259
AAS-5460	AMNIOFIX 4 X 6 CM	18
GS-5230	TISSUE HUMAN ALLOGRAFT AMNION CHORION MEMBRANE/SHEET 2CMX3CM	374
GS-5440	TISSUE HUMAN ALLOGRAFT AMNION CHORION MEMBRANE/SHEET 4CMX4CM	186
GS-5560	TISSUE HUMAN ALLOGRAFT AMNION CHORION MEMBRANE/SHEET 5CMX6CM	104
EI-5125	TISSUE HUMAN ALLOGRAFT AMNION CHORION PARTICULATE 100MG	287
AI-5125	TISSUE HUMAN ALLOGRAFT AMNIOTIC PARTICULATE 100MG	254
AI-5200	TISSUE HUMAN ALLOGRAFT AMNIOTIC PARTICULATE	

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The reprieve offered by this LSJ will allow VHA to continue placing orders under the MSPV contracts on a temporary basis, and avoid an interruption in the healthcare supply chain while SAC pursues competitive procurements for the MSPV formulary items.

The proposed types of medical supplies will be ordered under the authority of this LSJ. These items have been identified as high-use medical items vital to the successful implementation of the MSPV program. VHA analyzed the fiscal year (FY) 2015 Medical Products Data Bank, focusing on the top high-volume purchases and identified 9 types of critical medical supply distributed by Mimedx Group, Inc. Until the MSPV formulary is completed, VHA's ordering officers will be allowed to place orders for the required medical supplies. The anticipated total value of the proposed BPA over the life of the agreement is \$2,583,692.12. The period of performance is not to exceed 12 months.

5. Statutory Authority and Supporting Rationale: The statutory authority permitting other than full and open competition is in accordance with FAR 8.405-6(a)(1)(i)(A), an urgent and compelling need exists, and following the procedures would result in unacceptable delays.

6. Rationale Supporting the Authority Cited Above: Urgent and compelling circumstances which significantly affect the interest of the Government will not permit competition in accordance with FAR 8.405-3, "Blanket Purchase Agreements (BPAs)". Significant adverse consequences will occur if the LSJ is not approved as the VA health care supply chain will be negatively impacted. Continuance of the MSPV Distribution Program is vital; any delay of distribution will directly impair the delivery of healthcare and services to approximately 9.5 million Veterans currently receiving care through the VA Healthcare System. A break in the health care supply chain will hinder or halt the delivery of essential medical, surgical, dental, and laboratory supplies and other contracted medical/surgical, cleaning, rescue and safety supplies and services used in the direct delivery of patient care.

The VA Healthcare System receives approximately 40% of its medical and surgical supply support through the national MSPV Program. Many of these items are standardized throughout the VA Healthcare System, and are a part of the formulary being developed for use in the VA. The formulary drives efficiency and familiarity in clinical practice which leads to improved patient outcomes and safety. It also decreases variation, thus reducing time to train and results in fewer errors when providing care. Standardization provides healthcare system benefits that are maximized because standardized items are interoperable. Facilities can then reinvest the savings earned into equipment and personnel that further enhance patient care.

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Estimated cost reduction for purchase of individual items through the MSPV formulary is approximately \$4M over the course of the twelve months proposed under this LSJ. The \$4M estimate does not account for efficiencies in the ordering and inventory management processes. Overall annual inventory reduction specifically attributable to MSPV is estimated at approximately \$40M.

Disapproval of the LSJ will result in a disruption in the health care supply chain and negate these potential savings as facilities source supplies through other means. Workload, man-hours, and cost of operations will increase as already depleting resources are lost and the agency will revert to the inefficient means of sourcing medical supplies as before the introduction of the national MSPV program in 2005. Those inefficient methods include use of purchase cards and local VHA contracting.

Use of purchase cards as an ordering method has shown to be more than 5 times the workload burden of using the delivery order method under the MSPV program. In addition, there are approximately 2000 contracting staff in VHA, processing 576,134 formal contracting actions annually. If the MSPV Ordering Officers were unable to place orders via MSPV, and those transactions were added to the workload of an already overburdened contracting staff, the result would be catastrophic.

Lead times to procure these items through contracting for other than emergency orders are 45 days; emergency orders require action within three days. All orders would become emergencies to ensure timely delivery of healthcare to Veterans. Canceled surgeries due to lengthy supply lead times would possibly become the norm, and thus, adversely affecting timely access to care. Items critical to provide immediate care will be jeopardized, and will directly impact the safety and lives of Veterans.

VA has a critical role in the comprehensive emergency response to support local, regional, or national emergencies or disasters. VA is charged with the delivery and coordination of support missions for VA facilities affected by disasters, and also performs missions assigned to VA by FEMA or US Dept. of Health & Human Services for response to and recovery from nationally-declared emergencies and disasters. The Prime Vendor Program is critical to ensure VA provides a full range of support to healthcare facilities to ensure resiliency, continuity and rapid recovery of healthcare services during disasters and other potential disruptions to healthcare service delivery. VAMCs and other select Federal facilities are designated Federal Emergency Medical Facilities with significant contingency and emergency response roles. Accordingly, the MSPVs provide emergency supply support during major catastrophic events. Any interruption in the health care supply chain significantly jeopardizes the ability of VA to ensure minimum disruption to delivery of critical services in a contingency situation. This would directly impact healthcare delivery to our nation's Veterans.

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Other alternatives were considered, including using both the legacy bridge contracts, and the MSPV contract concurrently until all of the required items can be competitively awarded. The confusion this would create in the field is insurmountable, as field staff will face the uncertainty of which contracts to use and when. A well coordinated supply chain is necessary to ensure facilities are supported, and Veterans are cared for timely. There are no reasonable alternatives that would adequately address the circumstances presented. Any financial costs incurred by the Government to execute the BPAs under the authority of the LSJ, and any potential costs or cost avoidance not realized through competition would not outweigh the benefits received through continuance of the health care supply chain. Approval of the LSJ is in the best interests of the Government and is justified by the urgency of the circumstances.

The cost to the Government if the LSJ is not approved would not be primarily financial, although it is significant. The non-monetary costs of the health, welfare and safety of millions of Veterans cannot be quantified. Every effort was made to compare these costs, benefits and other options; the VA cannot rationally find any other reasonable or timely alternative.

VA considered the cost to the integrity of the procurement system and VA acknowledges the importance of protecting the integrity of the procurement system. However, VA feels this is an extraordinary situation, and maintains that due to an already constricted schedule, and the significant impact of these BPAs on the delivery of medical and surgical supplies and services to millions of Veterans, the facts of this case justify the unusual measure proposed under this LSJ. VA considered the balance of the integrity of the procurement system, and the interest of the Government and determined that the issuance of the BPAs under the authority of this LSJ is mitigated and justified. A break in the health care supply chain will be costly and detrimentally disruptive to VA operations and delivery of critical healthcare services to 9.5 million Veterans. Items procured under the authority of this LSJ will be included in the MSPV supply chain for a maximum period of twelve months until the item can be competitively awarded. At such time the item will be removed from the supply chain and replaced with the competitively awarded functional equivalent.

This action is vital to support VA's nationwide healthcare system and prevent disruptions to Veteran care. The identified medical items represent supplies collectively determined essential by VHA medical centers to meet VA patient care needs. Continued use of these products and source of supply will ensure timely delivery and minimize VA supply chain interruptions. The vendor for these items was selected through use of data analytics tools and the Medical Product Data Bank (MedPDB).

The MSPV program is the primary means to obtain medical supplies; these items are regarded as critical to patient care. These items are currently available under the legacy MSPV contracts. Failure to make them available under MSPV would have

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catastrophic effects on the field's ability to support medical centers. Each item would have to be purchased individually either via purchase card, or through local VHA Contracting Offices, with lead times of up to 45 days. VHA Logistics and Contracting do not have the capacity to meet the constant throughput of high cost/high volume daily individual orders required to meet clinical care needs. Bottlenecks resulting from capacity issues would result in insufficient inventory to meet critical needs for Veteran patients, and will have a significant patient safety impact. It is imperative that VA transition from the present way of doing business under the current MSPV program to the new and revised mandatory MSPV program. In executing this change the following improvements will be realized:

- a. The MSPV distributors shall not ship any medical/surgical or any other supplies that are not on the Government-provided MSPV formulary of approved medical/surgical supplies.
- b. The MSPV distributors shall not charge any VA formulary approved suppliers to handle their product in conjunction with the contract.
- c. The Government mandates all distributors to be Electronic Data Interchange compliant and it is in the BPAs/contracts.
- d. The MSPV distributors shall not require product suppliers to carry liability insurance in excess of \$1,000,000, charge tracking fees, and/or require additional discounts from product suppliers.

7. Efforts to Obtain Competition: MSPV distribution contracts were awarded on February 24, 2016, and performance is scheduled to begin on October 20, 2016. The MSPV distributors require VA's formulary in order to fulfill the medical requirements at VA hospitals and clinics. As stated previously, the Government intends to compete all line items within the next 12 months. Market research shows there is adequate competition in support of the new requirements. In accordance with FAR [5.301](#) and [8.405-6\(a\)\(2\)](#), these actions will be synopsisized on Federal Business Opportunities Page (FBO).

8. Determination of Best Value: In accordance with FAR Subpart 8.404(d), the prices for supplies offered on FSS have already been determined to be fair and reasonable by NAC Contracting Officers. Given VHA's critical need for the previously identified formulary supplies, and the short turn-around time until the MSPV formulary is fully implemented, VA intends to select the lowest published FSS vendor and seek additional discounts. To compete these items would result in unacceptable delays, and potential mission failure. In the future, additional discounts will be sought through competition for these products as part of the transition to the MSPV formulary.

9. Market Research: The market research conducted for the MSPV requirement showed there are multiple suppliers capable of providing medical products however; performance is required by October 2016, and VA does not have adequate resources

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for timely completion of the required items. VA has a need to have consistent, uninterrupted sources of supply that meets system-wide requirements without compromising direct patient care to VA medical centers and/or related facilities. VA has a plan to compete these items and market research supports this acquisition strategy.

10. Any Other Facts Supporting the Justification: SAC is currently establishing competitive single-award BPAs that are beginning to populate the MSPV formulary. Competition is on-going; however, at the onset of MSPV period of performance, the formulary will not have sufficient breadth of medical products to meet the operational needs of VA. It is anticipated the MSPV distributors will begin accepting and delivering orders on approximately October 20, 2016, for all items covered in this LSJ.

11. Actions to Increase Competition: As described above, VA will compete future requirements and continuously add necessary products to the MSPV formulary. SAC will work with VHA's program office to remove or overcome barriers to competition in future acquisitions. VA has and will continue to meet with industry on a periodic basis for continued input and feedback on acquisition strategies. All future acquisitions of MSPV BPAs will be solicited and awarded in a manner that promotes competition to greatest extent practicable.