Class Justification and Approval
for
Other than Full and Open Competition

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Strategic Acquisition Center (SAC)
10300 Spotsylvania Avenue, Suite 400
Fredericksburg, VA 22408

2. Description of the Action: VA proposes to justify and obtain approval for the execution of contract modifications to modify the process of creating Master Item Lists for VA's Medical-Surgical Prime Vendor-Next Generation (MSPV-NG) Indefinite-Delivery Indefinite-Quantity (IDIQ) contracts. The contracts which require modification are:

VA Contract Number	Prime Vendor Contractor
VA119-16-D-0002	Kreisers, Inc.
VA119-16-D-0004	American Medical Depot (AMD)
VA119-16-D-0005	Cardinal Health 200, Inc.
VA119-16-D-0006	Medline Industries, Inc.

These contracts are for the distribution of healthcare supplies under VA's MSPV-NG program. The MSPV-NG Program was developed as the key element in VA's integrated healthcare supply chain improvement initiative and was designed to significantly improve efficiency, accuracy, and patient safety. The MSPV-NG Program was intended to support the establishment of a national strategic sourcing solution that combines a Government provided capability for ordering a wide range of medical and surgical supplies via a master listing with electronic cataloging (e-catalog) and ordering capability. The MSPV model offers VA critical benefits not available through other contract models, including traditional single source supply contracts. Comprehensive distribution support simplifies VA's supply chain objective: to achieve timely delivery in response to the heavy volume of orders in support of Veterans Health Administration's (VHA) urgent operational medical/surgical supply needs. The Prime Vendor (PV) model is required because VA lacks sufficient internal capability to warehouse, coordinate deliveries, and consolidate supply stores. Moreover, once a master list of medical/surgical supplies has grown to sufficient size and maturity, substantial savings in VA's cost to purchase those supplies is anticipated. However, the MSPV-NG has fallen considerably short of the intended outcomes.

In order to address patient safety concerns resulting from VA's current supply chain inefficiencies, the scope of the proposed modifications includes changing the regional MSPV-NG contracts from "distribution" contracts to "distribution and supply" contracts Enabling the MSPV-NG PVs with the capability to supply and distribute required healthcare supplies is critical in order to fully meet the diverse needs of VHA's facilities and the Veterans which they support. The primary objective is to increase the number

of healthcare supplies available to VHA facilities nationwide in order to enhance the quality of care provided to Veterans. Another anticipated benefit of the proposed modifications is that they will improve efficiency by reducing the use of non-preferred sources that do not leverage the distribution efficiencies of the PV (example: Government Purchase Card (GPC), local/regional contracts, etc.) By leveraging already existing PV distribution and supply channels, VA also anticipates being able to generate increased Veteran-owned business opportunities. In short, these modifications will help VHA achieve many of the intended outcomes not currently realized under MSPV-NG.

3. Acquisition History: VA manages the United States' largest integrated healthcare system. The system consists of 18 Veterans Integrated Services Networks with approximately 1,243 healthcare facilities including 170 medical centers. VA's healthcare system also includes 1,063 outpatient sites of care of varying complexity to include outpatient clinics, community living centers, Veteran centers and domiciles. Together these healthcare facilities, and the more than 53,000 independent licensed healthcare practitioners working within them, provide comprehensive care to approximately 9 million enrolled Veterans. Although VA's healthcare system is designed to receive a significant portion of its medical and surgical supply support via a national MSPV-NG program, the current MSPV-NG program is not capable of meeting VA's healthcare system demands.

In order to facilitate patient care within VA, a legacy program known as "Medical-Surgical Prime Vendor (MSPV)" was put into place to supply and deliver required, recurring expendable medical, surgical, and related supplies. The legacy program strived to achieve 40 percent of all VA medical and surgical spend through the MSPV program. The MSPV legacy program has since ended and a new program, MSPV-NG, has taken its place. Due to such a significant portion of VA's healthcare system's medical and surgical items being delivered via the national MSPV-NG program, the MSPV-NG contracts have experienced significant challenges in meeting demands thus jeopardizing patient health and safety.

It is estimated that approximately 80,000 items will be needed to support VA Medical Centers until logical product grouping can be negotiated with manufacturers or their authorized distributors utilizing a formalized clinically driven sourcing process. The current MSPV-NG program includes four regional PV contracts for distribution. The underlying Government provided master listing of products these PVs distribute from is created using a procurement-like process that has yielded a master list of approximately 7,800 items. Currently, VA's healthcare facilities are utilizing a variety of non-preferred contract methods to procure necessary items not available on the Government master list. The substantial number of necessary items that are unavailable in the catalog complicates local delivery and logistics and often leads to higher costs for these supplies. This includes significant over-reliance on GPCs transactions, which jeopardizes the MSPV-NG program's ability to adequately monitor and review supplies being purchased and used for direct patient care. Without the ability to adequately monitor and review the purchased supplies through the Government master list, there is

extreme risk to patient health and/or safety when it comes to ensuring the supplies are compliant with Food and Drug Administration (FDA) regulations for medical supply-items, monitoring and conducting appropriate safety and defective-item recalls, and compliance with all Buy-American Act (BAA) and/or Trade-Agreements Act (TAA) compliant items. Currently, the required Government master list has only a mere fraction of the required supplies needed for adequate patient care, health, and safety needs. The current acquisition-like process for determining items, prices, and suppliers on the master list involves soliciting industry and awarding Blanket Purchase Agreements (BPAs) to vendors meeting the stated requirements at the lowest offered price. However, actual orders are never issued against these BPAs. The BPA process serves only to identify the items and prices for the PV's distribution agreement with the BPA holder. No Government funds are disbursed directly to the BPA holder, only to the PV. Although this process awards no contracts per se, it exposes the Master List generation process to all of the delays inherent in the acquisition process including multiple protests, spotty vendor response, and several rounds of canceled competitive solicitations.

This modification seeks to streamline the MSPV-NG process in order to rapidly expand the quantity and types of items contained on the Government master list, thus allowing the MSPV to continue maturing as a viable enterprise which is ultimately expected to yield substantial efficiencies. While the BPA or similar process will continue for high volume items with potential for significant strategic sourcing efficiencies, this modification will enable the PVs to assist the Government in sourcing thousands of new items quickly. This will be accomplished by allowing the PVs to leverage their existing commercial network in order to propose sources and prices for items identified by the MSPV Program Office. After an examination of the prices and sources identified by the PV by the MSPV-NG Program Office and SAC's contracting team, approved items will be added to the Government master list. The PV will then execute a distribution agreement with the supplier and the process will continue as before. In effect, the PV's supply chain network and expertise will be leveraged to assist the Government in conducting market research and price discovery for thousands of critical commercial medical items.

4. Description of Supplies/Services: Because of VA's ongoing requirement to quickly fill critical gaps in its healthcare supply chain and increase sourcing flexibility to obtain healthcare supplies critical to patient care, VA medical facilities have a critical need to access a wider variety of medical/surgical supplies than is currently available via the MSPV-NG catalog. By modifying the Government master list determination process of the existing MSPV-NG contracts, facilities will be able to expeditiously procure a broader array of supplies using normal MSPV-NG PV channels. This ability will improve patient care and safety as VA medical facilities will be able to keep and maintain Veteran appointments and will be able to safely and expeditiously procure the supplies needed for Veteran patient care.

Under the proposed modification, the MSPV-NG PVs will assist in sourcing, maintain and distribute all of the currently required medical, surgical, dental, laboratory, prosthetic supplies, other medical/surgical, cleaning, rescue and safety supplies and non-expendable equipment used by a medical facility. Required items continue to include the following Product Service Codes (PSC): 4240 (Safety and Rescue Equipment); 6505 (Drugs, biologicals). However, prescriptive drugs and prescriptive biologics requiring an FDA license will not be sourced through the MSPV-NG program; 6509 (Drugs and Biologicals, Veterinary Use); 6510 (Surgical Dressing Materials); 6515 (Medical & Surgical Instruments, Equipment and Supplies); 6520 (Dental Equipment, Instruments, Supplies); 6525 (Imaging equipment and supplies); 6530 (Hospital equipment); 6532 (Hospital and Surgical Clothing and Related Special Purpose Medical/Surgical Supplies);6540 (Ophthalmic instruments, equipment and supplies); 6545 (Replenish-able Field Medical Sets, Kits, and Equipment); 6550 (In Vitro Diagnostic Substances, Reagents, Test Kits and Sets); 6630 (Chemical Analysis Instruments and Equipment); 6640 (Laboratory Equipment and Supplies); 6650 (Optical Instruments, Test Equipment, Components and Accessories); 6670 (Scales and Balances); 7910 (Floor Polishers and Vacuum cleaning Equipment); 7920 (Brooms, Brushes, Mops and Sponges); 7930 (Cleaning and Polishing Compounds and Preparations); 8305 (Textile Fabrics); 8520 (Toilet Soap, Shaving Preparations, and Dentifrices).

The solution offered by this Class Justification and Approval (J&A) will allow VA healthcare facilities to continue placing orders under the MSPV-NG contracts and avoid an interruption in the healthcare supply chain. The PVs will continue to distribute items that are procured through current VA contracts, IDIQ contracts, Blanket Ordering Agreements, and BPAs that are on the existing Government-provided master listing and any other items identified for high potential strategic sourcing efficiencies in the future. The items to be added under this Justification and Approval have been identified as high-use medical items vital to the supply chain. VHA's Program Office analyzed the FY 2017 Medical Products Data Bank focusing on the top high-volume purchases and identified various types of critically needed, high use medical supplies, enabling VHA's ordering officers to place orders for required medical supplies. The supplies to be added for distribution via the MSPV-NG contracts are based on market research consisting of a review of medical surgical supply usage annualized based on 2017 calendar year usage data. With these modifications, PVs will be allowed to assist in sourcing and continue to distribute items on the attached pre-negotiated price list which is based on comparison to an index of current commercial prices as well as other applicable market price information. There is no increase in value to the prime vendors, because the prime vendors are using the master list to procure the items, and the items are within the number originally solicited. The products the sites order are not going to increase beyond the original scope of the contracts. To the extent there is any value (though I consider this to be a no-cost modification), any such value is reflected by the 24 months' period of performance. The period of performance is not to exceed 24 months.

5. Statutory Authority: If the proposed action is a change in scope to the current PV contracts, the statutory authority permitting other than full and open competition is 41 U.S.C. 3304(a)(1) as implemented by the Federal Acquisition Regulation (FAR) Subpart 6.302-1 entitled, "Only One Responsible Source and No Other Supplies Will Satisfy Agency Requirements." Full and open competition need not be provided for when supplies required by the agency are available from only one responsible source, or from only one or a limited number of responsible sources, and no other type of supplies will satisfy agency requirements. However, it is the position of the Contracting Officer that this action does not change contract scope as the PV continues to perform the core function of this contract.

6. Rationale Supporting the Use of the Authority Cited Above: As regional distributors for the MSPV-NG program, the current PVs have the existing infrastructure, ordering capability, and required resident knowledge which makes them uniquely qualified and the only sources currently capable of both enhanced sourcing and distributing required medical commodities throughout the entire VA healthcare network. Any attempt to award the required supplies through a different source would cause unacceptable delays in fulfilling the VA's requirements and would directly impact the health, safety, quality and timeliness of care to Veterans. The proposed action will not expand the scope of the current contracts because the original competition for the PV contracts was clear and unambiguous: it is/was the Government's intent to rapidly increase the MSPV-NG Master Lists to approximately the 80,000 item level.

Significant adverse consequences will occur if the proposed J&A is not approved as VA's healthcare supply chain will continue to be negatively impacted, directly affecting patient care and treatment. Continuance of the MSPV-NG Distribution Program is vital; any delay of supply and distribution will directly impair the delivery of healthcare and services to approximately 9.5 million Veterans currently receiving care through VA's healthcare system. A break in VA's healthcare supply chain will hinder the delivery of essential medical, surgical, dental, and laboratory supplies and other contracted healthcare such as cleaning, rescue and safety supplies and services used in the direct delivery of patient care.

To solicit, evaluate and fully implement new competitive contracts rather than fulfill this requirement via the proposed modification would result in unacceptable delays. Based on an analysis of acquisition timelines experienced in competitively awarding the current generation of MSPV contracts in 2016, a minimum of 16 months is projected to complete all necessary steps from the time FedBizOps publication to contract award(s). The 2016 MSPV-NG contract awards, which were solely for distribution services, required 13 months to publicize and competitively award (four months to synopsize the requirement, publish a draft solicitation and solicit industry comments; two months from solicitation release to solicit proposals; and seven months from solicitation closing to conduct evaluation and source selection following solicitation closing). In comparison to the 2016 effort, the proposed modification effort would likely take three additional months to evaluate due to a more complex requirement that incorporates not only the distribution services already being provided in the current MSPV-NG contracts, but also an additional supply component not contained in the current contract (nor its any MPSV

predecessor contracts. Once a competitive award is made, protests are deemed likely due to the visibility and magnitude of these contracts; the minimum duration needed to resolve any protest is slightly over three months. Once any/all protests are resolved and performance can proceed, a substantial period for ramp-up/transition and implementation must be completed before PVs can attain performance levels and commence handling MSPV orders. Based on the terms of the current 2016 MSPV-NG contracts, the ramp-up/transition/implementation period requires a minimum of 4 months during which the MSPV PVs will gather product utilization data from facilities, load all supplies into an ordering database, coordinate and set up performance with facilities; provide training to facility staff on ordering procedures; and coordinate and provide training to necessary refresher training to using facilities. Market research with qualified commercial vendors shows that this timeframe could possibly be reduced but only minimally, by no more than one month based on the vendors' most optimistic projections. Permitting orders to proceed in advance of full implementation, and complete PV readiness would jeopardize patient safety based on the nature of the medical/surgical supplies to be ordered.

There are no other vendors other than current PVs that the Government could negotiate with in order to quickly add the volume of required items. There is also a need to add and delete products as necessary in order to meet the needs of VA Medical Centers and medical practitioners. The current PVs are positioned and equipped to assume the sourcing and distribution of requirements to be added as a result of this J&A because they already have established commercial contracts with suppliers and have existing relationships with many of the suppliers where products need to be added. Under the proposed modification, VA's healthcare facilities will be able to expeditiously procure their required supplies using the mandated MSPV-NG channels, which account for FDA safety requirements, as well as requirements to inform healthcare providers and process required product recalls and replacements, as well as conform to the BAA and TAA.

In terms of overall quality of care, the proposed J&A will significantly increase the safety and efficiency of patient care because VHA's Ordering Officers will be able to procure necessary supplies while simultaneously monitoring the full supply chain for any critical issues (i.e. medical item recalls, filtering out non-FDA compliant or grey-market items or non BAA/TAA compliant items). The four current regional PVs are the only sources within their given geographical regions that are capable of meeting their contractual duties through use of authorized Government sources of supply, as proposed in this modification. No other contractor currently has the required infrastructure, ordering capability, or Electronic Data Interchange (EDI) in place to deliver the necessary medical supplies required to support patient care and safety without interruption or degradation to quality of care. Furthermore, the current MSPV-NG PVs are the only sources that have the cognizance to manage previously shipped and current inventory and supply issues critical to patient safety: management and processing of product safety recalls and filtering of "grey market" non-approved FDA medical supply items. Only the current MSPV-NG PVs have the infrastructure in place to support any

mandated or optional product recall, as well the capability to provide sourced replacement items without incurring a reduction or interruptions in patient care.

The current PVs have pre-existing business relationships throughout the medical supply industry and the medical commodities required by VA are commercial off-the-shelf items. Given these two facts, VA's ability to consolidate and maximize its buying power by moving those medical requirements currently being purchased via GPCs over to the MSPV-NG will without doubt, result in substantial savings to the Government. Under the proposed Class J&A, the estimated cost reduction for purchase of individual items via the MSPV-NG Formulary is approximately $32M over the course of 24 months. Note: The $32M estimate does not account for efficiencies in the ordering and inventory management processes.

Disapproval of the J&A will result in the continued disruption of VA's healthcare supply chain and negatively affect the Department's ability to provide world-class patient care to our nation's Veterans. Other negative ramifications include negated potential savings as facilities source supplies through other means. Workload, man-hours, and cost of operations will increase as already depleting resources are focused on obtaining supplies, and VA will revert to the inefficient means of sourcing medical supplies as occurred before the introduction of the national MSPV program in 2005. Those inefficient methods include use of GPCs and local VHA contracting initiatives.

Without the issuance of the proposed sole source action, the continued use of non-preferred acquisition methods will increase the workload for VA contracting professionals exponentially. Use of GPCs as an ordering method has shown to be more than five times the workload burden of using the MSPV-NG ordering method. In addition, VHA has approximately 2,000 contracting staff processing 576,134 formal contracting actions annually. In the event MSPV-NG's Ordering Officers were unable to place orders via the MSPV-NG catalogs and those orders are 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; however, emergency orders require action within three days. Virtually all orders would become emergencies in order to ensure timely delivery of safe, reliable healthcare to Veterans.

The MSPV-NG PVs are currently the only sources serving in the critical role of comprehensive emergency supply response in support of local, regional, or national emergencies or disasters. Additionally, VA supports the Federal Emergency Management Agency (FEMA) and US Department of Health & Human Services with the delivery of medical supplies and coordination of support missions for response to and recovery from nationally-declared emergencies and disasters. VA accomplishes this requirement through the current regional MSPV-NG PVs, who are contractually required to perform 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. VA Medical Centers and other

select federal facilities are designated FEMA facilities with significant contingency and emergency response roles. Accordingly, the PVs are the primary providers of emergency medical supplies during major catastrophic events. Any interruption in VA's health care supply chain or in the nation's emergency supply chain significantly jeopardizes VA's ability to ensure minimum disruption in the delivery of critical services in a contingency situation. In the event of a national, regional, or locally designated emergency, a supply chain interruption would not only negatively impact healthcare delivery to our nation's Veterans and their dependents, but also potentially have a direct, negative impact on the greater public. The proposed J&A is vital to support VA's nationwide healthcare system and prevent disruptions to Veteran care. The identified medical items represent supplies determined essential to patient care and safety by VA medical centers to meet VA patient care and safety needs. Continued use of these products and sources of supply will ensure timely delivery and minimize VA supply chain interruptions.

A well-coordinated supply chain is necessary to ensure VA's healthcare facilities are fully supported and Veterans are cared for timely. There are no reasonable, short-term alternatives that would adequately address these critical circumstances. Any financial costs incurred by the Government under the authority of the proposed J&A, and any potential costs or cost avoidance not realized through competition would not outweigh the benefits received through continuance of the healthcare supply chain. Approval of the Class J&A is in the best interests of the Government and is justified by the circumstances.

Non-approval of this Class J&A would result in significant negative impact to the Government in terms of monetary cost, however, the far greater negative impact would be the undeniable risk to the overall health, welfare and safety of millions of Veterans Although every effort was made to compare costs, benefits and all other options, no reasonable, timely alternative has been identified.

VHA's MSPV Program Office has considered the impact to competition that will result from the proposed action, and acknowledges the importance of maximizing competition in the procurement system. However, VHA asserts this is an extraordinary situation, and maintains that due to the critical nature of the items that will be accessible on the delivery of medical and surgical supplies and services to millions of Veterans, and the need to quickly expand the number of supplies available from the PVs, the facts of this case justify the unusual measure proposed under this Class J&A. The Program Office considered the need to balance competitive procurement principles with the best interest of the Government and determined that the expedited infusion of the proposed critically needed medical supplies under the authority of this Class J&A is mitigated and justified. A break in the healthcare supply chain will be costly and detrimentally disruptive to VA operations and delivery of critical healthcare services to more than 9 million Veterans. Additionally, it is in the Government's best interest to continue to support the MSPV enterprise to maturity, at which point substantial efficiencies and cost savings to VA are expected to be realized. Items procured under the authority of this

Class J&A will be included in the MSPV-NG program for a maximum period of twenty-four (24) months until the medical supplies can be competitively awarded. At such time, the items will be replaced with the competitively awarded functional equivalent.

The MSPV-NG program is the mandated means to obtain medical supplies; these items are regarded as critical to patient care. In executing this change the following improvements will be realized:

a. The MSPV-NG distributors shall continue to not charge any VA formulary-approved or other Government source of supply to handle their product in conjunction with the contract.
b. The Government mandates all distributors to remain EDI compliant.
c. The MSPV-NG distributors shall not require product suppliers to carry liability insurance in excess of $1,000,000 charge any tracking fees, and/or require additional discounts from product suppliers.

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 patient care needs. The inclusion of these medical supplies and distribution will ensure timely delivery and minimize healthcare supply chain interruptions.

7. Efforts to Obtain Competition: Substantial previous and ongoing efforts have been made to maximize and obtain competition for the required supplies. The following timeline and description of past efforts to obtain competition are provided:
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 PV 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. The MSPV contract expired in October 2015 and was replaced by the MSPV-NG contract. However, because of delays with MSPV-NG, 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, in 2014 SAC assumed responsibility of awarding the MSPV-NG contracts. Due to a protest and continued technical evaluations, SAC's Contracting Officer determined that a second set of bridge contracts was 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, SAC awarded the second set of bridge contracts. The bridge contracts 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, with an expiration of April 19, 2017.

Leveraging the NAC's lessons learned, VHA Program Office and SAC developed a procurement strategy that included a complete VA-wide MSPV-NG Government provided master listing of approved supplies that would be available for use by April 2016. To execute this plan, VHA and SAC formed a team in February 2015 to initiate development of the MSPV-NG Government provided master listing of medical/surgical supplies. The team's goal was to solicit and award approximately 7,000 individual line-items, identified as an optimal initial level, for the pending MSPV-NG Government master listing. 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, the MSPV-NG Program Office 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, 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-NG Industry Days. When queried, the vendors identified two main problems: (1) VHA's salient characteristics were often flawed and/or insufficient. The salient characteristics did not appear to be based on clinical input, and often cited unnecessary manufacturer-specific features which prohibited timely, quality responses, or in many cases, no responses at all. ; (2) Vendors indicated that VA's practice of requesting single item quotes was an administrative burden and not cost effective enough for them to provide quotes.

To obtain a better success rate and to work on completing the new MSPV-NG Government approved master listing supplier 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. To validate this strategy, a Request for Information (RFI) was issued to industry in February 2016. The RFI responses confirmed the supply-line category approach as the most appropriate method to solicit BPAs for item inclusion in the approved Government provided master listing.

On February 24, 2016, competitive awards were made to four MSPV-NG PV distributors, with an estimated performance starting 120 days after notice to proceed. The period of performance under these contracts was scheduled to begin October 2016. It was anticipated the PVs would have a full-line of approximately 12,000 to 15,000 competitively awarded BPA line-items to populate their electronic catalogs at

contract award with another 15,000 to 35,000 items to be added during performance. Due to lack of vendor response, the Government provided master listing of medical/surgical supplies fell short of the necessary items required to complete the PVs' e-catalogs. In an attempt to resolve the shortfall identified above, numerous changes in VA's strategy for populating the Government provided master list were considered. This directly resulted in the need to establish additional MSPV-NG bridge distribution contracts to ensure continuation of service. The MSPV-NG bridge contracts were awarded with a start date in April 2016. This included a 3-month base period of performance, and three 3-month option periods. The final period of performance expiration date was not-to-exceed 12 months.

October 2016 saw the transfer of the MSPV-NG contracts to the new PVs; however, the Government provided master list fell drastically short of the anticipated range of approximately 80,000 items; only about 1,600 items that were previously competed by SAC and NAC were transferred to the Formulary/Catalog. Limited Source Justifications (LSJs) were established, on a not to exceed 12 month basis, to add the most widely used medical supplies to the Government provided master list. These items were identified using spend data from Medical Products Data Bank; only items available under the FSS were eligible for the LSJs. The reprieve offered by these LSJs allowed VHA's Ordering Officers to continue placing orders under the MSPV-NG contracts on a temporary basis and avoid an interruption in the healthcare supply chain while SAC continued to pursue competitive procurements for the MSPV-NG Government provided master listing of medical/surgical suppliers. Three rounds of solicitation packages were planned for staggered release during the summer of 2017; these solicitations would have yielded over 2,600 unique line items. However, the first round of solicitations was protested, which stalled release of the subsequent solicitations. It was decided that these packages needed to be reworked. The LSJs began to expire during the fall of 2017. As a short-term solution to keep these items on the Government provided master listing, SAC transferred these LSJs to distribution and pricing agreements. The SAC solicited approximately 1,400 line items via FSS in October 2017, all solicitations were protested. Those solicitations for set-aside items are currently working towards award and those solicitations not set aside were cancelled. Of the 1,400 items solicited, less than 150 items will be eligible for award.

New packages are currently being developed for a projected release of quarter one of 2018. Due to protests and low response rates, multiple acquisition efforts for medical supplies resulted in little to no return on investment; hence the current need to amend the competitively awarded MSPV-NG distribution contracts to enable them to function as supply and distribution contracts while a truly clinician driven and value analysis based Government provided master listing is pursued.

In addition to the corporate subcontracting plans provided by PVs that are large businesses, VA will negotiate individual contract subcontracting plans with all Medical Surgical PVs, regardless of business size, in order to address subcontracting with Veteran Owned Small Business (VOSB) and Service Disabled Veteran Owned Small

Business (SDVOSB). Performance results against the individual subcontracting plans will be considered in determining past performance ratings submitted to the Contractor Performance Assessment Reporting System. VA's Office of Small and Disadvantaged Business Utilization will assist the PVs in identifying qualified SDVOSBs and VOSBs for subcontracting consideration throughout the contract performance period.

8. Determination of Fair and Reasonable Cost: As the Contracting Officer, I hereby determine that the anticipated cost to the Government will be fair and reasonable. These are widely available commercial items for which fair and reasonable pricing can be easily established. In negotiating pricing for the modifications, the Government will approve "not to exceed" prices for added supplies based on commercial indices.

9. Market Research: The market research conducted for the MSPV-NG requirement has been conducted on a continuing basis, concluding immediately prior to this justification being finalized. It showed there are multiple individual suppliers capable of providing the needed healthcare supplies; however, there are currently no suppliers outside of the existing PVs that can immediately integrate the necessary supplies into the VA's supply chain on a nation-wide basis, as required. The MSPV program observed a $202M decrease in MSPV purchases between FY 2016 and FY 2017 due to decreased availability of products in the MSPV catalog. In FY 2017, GPCs accounted for more than $4B of VA's medical supplies, equipment and services spend. The principal reason for the decline in MSPV usage and high GPC volume was the lack of items available via MSPV-NG catalog. The current process produced a catalog of approximately 7,000 line items, far short of the estimated enterprise requirements.

VA has a need to have consistent, uninterrupted sources of supply that meets system-wide requirements without compromising direct patient care to VA's medical centers and/or related facilities. Current PVs understand VHA systems, have insight into what VHA buys, and have the infrastructure in place to support quick implementation. The capability is there and only the current PVs can fulfill the imminent requirement to supply and distribute healthcare supplies throughout VA. VHA's MSPV Program Office is developing a long-term strategy that is both supported by market research and clinically driven.

10. Any Other Facts Supporting this Class Justification: VA has been unsuccessful in implementing a clinically driven sourcing capability which is a fundamental foundation for modern best-in-class healthcare supply chains, including VHA's healthcare supply chain. VHA is diligently working to develop improved, clinically driven sourcing capabilities but benchmarking with world-class commercial healthcare systems reveals that success in this area typically takes between ten and fifteen years. To avoid potential catastrophic disruption to VA's healthcare supply chain, the only feasible alternative to quickly supply current and urgent healthcare supply chain needs across the VA network is to use a more agile process to satisfy requirements. To quickly fill critical gaps in VA's healthcare supply chain (impacting both access to care and quality of care) it is essential that PVs have appropriate authority to leverage commercial

contracting capabilities while VA continues to pursue its goal of maximizing cost, quality and healthcare outcomes in the context of clinically driven sourcing. This additional sourcing flexibility to obtain critical healthcare supplies will more closely approximate VHA's existing best in class pharmaceutical PV program that relies heavily on commercial buying practices. In an effort to mitigate current capacity gaps negatively impacting implementation of clinically driven sourcing, VHA's MSPV Program Office intends to conduct market research seeking commercial research, analytical and documentation capabilities that will simplify and accelerate evidence-based decision making by VHA clinical communities.

Given the urgent need for facilities to access a much broader listing of medical and surgical supplies via the MSPV-NG PVs and given that fair and reasonable prices can be confirmed using commercial cost indices, it is in the best interest of VA to ensure a broad suite of medical surgical supplies are available to the facilities through normal distribution channels (Medical-Surgical PVs) while the VHA Program Office implements future programs, incorporates clinician-driven sourcing, value analysis led by clinicians, and a national catalog of medical surgical supplies.

The current MSPV-NG contracts have fostered creation of an undocumented GPC enabled medical/surgical supply chain. Non-supply GPC holders can easily order supplies independently without supply personnel involvement. Under these circumstances, the items ordered would not be recorded in the master data base, and would be invisible to supply personnel reviewing patient safety recalls. In other words, a clinic or ward could unknowingly be using a hazardous product and endangering Veteran patients because there was no record of the item in the healthcare facility's master file.

These recalls are common. Per the Stericycle Expert Solutions Q3 2017 Recall Index Report, 167 medical device and 89 pharmaceutical recalls occurred nationwide in the subject quarter; and 15.7 percent of pharmaceutical recalls were due to sterility problems and 17.4percent of quality issues were attributed to medical device recalls.

GPC vendors may not consistently track items to ensure product guarantees and the chain of custody that the MSPV program automatically provides. GPC provided items may appear to be U.S. approved, but may be repackaged items acquired from non-US sources. They may also have been expired prior to repackaging.

The Joint Commission International white paper titled, "The Effect of Illicit Supply Chains on Patient Safety" (© 2017) highlighted, "a major threat to patient safety is the debilitating/compromising effect caused by healthcare commodities that are purchased inadvertently or purposely from the "grey market." These items may appear to be the same as the manufacturer's items but may be counterfeit, contaminated, adulterated, diverted, expired, and or illegally obtained and therefore pose a significant risk to patient safety and the integrity of the healthcare organization. "

Contrary to GPC transactions, MSPV-NG PVs must acquire healthcare commodities directly from manufacturers, or from authorized distributors that have an established relationship with the federal Government through FSS contracts or VA written contracts/BPAs/BOAs. These items are researched and sourced by diverse teams that include expert clinicians and National Center for Patient Safety representatives. The items also undergo technical review by the same teams prior to contract award to ensure they meet clinical requirements.

In addition, only FDA approved medical/surgical supplies that are compliant with Global Standard 1, Health Industry Business Communications Council, and/or International Society for Blood Transfusion 28 standards are available through the MSPV-NG program. Unlike some GPC vendors, PVs are subject to inspection by both VA facility and VHA supply chain management experts to ensure the handling and distribution and U.S. approved sources clauses of the MSPV-NG contract are met.

For the reasons described above, the proposed J&A is urgently needed to ensure the robustness of the MSPV-NG catalog and the availability of safe clinician required commodities for the treatment of our Veterans.

11. A Listing of the Sources, if any that Expressed, in Writing, an Interest in the Acquisition: None

12. Actions to Increase Competition: The MSPV-NG Program Office is moving forward with a plan to streamline the procurement and delivery of high-use medical, surgical, dental, select prosthetic, laboratory and facility management supplies throughout VA. This plan is outlined in the MSPV-NG Program Implementation Directive soon to be published. MSPV-NG is a national mandatory program, providing a customized distribution system to meet or exceed facility requirements by providing an efficient, cost-effective, just-in-time distribution and catalog ordering processes.

To fulfill the objective of providing a streamlined ordering capability across VA, the Program Executive Office (PEO) envisions a future, clinician-driven formulary/catalog that is robust, agile, and proactively responsive to the requirements of users in the field. Clinician-driven sourcing is a central component of MSPV-NG formulary/catalog development and collaboration across VA will facilitate ongoing improvement of VA's sourcing of key, high-use medical and surgical supply items. Clinician-driven sourcing requires accountability, participation, and collaboration amongst clinical specialists who have the knowledge and education of items needed for the highest quality of care for Veterans. In the future state, the national Clinical Program Offices (CPOs) will work in partnership with the PEO to ensure that clinicians in the field have access to the right medical products at the right time. In order to ensure the MSPV-NG program is fully based on a foundation that is rooted in clinician-driven sourcing principles, a clear strategy and plan of action must be developed in concert with collaboration of Executive Leadership from the MSPV-NG PEO, the Healthcare Commodities PEO, VHA, VHA Procurement and Logistics Office, VA Office of Acquisition and Logistics, National

CPOs, Chief Medical Offices, National Center for Patient Safety, and other key offices as required.

Due to the immense amount of executive-level, clinical, functional, and national coordination required to institute a fully-functional, clinician-driven healthcare product supply chain, the plan to implement and improve the program includes the following high-level milestones and interim objectives:

- **Quarter 1- Quarter 2 CY2018: VA / VHA Executive Leadership and National Clinical Program Office Engagement**
  - MSPV-NG PEO will conduct roadshow to engage with VHA Executive Leaders and National Clinical Program Offices to:
    - Solicit clinical stakeholder/leadership buy-in
    - Identify key points of contact for continued CPO engagement with MSPV-NG PEO
    - Initiate development of a long-term plan to ensure VHA's Program Office has a sustainable and comprehensive clinician drive sourcing strategy. Draft and obtain approval for clinical-driven governance structure
- **Quarter 3 CY2018: Align Clinician Driven Sourcing Strategy to Meet Future Clinical Operations and Veteran Needs**
  - If required, issue an RFP for a Formulary/Catalog management source to continuously provide access and pricing for commercial medical surgical items at prices commensurate with VHA volume.
  - Establish clinical-driven governance structure
  - Continue development of a long-term plan to ensure VHA has a sustainable and comprehensive clinician drive sourcing strategy
  - Engage with VA leadership to ensure all key stakeholders buy-in to the clinician driven sourcing approach and strategy
  - Develop and approve processes for MSPV-NG Formulary/Catalog refinement to include, item additions, retirements, etc.
- **Quarter 4 CY2018 and Beyond: Implement Clinician Driven Sourcing Strategy to Meet Future Clinical Operations and Veteran Needs**
  - Stand-up and implement governance and processes for clinician-driven sourcing strategy for new product identification, value analysis, and product retirement.
  - Full implementation of sustainable processes to support MSPV-NG program

This J&A will be required until a new MSPV contract can be awarded and implemented. It is estimated that this can be accomplished within 24 months of final signature.

Technical and Requirements Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.

[redacted]

Date

[redacted]

Date

Determination of Best Value/ Procuring Contracting Officer Certification: I hereby determine that the proposed contract action will represent the best value to the Government and certify that this justification is accurate and complete to the best of my knowledge and belief.

[redacted]

Date

Legal Sufficiency Certification: I have reviewed the justification and find it legally sufficient as to formalities and compliance with the requirement set forth in FAR 6.302-1 only.

[redacted]

Date

Concurrence

Based on the foregoing justification, I concur with the execution of a modification and class justification for medical commodities on an other than full and open basis, pursuant to the authority cited in 41 U.S.C. 3304(a)(1) as implemented by the Federal Acquisition Regulation (FAR) Subpart 6.302-1 entitled, "Only One Responsible Source and No Other Supplies Will Satisfy Agency Requirements," subject to availability of funds, and provided that the services and commodities herein described have otherwise been authorized for this acquisition.

[redacted]

Date

[redacted]

Date