STATEMENT OF ROGER D. WALDRON

PRESIDENT OF THE COALITION FOR GOVERNMENT PROCUREMENT

BEFORE THE

HOUSE COMMITTEE ON VETERANS AFFAIRS

UNITED STATES HOUSE OF REPRESENTATIVES

DECEMBER 7, 2017

Good Morning Chairman Roe, Ranking Member Walz and Members of the House Committee on Veterans Affairs. Thank you for the opportunity to appear before you to address the VA Medical/Surgical Prime Vendor (MSPV) program, including its "Next Generation" and "2.0" iterations.

The Coalition for Government Procurement (The Coalition) is a non-profit association of firms selling commercial services and products to the Federal Government. Our members collectively account for more than $145 billion dollars of the sales generated annually through government contracts including the GSA Multiple Award Schedules (MAS) program, VA Federal Supply Schedule (FSS), the Government-wide Acquisition Contracts (GWACs), and agency-specific multiple award contracts (MACs). Coalition members include small, medium, and large business concerns that provide more than $12 billion worth of medical/surgical products and pharmaceuticals to support the healthcare needs of veterans. The Coalition is proud to have worked with Government officials for more than 38 years towards the mutual goals of common sense acquisition and to support our veterans.

As you know, the VA uses several strategies to acquire medical/surgical equipment and supplies including national contracts, federal supply schedules and the Medical/Surgical Prime Vendor (MSPV) program. It is critical that these programs work together consistently and effectively to create a high value acquisition and distribution system. The VA faces numerous challenges associated with the management of its hospitals and supply chain. Studies, reports, and analyses have been published about these challenges and possible solutions. In September 2016, the Government Accountability Office (GAO) made 10 recommendations to improve the efficiency and effectiveness of VA acquisitions. [1] On Monday GAO released a new report, GAO -18-34, "Veterans Affairs Contracting: Improvements in Buying Medical and Surgical Supplies Could Yield Cost Saving and Efficiency" which documents many of the challenges and impacts the of the MSPV-NG on the VHA customer and the VA's industry partners over the last two years.

Earlier this year, the Coalition was pleased to have submitted recommendations to the VA to reform its procurement operations in connection with the VA modernization program. Attachment 1 to this statement contains our detailed recommendations for:

[1] GAO-16-810, Improvements in Policies and Processes Could Yield Cost Savings and Efficiency, September 2016

1. Establishing Clinician Leadership/Program Management

2. Centralizing VA Procurement Operations

3. Streamlining Unnecessary and Duplicative Regulations

4. Improving IT Systems

5. Reorganizing Pharmacy Benefits Program

6. Reforming the Role of the VA Office of the Inspector General in Contracting

The Coalition also has been privileged to prepare comments in response to the VA's proposed MSPV 2.0. The MSPV program seeks to deliver a national strategic sourcing solution that combines a formulary approach with electronic cataloging and ordering to support the Veterans Administration Medical Centers. VA's version 2.0 would outsource the program to a single commercial contractor. The contractor would determine what the agency would buy, and how the items would be sourced, managed and distributed; administer contracts; and ensure quality control. Nationwide electronic ordering and invoicing would be facilitated using the commercial contractor's e-commerce platform.

Coalition members support VA's objectives related to aligning the acquisition of medical/surgical products more with commercial best practices and increased efficiency. The current MSPV 2.0 proposal, however, leaves so many questions unanswered that, at this time, we are unable to make a realistic evaluation of its impact on veteran's health, VA suppliers or the contracting process. Our questions and areas of concern are described in detail in Attachment 4 to this statement.

The Coalition has several fundamental concerns that our members believe must be addressed to ensure the success of the MSPV program and/or any future VA program for the application of medical/surgical equipment and supplies. Specifically, we believe that the VA needs to:

1. Establish a strong program office, led and managed by clinicians

2. Be clear that best value for the veteran, not price, will drive program requirements

3. Maximize alignment with commercial practice

4. Leverage competition to benefit the prime vendor program

A Clinically Led and Managed Program Management Office

Our members continue to emphasize that a program office led and managed by clinicians is a commercial best practice and is critical to implementation of a successful prime vendor program that supports President Lincoln's promise "To care for him who shall have borne the battle, and for his widow, and his orphan". The foundation for an effective and efficient VA medical supply program, focused squarely on the needs of veterans, is a VHA program office that is led by health care professionals with both clinical and medical supply chain expertise. A clinically led program office possesses the breadth of skills and experience to make effective and efficient evaluation of medical devices and overall product decisions that result in optimal outcomes and best value for patients and practitioners across the VA health care system. Our experience with MSPV-NG has shown that without clinical program leadership and management, VA is destined to have MSPV strategies and decisions that are focused on, and driven by, the government "procurement process," potentially compromising the healthcare needs of veterans.

The lack of clinician and medical supply chain experience within the VHA medical/surgical Program Office has led what appears to be the view that medical and surgical products are simple and interchangeable commodities. This view simply is not the case; these acquisitions cover highly regulated and complex medical products with unique characteristics that directly impact patient outcomes in VA facilities. Under the current program, there have been several issues which seem to be contract-driven, rather than clinician-driven. For example, the practice of awarding a limited number of line items, rather than the standard commercial practice of awarding contracts for coordinated suites of products. This practice:

1. Leads to inefficiencies at VA facilities. The unavailability of certain products can impact the ability to perform medical procedures, often resulting in cancellations, and it consumes valuable nursing time to find and source products;

2. Challenges industry in the solicitation process to recognize individual product codes that may be buried in unfamiliar groupings, increasing the potential misalignment of expectations and performance; and

3. Raises concerns for the practice of medical care by end-users. Awarding different medical products within a suite of products may require additional training for VA medical staff to

ensure appropriate use, increasing time pressures on already stressed medical staff, and potentially introducing safety risks through the expansion of product variation.

The proposed MSPV 2.0 does not address the imperative of a clinically-led, successful program office. In fact, MSPV 2.0, as we understand the vision, likely will exacerbate the clinician vacuum by vesting in a commercial entity, the responsibility and authority to develop, determine and manage what products are included on the MSPV formulary and how such products are sourced. Coalition members have raised questions as to how the VA will ensure that this "super" prime vendor will ensure an appropriate clinical role when making formulary decisions that prioritize patient outcomes for our nation's veterans. Moreover, they are concerned that there is no assurance that formulary items are NOT selected by the MSPV 2.0 contractor based on competing business interests/decisions rather than the healthcare needs of veterans. The establishment of a program office with strong leadership by clinicians who have medical supply chain expertise is necessary to assure well-developed technical requirements that address these concerns. Best value outcomes start with sound, effective and clear customer requirements in this regard.

Coalition members continue to report a lack of clinician input in developing technical requirements. For example, in connection with MSPV-NG, the Strategic Acquisition Center (SAC) establishes IDIQs and BPAs based on requirements developed in consultation with the procurement and logistics arm of the VHA. Clinicians apparently provide input in some instances, though there is a lack of transparency regarding these decisions. Under these circumstances, members are concerned that award decisions are based on price and not best value for veterans' healthcare. It is their experience that a lack of clinical input has led to an incomplete formulary, which causes supply shortages and may require facilities to purchase items via the open market, often at a high cost, on government purchase cards. Robust clinical leadership during the requirements development process would avoid such problems. It is not enough to formalize the current "clinical input" process (the VHA's Integrated Product Teams) being utilized under MSPV-NG for the future 2.0 program. See Attachment 2 providing additional background and recommendations on creating a clinician led program office.

Best Value

Veterans cannot be relegated to "low price technically acceptable" healthcare, and for this reason, the VA must clearly assert that value, i.e., the facilitation of the most positive healthcare outcomes for veterans, not raw low price, is the objective when acquiring medical equipment and supplies for our nation's veterans. Value drives positive healthcare outcomes for veterans. Coalition

members understand that a significant objective for the MSPV 2.0 is cost savings. The MSPV 2.0 vision, to date, however, provides little-to-no detail regarding how cost savings will be measured and considered in the context of medical outcomes, supply chain efficiencies, or the like. Further, there is no detail as to whether the responsibility for making these important decisions will rest with the MSPV 2.0 contractor or the government. Without a clear articulation of a VA position that value, not price is the driving force, there is little incentive for a contractor to offer the latest innovative, but perhaps more expensive new, life-saving technology for our veterans. Given this lack of clarity, coupled with the abense of a clinician led and managed program office, the Coalition members are concerned that financial incentives, rather than a focus on patient outcomes, will drive the program. Clinical expertise is essential to making best value selections of medical and surgical products.

Attachment 3 includes a letter from the Coalition to the VAC SAC regarding low price technically acceptable evaluation methodology for medical/surgical items.

Commercial Practice

To assure streamlined processes and reasonable prices, we strongly urge the VA to align with best commercial practices. In issuing the RFI for MSPV 2.0, VA stated that alignment with commercial practice was a key objective. Paragraph 2.0 of the Scope section of the RFI, however, provides that one contractor will be responsible for "developing a medical surgical supply and equipment formulary for each facility in the VA…., [and will] provide strategic sourcing, life cycle management, distribution, inventory management and analysis services, quality control/quality assurance support services, and warranty management services for materials they are responsible for providing." This approach is inconsistent with commercial practice. Indeed, Coalition members report that there is no comparable commercial model that provides for a super prime vendor essentially responsible for developing, designing, and managing a formulary while at the same time distributing, delivering, and managing all the products listed on that formulary.

In particular, as noted in Attachments 2 and 4, the RFI's approach does not reflect the complexity associated with establishing, competing, and managing the requirements for a medical/surgical prime vendor catalog world-wide. As currently constructed, the RFI proposes the execution of a competition within a few months. For comparison, our members have explained to the VA that pursuant to the commercial model, which represents 98-99% of the US market for medical devices, a commercial organization, with a clinically led program office, typically takes approximately four years to successfully compete such a catalogue.

In addition, our experience with MSPV-NG has shown that the VA does not utilize the established medical product categories that are used in the commercial market. Although VHA has attempted to create product categories, an improvement upon the current line item competitions, these categories are government-unique and not recognized by industry. Following product categories that are well known in the commercial market increases the likelihood of developing a comprehensive scope of formulary products that meet the needs of clinicians in the VA medical system. To do otherwise risks suffering significant gaps in the availability of medical and surgical products on the Formulary, similar to the experience under the current MSPV-NG contracts

Further, MSPV 2.0 should allow companies to distribute their products to the VA as they do for commercial hospitals. Specifically, although many medical products are available through medical/surgical distributers, a considerable number of medical devices are only available through direct acquisition from manufacturers. Direct ordering from manufacturers for certain products is a standard commercial practice typically driven by medical safety requirements and the corresponding chain of custody tracking to ensure traceability of product. In these circumstances it is neither appropriate nor efficient to stock these through distributors. Thus, the VA should look to other alternatives such as separate IDIQ contracts of the Schedules program, as appropriate.

In sum, prior to launching MSPV 2.0, the Coalition recommends that the VA take the time to identify commercial best practices for the medical supply chain and align the VA's purchasing strategy accordingly.

Competition

Finally, VA's proposal for MSPV 2.0 in the RFI assigns one commercial entity responsibility for making critical decisions that, generally are reserved to the government, specifically, what to buy, how to buy, and contract administration. The Coalition cannot emphasize enough its recommendations that the VA establish the MSPV 2.0 formulary, based on requirements developed by a clinically led program office, rather than outsourcing this function to a contractor. The establishment of the formulary for veterans is an inherently governmental function that should be conducted by the government and not a private entity. It is the VA's responsibility to identify the medical and surgical products that meet the health care needs of veterans at best value to taxpayers, as the VA possesses unparalleled expertise and intimate understanding of the panoply of needs of this client base. A private entity does not, and thus to allow that private entity to do so would risk formulary decisions being made based on an individual contractor's business and financial incentives, rather than the best interest of veterans. It is also a direct

business conflict of interest for a single contractor to both manage and perform the requirement. Here, the contractor would be responsible for the overall development/management of the formulary and delivery of all the items listed on that formulary

The VA's proposal also would allow a single 2.0 prime vendor to have total control over the program, without any readily discernible checks, and it assumes that further consolidation of the MSPV program is desirable. The Coalition believes that this approach is flawed because it fails to recognize the is the value to competition and having multiple prime vendors to supply VA health care facilities world-wide. For instance, distribution is a commercial activity, with many competent players at a regional or sub-regional level. Rather than leverage competition among those players, VA's MSPV 2.0 vision cedes disproportionate market power to one firm. Over time, vesting too much authority into a single contractor is not good for government or its supplier base because it enables the contractor to control not only the federal market, but also federal suppliers in ways that may be detrimental to the government and the ultimate customer, veterans. By way of example, this disproportionate market power can affect:

- VA's ability to replace a non-performing prime vendor
- A supplier's ability to access VA procurement through a single point of entry
- Continual performance improvement over the life of the contract due to competition
- The ability of small/small disabled veteran businesses to either contract with VA directly as prime contractors or successfully participate in the prime vendor program.

VA is still in the process of creating its vision for MSPV 2.0. Program development and implementation will likely occur over an extended period of time. Given the millions of veterans impacted by the program, the Coalition strongly urges VA to stabilize the current program while it takes the time to explore future options.

We recommend that VA immediately launch a clinician led management program office that will lead initiatives to both shore up the current MSPV-NG program, and help build future programs. The program office should have a clinical leader and clinical staff, mixed with experienced medical supply chain professionals. We also recommend that VA reinvigorate use of the VA Federal Supply Schedule contracts (Schedules) to help stabilize the current program and streamline procedures at the VA

National Acquisition Center to support the MSPV-NG program. In the past the VA and its prime vendors relied heavily on Schedules to supply medical/surgical equipment and supplies. The Schedules feature:

- Established contract relationships with major suppliers;
- A broad representation of small and large contractors;
- Extensive choices among commercial products; and
- Streamlined ordering that allows VA to leverage its volume.

With an anticipated rise in the micro-purchase threshold, the Schedules should become easier to use than they are now. The Coalition has submitted to VA a number of recommendations to streamline the Schedules contracting process and enhance the government's ability to add new and innovative products and services. We have attached those recommendations to this statement.

Thank you for the opportunity to submit this statement. I will be happy to answer questions.

Attachment 1

August 2, 2017

Mr. Greg Giddens
Modernization Lead
Department of Veterans Affairs
810 Vermont Ave, NW
Washington, DC 20420

Subject: Department of Veterans Affairs Modernization

Dear Mr. Giddens,

The Coalition for Government Procurement (Coalition) appreciates the opportunity to submit comments regarding the reorganization and modernization efforts at the Department of Veterans Affairs (VA).

The Coalition for Government Procurement (The Coalition) is a non-profit association of firms selling commercial services and products to the Federal Government. Our members collectively account for more than $145 billion dollars of the sales generated through government contracts including the GSA Multiple Award Schedules (MAS) program, VA Federal Supply Schedule (FSS), the Government-wide Acquisition Contracts (GWAC), and agency-specific multiple award contracts (MAC). Coalition members include small, medium, and large business concerns that provide more than $12 billion worth of pharmaceuticals and medical/surgical products to support healthcare needs of our nation's veterans. The Coalition is proud to have worked with Government officials for more than 38 years towards the mutual goals of common sense acquisition and support for our veterans.

The Coalition is submitting these comments on behalf of our members in response to the "Executive Order on a Comprehensive Plan for Reorganizing the Executive Branch," directing agencies to enhance efficiency, effectiveness, and accountability by reorganizing and eliminating unnecessary agencies, components, and programs. The Coalition sincerely appreciates the opportunity to provide input regarding opportunities to increase efficiencies in VA's acquisition functions. If there are any questions I may be reached at (202) 331-0975 or rwaldron@thecgp.org.

Sincerely,

Roger Waldron
President

VA Modernization Recommendations

In Fiscal Year 2016, the VA obligated more than $23.2 billion to prime contractors—more than a third of the VA's total discretionary budget. Contractors are essential to the VA's mission, providing pharmaceuticals, services, and medical supplies and equipment that are required for the care for our Nation's veterans. The VA faces numerous challenges associated with the management of its hospitals and supply chain. Studies, reports, and analyses have been published about these challenges and possible solutions. Instead of duplicating this work, the Coalition's comments solely focus on recommendations for reforming the VA's procurement operations in order to maximize quality healthcare services for veterans. The Coalition recommends:

1. Increasing Clinician Input
2. Centralizing VA Procurement Operations
3. Streamlining Unnecessary and Duplicative Regulations
4. Improving IT Systems
5. Reorganizing Pharmacy Benefits Program
6. Reforming the Role of the VA Office of the Inspector General in Contracting

1. Increasing Clinician Input

Coalition members report that there is a lack of clinician input in the VA procurement process. For example, for MSPV-NG, the Strategic Acquisition Center (SAC) establishes IDIQs and BPAs based on requirements developed in consultation with the procurement and logistics arm of the Veterans Health Administration (VHA). Clinicians apparently provide input in some instances, though there is a lack of transparency regarding these decisions and members are concerned that the awards are primarily based on price, rather than best value for veterans' healthcare. A lack of clinical input will lead to an incomplete formulary, which causes supply shortages and may require facilities to directly purchase items. Likewise, input by clinicians into the selection of drugs and biologics for the National Formulary is not transparent and there are impediments to drug company representatives providing information to VA medical professionals regarding clinical aspects of non-formulary drugs. By comparison, as discussed below, the Department of Defense (DoD) has a process for formulary

decision-making that includes input from manufacturers and representatives of Tricare beneficiaries and publication of the basis for the Pharmacy and Therapeutics Committee recommendations. Additionally, there is no visibility into the process for transitioning care from DoD to the VA, including integration with DoD clinicians, to ensure the VA is providing access to products based on their effectiveness and appropriateness and not just low cost.

Recommendations:

- Create an office (similar in function to Pharmacy Benefits Management (PBM) and Prosthetics and Sensory Aids Service) which is responsible for providing clinician input to the MSPV-NG
- Streamline the VHA procurement bureaucracy to allow clinicians to have more input in ordering—including, as suggested below, streamlining and merging the acquisition functions of the VHA and OALC.
- Provide greater transparency in clinician's product recommendations similar to the PBM

2. Centralizing VA Procurement Operations

The decentralized nature of the VA's procurement operations at the VA headquarters level and within the Veterans Health Administration (VHA) leads to significant inefficiencies and delays in the delivery of healthcare products and services to veterans compared to the commercial market.

VA procurement offices, like the Strategic Acquisition Center and National Acquisition Center, report to different management offices at VA headquarters leading to duplication, and a lack of coordination and consistency in how healthcare products and services are purchased by the VA. Currently, many VA suppliers invest in contracting with the VA through both the Federal Supply Schedules (FSS) program and the Medical/Surgical Prime Vendor (MSPV) program for the same products. Consolidating the operations and leadership of these programs would lead to greater consistency and drive process improvements that would reduce costs for contractors. Reduced operational costs will allow for increased healthcare services for veterans.

Recommendations:

- Streamline and centralize the VA's acquisition operations--move the NAC and the SAC into the same organization. Additionally, the VA should merge the acquisition functions of the OALC and the VHA in order to streamline the procurement process. Coalition members remain concerned that clinician input (which comes from VHA) is divorced from contracting decisions made by the NAC and the SAC.
- Develop standard operating procedures for the MSPV-NG and VAFSS programs with the goal of reducing acquisition lead times, developing greater consistency in requirements and interpretations of policies/procedures, adding new products to contract, streamlining

solicitations and awards

- Increase transparency and communications by:
    - Improving coordination and shared internal and external communications from the NAC and SAC
    - Establishing an Industry Liaison or ombudsman within each program to respond to general questions, refer contractors to appropriate VA resources, raise issues of concern with leadership
    - Establish standard processing times for the completion of modifications
- Update the Priority for Use of Government Supply Sources to provide greater clarity to both VA purchasers and contractors
- Extend VAFSS contract term to 5-year contracts with three 5-year option periods consistent with GSA Schedules to streamline processes for government and industry
- Additionally, the VA's should establish additional national contracts with Ordering Officer Delegation (OOD). Currently, only two national contracts have OOD; the lack of this capability forces contracting to a local level resulting in a slow process.

3. Streamlining Unnecessary and Duplicative Regulations

The current VA regulatory environment for procurement is overly burdensome and complex. Coalition members report that contract actions on the VA Schedules can take as much as three times longer than comparable actions on the GSA Schedules. While these regulations and long delays represent a significant burden for industry (including Veteran-Owned Small Businesses), the VA's contracting workforce must also devote significant resources to compliance with certain regulatory requirements. Most importantly lack of a streamlined process fails to ensure that high quality products and services are available to veterans as quickly and efficiently as possible.

Recommendations:

- Eliminate the Price Reductions Clause (PRC). While the Coalition has consistently advocated for the removal of the PRC from the Schedules program, the need to remove the PRC is particularly evident for Schedule 65 I B Drugs, Pharmaceuticals, & Hematology Related Products, since the Veterans Health Care Act already controls the price of covered drugs. Ultimately, the PRC's only one regulation which is unnecessary and duplicative. The VA Regulatory Reform Officer, in compliance with Executive Order 13777 "Enforcing the Regulatory Reform Agenda," should be given the appropriate resources, particularly staff, to complete a thorough review to identify other unnecessary practices to eliminate and/or reform.
- Create a FSS Program Office housed within GSA which would include VA acquisition professionals on detail. The office would ensure the alignment of GSA and VA/MAS policies, increase productivity, and reduce cycle time. The FSS Program Office would also be responsible for

resolving differences between the VA and GSA on key regulatory and policy matters. The Coalition has identified several areas where the VA and GSA have different policy interpretations including: (i) negotiating for lowest price, considering terms and conditions, (ii) negotiating for products versus product lines, and (iii) the approach to resellers.

4. Improving IT Systems

There has been significant attention given to the VA's electronic health records, but there are other IT systems which are in dire need of updates to support a better healthcare system for veterans. For example, the VA needs updates to its IT systems that handle basic business functions such as billing, claims, payment, and contract administration. An IT system that collects information on the VA's supply chain utilization is also essential to identifying what the VA is purchasing, and how improvements can be made over time. Outdated IT systems and manual processes lead to unnecessary delays and inefficiencies in the VA healthcare system.

Recommendations:

- For the FSS program, leverage existing resources of the GSA such as e-offer and e-mod, which will reduce contracting time at the NAC. When administering the VA Schedules, the VA should focus on healthcare for veterans and leave FSS administrative matters to GSA.
- The VA should establish an integrated IT system to support supply chain management. This system would be essential to resolving issues such as late payments and product shortages and better inform the VA about purchasing trends and behaviors.

5. Reorganizing the Pharmacy Benefits Program

DoD, in managing its pharmaceutical benefits program, permits clinical input from industry and beneficiaries during a transparent decision-making process that considers clinical and cost effectiveness of products. Ultimately, decisions focus on clinical/therapeutic attributes, as well as price. Additionally, DoD posts the basis for its decisions on a public website. Further, a Beneficiary Advisory Panel holds public meetings to comment on formulary recommendations before they are finalized including the effect on patients if prescribed medication will no longer be as accessible, for example if conditions are imposed on their use. New drugs are considered for formulary placement within a set time after coming on the market to ensure products are timely reviewed and those available through military treatment facilities are purchased. Additionally, DoD manages blanket purchase agreements (BPA) for pharmaceutical agents on its formulary through a class review process in order to leverage market forces. Coalition members remain concerned about the VA's formulary process, which less structured
than in DoD. The VA's process could be strengthened by implementing a similar process, while

increasing clinician input and improving outcomes for veterans. Finally, veterans receiving care remotely may not be able to easily travel to a VA facility to receive a prescription. Integrating retail pharmacies would resolve this issue and provide a better outcome for veterans.

Recommendations:

- The VA should modify their formulary process by creating an effective, efficient, and integrated pharmacy benefits program modeled after the DoD program (see 31 CFR § 199.21). Additionally, the VA should allow for manufacturer input and engage in frequent and effective communication with industry—for example DoD allows for manufacturer input in the decision- making process, will post the minutes from its meetings on their website, and has defined decision-making criteria.
- Another important aspect of DoD's process for procuring pharmaceuticals is that they will compete BPAs for agents that are added to the formulary, thereby taking advantage of volume discounts and market forces. The VA should adopt this model and issue a class deviation on the Multiple Award Schedule ordering procedures in FAR 8.405-3 to streamline the process for creating single award BPAs for pharmaceutical agents on the formulary. The Coalition raised this issue in 2011 when the MAS ordering procedures were proposed, and we believe that the VA would benefit from revisiting it.
- New drugs should be reviewed for addition to the formulary within six months after they are available commercially.
- Veterans receiving care remotely should not have to obtain their initial prescriptions from a VA facility, which could be many miles away, or through mail order, which could take two weeks. Allowing retail pharmacies to dispense initial prescriptions of 30-days while requiring refills of maintenance drugs through mail order. VA should implement a process that complies with Veterans Choice and ensures immediate access to needed medication without overburdening the beneficiary.

6. Reforming the Role of the VA Office of the Inspector General in Contracting

The VA OIG plays a crucial role in detecting waste, fraud, abuse within the VA and is essential to protecting the interests of veterans in the VA's care. However, the OIG's role in contracting is overly expansive, which, ultimately, leads to significant delays. Veterans may wait months in order to receive innovative products and pharmaceuticals. This is particularly true in the case of mandatory pre-award audits, which often must be repeated. GSA, which administers the Schedules program, does not require pre-award audits.

Recommendations:

- Eliminate the OIG's pre-award and post-award audit functions for the VA Federal Supply

Schedules (FSS). The administrative and pricing review functions can be completed by the contracting officer. The OIG should focus its efforts on investigating cases of suspected fraud related to the VA supply chain. Additionally, this would eliminate any potential conflicts of interest.

- Transfer pricing support staff to the National Acquisition Center (NAC). Members report that contract award and modification times at the NAC are at an all-time high—preventing veterans from accessing new and innovative products and discouraging veteran-owned companies from participating in the FSS. Transferring these staff to the NAC and removing the OIG's audits function will significantly speed up the process

Attachment 2

The Core Issue: VHA needs a Clinically Led and Managed VHA Program Office

Background:

- Medical devices are highly regulated and frequently very complex devices, which lead to specific medical outcomes in the hands of the surgeon or clinicians and often have variations in cost of use. Commercial hospital systems recognize these complexities, and create oversight organizations that are permanently staffed with individuals with both clinical and medical supply chain expertise to evaluate medical devices and make product decisions that result in optimal outcomes and best value for their patients and clinicians across their hospital system
- Industry supports and encourages VHA to follow the commercial models which represents 98-99% of the US market vs 1-2% for VHA, and make enterprise level decisions through their Program Office for medical devices to improve efficiencies for both VA and industry, however the overwhelming concern of the medical device industry as well as VAMCs is that the VHA Program Office is neither clinically led nor staffed with experienced medical supply professionals. *It is roughly the equivalent of trying to fly an airplane with individuals who are not pilots*

Problems that the current VHA Program Office creates:

- The absence of relevant expertise to lead the program has led to many challenging issues:
    - The NG-MSPV program was created without proper leadership from VHA, and instead was created by individuals unfamiliar with medical devices. It has been recognized as a total failure and costly to VA. Examples include:
        - *Naïve to sheer size and effort of task*: VHA did not recognize the level of complexity and the challenge of competing requirements for a med-surg PV catalog. A process that a commercial organization (like the GPO Premier) with all the key experienced clinical staff in place, would take four years to execute, was approached by VHA to complete in only a few months
        - *Poor procurement strategy by VHA:* VHA Program Office was unfamiliar with established medical product categories, and elected to compete individual line items rather than recognized product category suites, resulting in significant product suite gaps and confusing product mixes that did not meet the needs of VHA clinicians. When VHA later attempted to create product categories, they developed ones that were hospital departments (Exam Rooms, OR Supplies, Central Supplies, etc) rather than product categories industry would recognize and respond to
        - *Unrealistic goal to restrict medical products to only highest volume products:* VHA decided to severely restrict the number of lines on formulary that did not adequately support clinical care, eliminating critical product sizes needed by clinicians

- *Low price approach*: VA used a single award based on lowest price for most of the MSPV awards, resulting in products that were not acceptable to clinical users and also awards that did not take into consideration other factors such as:
    - Award for medical disposables that were lowest price but did not function with existing medical equipment at VAMCs
    - Award for medical disposables that did not factor that VAMCs would incur additional costs as other disposable products would need to be used with the awarded product, resulting in higher cost in use for VA
    - Award for medical product that did not factor total costs to VAMCs, such as construction costs for the change
- *Lack basic understanding of medical supply chain*: VHA was unaware of very basic medical supply chain structure that while many medical products are available through med-surg distributors, there is a significant number of medical devices that are only available direct from manufacturers, which led to VA SAC spending significant contracting time, dollars, and effort to create solicitations for the direct only products that manufacturers would not respond to as it was inconsistent with the commercial model. VA also created unrealistic goals for procurement through MSPV based on this lack of knowledge that VAMCs could never meet
- *Confused by medical products*: Many solicitations were posted that reflected that medical products confuse VHA, such as an ENT catheters posted in a Urology Supply solicitation.

Negative Impact to VA and Industry

- *VHA clinician satisfaction*: Clinicians at VAMCs are very unhappy with current product availability and access, as it impacts the ability to perform medical procedures, often resulting in cancellations, and also consumes valuable VHA nursing time trying to find and source products. This impacts veteran access and satisfaction with VA Medical Centers, and physician/nurse retention
- *VAMCs opinion of the VHA Program Office and their decisions is very low*: VAMCs are very aware and vocal that the VHA Program Office lacks the clinical and medical supply chain experience, which they view as being less than exists at their own VAMCs, and consequently ignore many of the decisions from Program Office as it fails to meet their needs
- *Purchase card use*: VAMCs are using government purchase cards at an increasing rate as needed products are no longer available from the MSPV, increasing costs but also increasing the very real risk of gray market and/or counterfeit medical device purchases outside of the secure medical supply chain (MSPV), and ongoing problem for VHA for a number of years
- *Industry opinion of VHA*: Industry is experiencing "bid fatigue", and has occurred significant costs in trying to respond to solicitations that are poorly developed and then cancelled. Industry extremely concerned about lack of resolve from VHA leadership to correct and lead the program

The Solution

- *Create an Effective VHA Program Office*: An effective VHA Program Office would be staffed in similar fashion to other federal agencies that manage medical products: have a clinical leader and clinical staff, mixed with experienced medical supply chain professionals, and preferably all these individuals would have experience working within the VA system and have knowledge of the unique processes. Models to replicate would be DHA MedLog, which is the med-surg equivalent for DoD and is led by a critical care nurse, and staffed with seasoned medical logisticians and nurses who have actually worked in Military Treatment Facilities. The VA PBM is a good VA example of what a program office should look like, led by a pharmacist and staffed with clinicians who have experience working in VAMCs. *Common elements of a good federal medical program office:*

- **Leader is a clinician (RN, pharmacist, or MD) who has also worked in a VA/DoD medical center and familiar with VA/DoD medical supply chains**
- **Staffed full-time with other clinicians and medical supply chain professionals (logisticians), who have also worked in a VA/DoD medical center**
- **VHA needs to create career paths for medical supply professionals to insure VHA has a bench of qualified individuals to work at the national Program Office level, similar to how DoD develops medical supply professionals**

Attachment 3

August 8, 2017

Phil Christy
Acting Executive Director, Office of Acquisition Operations
Department of Veterans Affairs
810 Vermont Ave NW
Washington, DC 20420

Subject: Solicitation for MSPV- Next Generation

Dear Mr. Christy,

The Coalition for Government Procurement appreciates the Strategic Acquisition Center (SAC) publication of draft solicitations for the Next Generation Medical/Surgical Prime Vendor (MPSV) program and the opportunity for industry to provide feedback in response. We would like to submit the following comments on the MSPV solicitations on behalf of our member companies.

The Coalition for Government Procurement (The Coalition) is a non-profit association of firms selling commercial services and products to the Federal Government. Our members collectively account for more than $145 billion dollars of the sales generated through government contracts including the GSA Multiple Award Schedules (MAS) program, VA Federal Supply Schedule (FSS), the Government-wide Acquisition Contracts (GWAC), and agency-specific multiple award contracts (MAC). Coalition members include small, medium, and large business concerns that provide more than $12 billion worth of pharmaceuticals and medical/surgical products to support healthcare needs of our nation's warfighter and veterans. The Coalition is proud to have worked with Government officials for more than 38 years towards the mutual goals of common sense acquisition and support for our veterans.

Based on our member companies extensive experience with medical device supply chains in both the government and commercial sectors, and also consistent with feedback member companies have heard from VA Medical Centers, many believe the current MSPV-NG program formulary is being driven through a process that may actually result in significantly less use of the MSPV. Rather than the VA developing a program designed to meet the clinical end-users needs which creates efficiencies and reduces VA system costs, the NG-MSPV program is

being driven by government contracting goals that do not reflect the reality of effectively managing medical devices. Our concerns include the following:

- Lowest price technically acceptable (LPTA) source selection
- A lack of consistent and effective clinician input
- Risks associated with grey market items

We appreciate your attention to these matters impacting the efficiency and effectiveness of the medical and surgical supply chain and the quality of healthcare for veterans.

Lowest Price Technically Acceptable Source Selection

The MSPV program seeks to deliver a national strategic sourcing solution that combines a formulary approach with electronic cataloging and ordering to support the Veterans Administration Medical Centers. The program relies on four Prime Vendor Contracts and supporting Indefinite Delivery-Indefinite Quantity (IDIQ) contracts with suppliers. Additionally, Section E.14 of the Request for Proposals (RFP) notes that the contract award for the IDIQ's will be determined in accordance with FAR 15.101-2, LPTA Source Selection Process. LPTA source selection procedures are being used in the RFP's for Patient Care Products, Urology, Respiratory Products, Medical Imaging Products, and many other hospital department level groupings.

Given the nature of these procurements, a LPTA source selection raises significant concerns. LPTA source selections are most effective in situations where unsuccessful contractor performance is minimal and where there is little value or need to pay for higher performance. Those criteria are not met in this situation. The SAC is procuring products that will be used in the care and treatment of our Nation's veterans—these are situations where the quality of the products is integral to the healthcare outcomes for our veterans. As such, an LPTA source selection is inappropriate. Further, products within these categories may be complex devices with unique features that differentiate them from a clinical perspective, or that reduce overall cost of care, making comparative clinical and cost effectiveness a more appropriate standard.

Section E.14 of the RFP's for Patient Care Products, Urology, Respiratory Products, and Medical Imaging Products also directs offerors to provide tiered pricing information based on unit volume. Additionally, offerors may be subject to a Unit of Measure adjustment (calculated at 4.4%) based on the Unit of Issue. This pricing approach ignores commercial practices where vendors usually sell products as packages or cases, rather than individual units.

We recommend that the VA reconsider its use of LPTA selection criteria for these and future MSPV solicitations, and instead focus on a program that is based on best value decisions with clinician input.

Clinician Input in the MSPV

Coalition members remain concerned about the level of clinician input in the MSPV program. There have been several issues which seem to be contract-driven, rather than clinician-driven.

The practice of awarding by line item rather than the standard commercial practice of awarding contracts by a coordinated suite of products 1) leads to inefficiencies with VA and industry contracting, 2) challenges industry with the basic recognition of the solicitations as individual product codes are buried in unfamiliar groupings, and most important, 3) concerns for the practice of medical care by end-users. Awarding different medical products within a suite of products may require additional training for VA medical staff for each product code to ensure appropriate use, increasing time on already stressed medical staff and potentially increasing safety risks by increasing variation. Robust clinical oversight during the requirements development would correct this issue and be aligned with the best practice of contracting by a coordinated suite of products.

Many products that are proprietary were posted under the Brand Name or Equal solicitations, even though there are no equivalents. These will include a number of products that are disposable components for capital equipment located at VAMCs, and using other disposables will typically not work with that equipment, may invalidate the equipment warrantee, or could cause patient harm. We believe that these items, if there was robust clinical input, would have been place in the Brand Name Only designation.

Additionally, products are being placed under improper categories. For example, a Coalition member identified an ear, nose, and throat product was posted under the urology category. Although this issue has been rectified, the Coalition remains concerned that the products and categories of the contract are not properly aligned. Duplicate product codes are also being uncovered in totally different solicitations (example: same product code listed in Medical Imaging and also in OR Supplies). This would be resolved if contracted by coordinated suites and product categories, rather than line item by hospital department.

We recommend that the SAC immediately incorporate clinician input into their contracting process, including individuals with robust medical supply chain experience. A model that the SAC could emulate is the Department of Defense (DoD) pharmaceutical formulary process (see 31 CFR § 199.21). The DoD Pharmacy and Therapeutics Committee assures that the selection of agents for the formulary is based on broadly representative professional expertise concerning clinical and cost effectiveness of products within the pharmaceutical agent class. The Committee's decisions and minutes are posted publicly, and industry is given the chance to provide their input and feedback to the Committee. This process ensures sufficient clinical input for the DoD formulary in assessing clinical differentiators and cost tradeoffs as well as identifying errors in category assignments. There should be a permanent organization in the VA responsible for ensuring clinician input, which is crucial to the MSPV's success.

Grey Market Items

The Coalition supports the SAC's efforts to prohibit grey market items from being sold through the MSPV-NG via unauthorized resellers. The MSPV solicitations include a definition of grey market goods that we recommend be modified consistent with commercial practice. Section B of the solicitation defines a grey market good as, "genuine branded goods sold outside of an authorized sales-territory (or by non-authorized dealers in an authorized territory) at *prices lower than being charged in authorized sales territories* [emphasis added] (or by authorized dealers)."

Instead, we recommend the following:

> *The Contractor shall provide only new equipment and new parts for the required products described herein. ABSOLUTELY NO "GREY MARKET GOODS" shall be provided under any Delivery Order. Grey Market Goods are defined as genuine branded goods sold outside of the manufacturer's authorized. Grey market goods purchased from unauthorized sources have left the authorized supply chain and may not be stored in conditions that meet the manufacturer's specifications, and medical devices could be counterfeit or adulterated which pose a threat to patient safety. Grey market items will typically invalidate a manufacturer's warranty. All Equipment must be covered by the manufacturer's warranty.*

We recommend that the "grey market good" definition be modified to remove the reference to price and to provide some rationale as to why grey market items are prohibited for delivery orders. Grey market items may have a lower price or a higher price than the price of items sold within the authorized medical supply chain. Unauthorized resellers could purchase the product from an authorized distributor and then resell to the government at a higher price. The price of an item does not relate to whether it is a grey market good or not. The revised "grey market goods" definition above also emphasizes the risk to patient safety of purchasing outside of an authorized distributor network and potential invalidation of the manufacturer's warranty.

In summary, the Coalition recommends that the SAC:

1) Reconsider use of LPTA source selection criteria for the MPSV RFP's. Instead we recommend a program based on best value decisions and clinician input.
2) Incorporate more clinician review into the MSPV RFP's. The Coalition has identified several aspects of the RFP's including the unit of measure adjustment and the groups that may not be supported by clinicians.
3) Host a meeting between the SAC, VHA, and industry, so that stakeholders can discuss the process for clinician input and identify solutions.
4) Create a permanent office that is responsible for delivering clinician input. This process could be modeled on DoD's pharmaceutical formulary process.
5) Revise the definition of grey market items as proposed.

Thank you for considering the Coalition's comments concerning the Next Generation MSPV.

If there are any questions, please contact me at (202) 331-0975 or rwaldron@thecgp.org.

Sincerely,

Roger
Waldron
President

Attachment 4

November 9, 2017

Brian C. Love
Contracting Officer, MSPV 2.0
Strategic Acquisition Center (SAC)
Department of Veterans Affairs
10300 Spotsylvania Ave, Suite 400
Fredericksburg, VA 22408

Dear Mr. Love,

The Coalition for Government Procurement appreciates the opportunity to respond to the Department of Veteran Affairs (VA) October 19, 2017, Request for Information and Statement of Objectives (SOO) seeking information about the capability, capacity, and viability of US businesses that provide product supply chain end-to-end management. VA is considering options for the next iteration of its current Prime Vendor program for medical surgical supplies and equipment.

The Coalition for Government Procurement (The Coalition) is a non-profit association of firms selling commercial services and products to the Federal Government. Our members collectively account for more than $145 billion dollars of the sales generated through government contracts including the GSA Multiple Award Schedules (MAS) program, VA Federal Supply Schedule (FSS), the Government-wide Acquisition Contracts (GWAC), and agency-specific multiple award contracts (MAC). Coalition members include small, medium, and large business concerns that provide more than $12 billion worth of pharmaceuticals and medical/surgical products to support healthcare needs of our nation's warfighters and veterans. The Coalition is proud to have worked with Government officials for more than 38 years towards the mutual goals of common sense acquisition and support for our veterans.

VA would like to improve the quality, effectiveness and efficiency of its medical/surgical prime vendor program by using best commercial practices and technology. To achieve these objectives, the Department is examining the possibility of a single contractor that would provide VA worldwide, a turn- key solution, for a one-stop-shop acquisition platform for medical supplies, equipment, and related products. As we read the notice, VA is anticipating that the potential contractor would:

A. Determine what the agency would buy

i. "…be responsible for developing a medical surgical supply and equipment formulary for each facility in VA …"

B. Acquire the items
   i. "…provide strategic sourcing..."
C. Manage and distribute the items
   i. " …life cycle management, distribution, inventory management…"
D. Administer contracts and assure quality control
   i. "…analysis services, quality control/quality assurance support services, warranty management services, and
E. Provide for electronic ordering, invoicing, and real-time status.

These services would be provided using an e-commerce platform that incorporates best business practices.

Coalition members support VA's objectives related to aligning the acquisition of medical/surgical products more with commercial best practices and increased efficiency. Before, however, we can realistically assess MSPV 2.0, there are a number of important questions that VA must address. Those questions are set forth below. Without answers to these questions, Coalition members are concerned that VA's vision could negatively impact the ability of government suppliers to adequately respond to the healthcare needs of veterans. The Coalition values opportunities for continued discussion with VA on these questions.

1. Is the MSPV 2.0 vision based on a viable commercial model?

Despite the expansive involvement of our member companies in the market for commercial items, our members question whether there is an existing commercial provider that can deliver the extensive scope of services described in the FBO notice for medical supplies and equipment.

VA's current prime vendor program supports more than 9 million veterans. An initiative that moves to a new, commercially untested e-commerce platform should be undertaken only in increments, after a series of periodic evaluations, over a period to time. To do otherwise risks failing the healthcare needs of veterans.

Prior to launching MSPV 2.0, the Coalition recommends that the SAC:

a. Identify through what channels the medical and surgical products considered for the program are purchased in the commercial market (recognizing that they are bought through different pathways, not just one)
b. Align the VA's purchasing strategy with these commercial practices
c. Coordinate with the program offices that are already contracting for these products, ensuring that there is no duplication of effort

We also recommend that the VA consider following the VHA's pharmacy/prosthetics/logistics working group as a model, which determines the responsibility and management for specific products. A MSPV/equipment/direct working group could be established to coordinate the efforts between the responsible program offices.

2. **Does the Veterans Health Administration (VHA) have a clinically led and managed program office that will determine which products will be acquired through MSPV 2.0?**

Coalition members note particularly that there is a lack of clinician involvement in determining what products are included on the current MSPV-NG formulary and how such products are sourced. To date, VHA has not taken responsibility for its medical supply chain by establishing a clinician led and managed MSPV program office. Under the proposed model, how would the VA ensure that the prime vendor has the appropriate clinical staff to make formulary decisions that prioritize patient outcomes? How would the VA ensure that formulary items are NOT being selected by business people based on business decisions?

The Coalition is concerned that under the current proposal, financial incentives rather than a focus on patient outcomes will drive the program. There is also concern that without the program being led and managed by clinicians at VHA, many of the same challenges with the current MSPV program will continue into the next iteration.

3. **Should "medical equipment" items be excluded from the formulary given that, commercially, they are sold direct from manufacturers and not through distributors?**

VA mentions that medical equipment items will be included in the Formulary. These types of products are typically purchased direct from manufacturers and not sold through distributors in the commercial market. Many equipment items such as Ventilators have various software options and accessories that are purchased with the equipment in a customized manner. Meaning that each particular end user customer could ask for a unique configuration of software options and accessory items. In addition, the VA has a Non-Expendable Medical Equipment program that would seem to conflict with including equipment items in a MSPV formulary.

4. **Are some of the functions contemplated for the contract, inherently governmental?**

The United States has been the long-standing policy that inherently governmental functions shall not be performed by a contractor. FAR 7.5 lists examples of functions that have been considered as inherently governmental. Those examples include processes that VA appears to contemplate contracting out, specifically:

- Determining what supplies or services are to be acquired by the Government
- Approving any contractual documents, to include documents defining requirements, incentive plans, and evaluation criteria
- Awarding contracts
- Administering contracts

- Determining whether contract costs are reasonable, allocable, and allowable

VA should examine its proposal and statement of objectives to assure that it will not outsource inherently government functions to a contractor.

5. Does the VA proposal establish an organizational conflict of interest that cannot be mitigated?

FAR 9.502 states that "[a]n *organizational conflict* of interest may result when factors create an actual or potential *conflict* of interest on an instant contract, or when the nature of the work to be performed on the instant contract creates an actual or potential *conflict* of interest on a future acquisition'.

The vision for MSPV 2.0 assigns one entity responsibility for decisions on what to buy, how to buy and contract administration. As described, the entity has total control over the system without any readily discernible checks. What prevents for example, a contractor from selecting products for formulary based on its commercial relationships?

The MSPV 2.0 approach presumes that further consolidation of the MSPV program is desirable. There is some thought that this approach is flawed. There is value to competition. Distribution is a commercial activity and there are many competent players at a regional or sub-regional level. Rather than leverage that competition, VA's MSPV 2.0 vision cedes disproportionate market power to one firm. If that contractor has difficulty performing, it would be very difficult to terminate and bring in a new
provider. Fewer choices is not in the interest of the VA facilities.

Over time, vesting too much authority into a single contractor is not good for government or its supplier base. The downside of consolidating that much authority into one entity is that it enables the contractor to control not only the federal market, but also to leverage federal suppliers in ways that may be detrimental. Will bargaining power between the suppliers and prime vendor be so distorted that the prime vendor will be able to influence not only federal but commercial business? For example, will the supplier fees be consistent with the 3% rate in the commercial market for medical devices?

6. Will MSPV 2.0 address compliance with underlying procurement policy?

The SOO does not offer guidance as to how fundamental procurement policies will be addressed. For example, must suppliers comply with the requirements of the Trade Agreement and Buy American Acts and who will determine compliance? Must prices be determined fair and reasonable and if so who will do so – VA or the Prime vendor? Will the small business "Rule of Two" be adequately considered?
Would it be the PV's responsibility to comply and how would they do so?

7. How will disputes between suppliers and the prime vendor be resolved?

Our members are concerned that conflict of interest concerns may drive disputes with the prime

vendor both in selecting items for formulary and handling future orders. Will a supplier have any ability to challenge these issues or others arising in the acquisition process?

Is the agreement between the supplier and prime vendor a federal or a commercial contract? Does VA envision such matters to be totally between the commercial parties or will the Government have a role?

8. **Does the e-commerce platform adequately protect government and contractor data?**

The draft SOO includes a requirement for a metrics dashboard and the ability to provide analytics to assess performance, supply chain costs, and forecast market expectations. Who would own the data generated in the electronic system? Will the prime vendor be required to provide sales tracings to suppliers consistent with commercial practices for medical devices? How will this data be protected?

Is the contractor able to also sell product through the program? Can they use/access this data to gain an unfair advantage in the government or commercial marketplace?

9. **Is a "requirements" type contract appropriate in this instance?**

The SOO (section 5.2.1) states the government intends to issue a single requirements contract using FAR parts 15 and 16. A requirements contract would obligate VA to filling *all* actual purchase requirements of the government during a specified contract period from one contractor. VA estimates that there will be 86.4 million patient care events in 2018. Given the broad scope of potential users of this acquisition platform, it would seem very difficult for VA to adequately police it users to ensure *all* orders go to the
contractor. "Leakage" from the contract could result in significant liability to the government.

10. **Has VA considered the impact of its cost objectives on innovation?**

A significant objective for the MSPV 2.0 is cost savings. How will cost savings be measured – lowest price or best value (medical outcomes, supply chain efficiencies, etc.)? Will the contractor or government be responsible for measuring such savings?

There is a potential for the contractor to limit innovation because the innovative product may be more expensive than current technology. Without sufficient clinician input, what incentive does a contractor have to offer more expensive new technology?

11. **What does the goal of a 95% usage rate for the "one-stop-shop" acquisition of consumable medical and related commodities described in 5.1.1 mean?**

VA has a goal for 95% of medical disposables to come through MSPV program. This goal may be

unrealistic depending on what medical products are considered within scope, as a significant portion of these products are available commercially only directly from manufacturers. It is unlikely that those manufacturers are going to change their commercial models for a customer that only represents 1-2% of US sales.

12. **Would the VA consider establishing separate contracts for direct only products?**

Again, the draft SOO states that there would be a 95% usage goal for the acquisition of consumable medical and related commodities. Much of this industry is direct only. It is not cost effective or efficient to stock them through distributors. VA should follow commercial model of establishing separate contracts. VA could use an Electronic Medical Catalogue (ECAT) like that used by the Department of Defense to facilitate ordering.

13. **What will be the drop shipping policy under MSVP 2.0?**

Will VA align more with the commercial market and establish contracts with manufacturers for direct- only products.

14. **Will prosthetics be excluded from MSPV 2.0?**

The variety of products and nature of procedures does not translate to MSPV purchase or delivery infrastructure. Although most cases are templated prior to surgery, the case often requires a change on the spot. As such, multiple sizes and types are made available to the surgeon during each case. This flexibility cannot be achieved by warehousing implants and having a single size/type delivered to the hospital on the date of surgery.

15. **The VA SAC would like access to the latest technologies under the formulary. What will the process be to add new products?**

Again, more clarification is needed as to how formulary decisions will be made. Members report challenges with the process to add new products under the existing MSPV-NG. What criteria will be used by clinicians to determine which products to add to ensure that veterans have access to the latest technologies?

16. **The draft SOO proposes a Period of Performance that could extend 12 to 15 years. What is the rationale for this timeframe?**

A performance period of 12 to 15 years far exceeds FAR limitations. Under FAR 17.204(e) the total period of base plus options "shall not exceed 5 years" in the case of services. For supplies, the base plus option quantities shall not exceed 5 years. These limitations do not apply to IT contracts. However, other statutes may further limit the contract term.

The performance period for the Pharmacy Prime Vendor contract is 8 years. Members would like

to better understand the SAC's rationale for a potential performance period of 12 to 15 years for MSPV 2.0.

17. **Would the VA further explain Performance Objective 5.1.6, which states, *"Allow maximum physician choice in consumable medical commodities, consistent with patient safety and enterprise-wide interoperability and standardization goals, used while maximizing cost saving possibilities?"***

Based on this statement, it appears that the VA program office and/or contracting personnel may view many technical medical devices as being commodities without recognizing the differences in brands that can impact patient outcomes. In addition, allowing maximum physician choice and having standardization goals appear to be two completely different initiatives. Further clarification on these points would be helpful.

18. **What are the implications of section 6.4 of the SOO that states, *"Only FDA approved Medical/surgical supplies that are compliant with Global Standard 1 (GS1), Health Industry Business Communications Council (HIBCC), and/or International Society for Blood Transfusion (ISBT) 28 standards will be available to VHA facilities through the MSPV program?"***

It is unclear whether the VA intends to exclude products from the formulary that do not meet these criteria/standards.

Again, the Coalition for Government Procurement sincerely appreciates the SAC's efforts to collect industry's input on the proposed next generation of the Prime Vendor program. We support better aligning the program with commercial best practices and ensuring that it is led and managed by clinicians at the Veterans Health Administration. Significant progress in achieving both objectives will result in more efficiencies and cost savings in the delivery of best value medical and surgical supplies to VA facilities worldwide.

Thank you for considering industry's input in designing MSPV 2.0. We look forward to working with the VA as it continues to explore options for building the next iteration of the Prime Vendor program.

Sincerely,

Roger
Waldron
President