THE COALITION
for Government Procurement

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