

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 publically 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