THE COALITION
for Government Procurement

June 3, 2019

Anna Zinser
Contracting Officer
Office of Procurement
Veterans Health Administration
810 Vermont Ave NW
Washington, DC 20420

Subject: Industry Best Practices for Establishing Commercial Agreements

Dear Anna,

The Coalition for Government Procurement ("the Coalition") sincerely appreciates the dialogue that the Department of Veterans Affairs (VA) has engaged in with industry concerning the upcoming MSPV 2.0 program. As the VA plans for the implementation of MSPV 2.0, we would like to share some additional information with you concerning industry best practices for the establishment of commercial agreements between distributors and suppliers.

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 $10 billion of dollars of Federal healthcare spending, including more than 40 percent of the spending on the VA Federal Supply Schedules (FSS), and manufacture more than 70 percent of the products on the MSPV formulary. Coalition members include small, medium, and large business concerns. The Coalition is proud to have worked with Government officials for 40 years towards the mutual goal of common-sense acquisition.

It is our understanding from the May 15, 2019 Industry Day, that the VA's market research indicates that commercial agreements between Prime Vendor distributors and Original Equipment Manufacturers (OEMs)/Suppliers can be established within 60 days. Our members report, however, that this can only be achieved in limited circumstances. Specifically, executing medical supply price loads for *existing* authorized distributors can be done by OEMs within 60 days.

However, **if the VA awards MSPV distributor contracts to distributors who do not have existing distribution agreements with OEMs, then the process to authorize those new distributors by OEMs will take a minimum of 3 months, and possibly as long as 6 months.** We believe that this is most likely in situations whereby new distributors are awarded via set-asides under the MSPV 2.0 Prime Vendor RFP.

Authorized Distributor Approval Process

To provide insight on the requirements for a new distributor to become an authorized distributor by an OEM, the following steps are requirements that are critical to patient safety and a robust medical product supply chain that cannot be bypassed:

1. Potential distributor completes application to become authorized distributor for OEM
2. Application received by OEM and reviewed, approved/denied
3. Credit check of distributor performed by OEM risk management team for approval/denial
4. OEM completes site visit to potential distributor to:
    a. Discuss EDI requirements
    b. Review anti-counterfeit policy
5. Security background check completed by both OEM and external security firm, including site visits by both
6. Distribution contract negotiated and executed between OEM and distributor
7. EDI set up and testing
8. Price books delivered
9. Contract pricing details shared
10. Inventory initial order determination and placement

Medical devices need to flow through supply channels that are secure. These processes are necessary to ensure both the safety and uninterrupted flow of critical medical products that will be used to support veterans' healthcare.

We strongly urge that the VA consider these safeguards, and respect these processes when creating timelines for industry under the MSPV 2.0 program.

Questions

Further, there are some critical questions that we ask the VA to clarify for industry in the final MSPV 2.0 solicitations.

1. What are the VA's expectations regarding the OEM/distributor relationship? How would SDVOSBs/VOSBs take ownership/title of products?
2. If drop shipments are the exception (as described during the May 15th Industry Day), how will ownership of a product be handled?
3. In the May 15th Industry Day, the following bullet was provided as part of the Evaluation Procedures discussion:
    - Comparative analysis (FAR 13.106-2 (b) (2) with clinical input

    However, we did not find specific reference to clinical input at FAR 13.106-2 (b). Therefore, clarification would be extremely helpful for industry concerning the following:

        a. We understand that quote evaluations will be based on clinical utility, price, and past performance. What is "clinical utility"?
        b. Will VHA clinicians participate in the evaluation of supplier quotes – if so, it is our understanding that the VA should identify these clinicians and state how

they are qualified to review specific categories of products under the legislation passed by Congress in December 2018.

4. Under the tiered proposal evaluation process, will the VA require two bids for any particular Manufacturer (OEM) brand products to satisfy the Rule of Two provisions and award a BPA?
5. What if after cascading is completed, there is just one response where a small business can provide the products at a fair and reasonable price, then will the VA choose that one small business or does there need to be two per the Rule of Two?
6. If clinical choice is deemed the most important factor for patient safety and veteran clinical benefit and second is the SDVOSB/VOSB Supplier, what happens if the SDVOSB/VOSB and OEM partnership changes after the Supplier BPA award? Would the default be for the OEM to supply the product or would another SDVOSB/VOSB need to be identified to replace the original SDVOSB/VOSB? Or does that OEM product simply fall off the formulary? If so, then how is the clinical choice met?

Realistic timeframes for distributors and OEMs/suppliers to establish commercial agreements, consistent with standard commercial practices, is critical to the establishment of a safe and secure medical supply chain for our nation's veterans under the MSPV 2.0 program. Therefore, we respectfully request that the VA provide at least 3 to 6 months for the establishment of these commercial agreements.

Again, we sincerely appreciate the continued dialogue on the future of the MSPV program. If you have any questions, I may be reached at (202) 315-1053 or rwaldron@thecgp.org.

Best regards,

Roger Waldron
President

CC: Andrew Centineo, Executive Director, Office of Procurement and Logistics
Rick Lemmon, Executive Deputy Chief Procurement Officer
Spencer Roberts, Director, Healthcare Commodities Program Office