B.2 STATEMENT OF WORK

Section I. Background

A. Background

- 1. The U.S. Department of Veterans Affairs (VA), Veterans Health Administration (VHA) manages the United States' largest integrated healthcare system, providing care at 1,243 healthcare facilities, including 172 medical centers and 1,062 outpatient sites of care of varying complexity (VHA outpatient clinics), serving approximately 9 million enrolled Veterans each year. The healthcare system receives the majority of medical and surgical supply support through the Medical/Surgical Prime Vendor (MSPV) program.
- 2. MSPV will utilize Prime Vendor (PV) contracts for distribution and supply management services. Facilities will order from the MSPV Product List, which will be formed by awarding Blanket Purchase Agreements (BPA) to Original Equipment Manufacturers (OEM), suppliers, and authorized resellers of medical/surgical supplies (referred to as "Authorized Suppliers" herein).
 - a. Any suppliers and resellers who participate in MSPV must be authorized to provide the supplies by the OEM. An Authorized Distributor Letter from the manufacturer shall be included with the response. See Section III.A Supply Services for additional parameters.
- 3. This procurement will establish multiple BPAs in direct support of the MSPV Program. This procurement is a key element in the success of the program as the BPAs will provide the mechanism that will supply an estimated 49,000 medical/surgical supplies for distribution to VHA facilities located in the United States (US) and US Territories and Other Government Agencies (OGAs) as identified by VA (referred to as "facilities" herein). The MSPV Product List will include all supplies awarded under BPAs.

B. Scope

- 1. The objective of this procurement is to establish BPAs for Dialysis medical/surgical supplies for nationwide usage. VHA aims to ensure availability and consistency of medical/surgical supplies and to obtain volume-based, standardized pricing. VHA desires to continue the practice of achieving cost avoidance while simultaneously balancing clinician considerations for obtaining quality medical/surgical supplies.
- 2. The response to this solicitation will include proposed pricing for medical/surgical supplies the Offeror wishes to provide to the government that are aligned to Dialysis. Supplies aligned to this category, and product descriptions, can be found in DIALYSIS QUOTE SHEET v4.1. Offerors may propose supplies from their respective catalogs they wish to provide to the government that fit within the scope of the respective product category, excluding any supplies already covered under the AbilityOne Procurement List. For a proposed supply item, for which the government has received multiple quotes across multiple product categories, the government will make the determination of a single product category for evaluation and award. Only supplies proposed under that product category will be evaluated and considered for

- award. Offerors are encouraged to submit quotes across all applicable categories to ensure their quotes are evaluated in the correct category.
- 3. An open market BPA will be established between the Authorized Supplier and the government under the terms and conditions incorporated in this BPA. This BPA does not obligate any funds and there is no obligation for the Government to purchase orders against this BPA.
- 4. Covered medical/surgical supplies eligible for order under MSPV are defined as medical, surgical, dental, and laboratory supplies excluding supplies already covered under the AbilityOne Procurement List.
- 5. Awards will be modified as additional supplies move through the evaluation process.
- 6. This BPA shall be administered by the VHA Office of Procurement and its assigned Contracting Officer(s) (CO).

C. Federal Acquisition Regulation (FAR) Requirements under FAR 13.303-3

- 1. Extent of Obligation: It is contemplated that purchases for medical/surgical supplies will be placed through the PVs.
- 2. Purchase Limitation: Purchases for medical/surgical supplies will be placed with the PVs. Although there are currently no plans for the government to order against this BPA, if that occurs, there is a \$500,000 individual order limitation.
- 3. Individuals Authorized to Purchase Under the BPA: Purchases for medical/surgical supplies will be placed through the PVs. Should it be necessary for the government to order against this BPA a list of authorized individuals will be provided.
- 4. Delivery Tickets: Purchases for medical/surgical supplies will be placed through the PVs. Should it be necessary for the government to order against this BPA, the delivery tickets or sales slips shall contain the minimum information outlined in FAR 13.303-3(a)(5).
- 5. Invoices: It is contemplated that purchases for medical/surgical supplies will be placed through the PVs.

D. Type of Contract

- 1. BPAs will be awarded under this Statement of Work (SOW) will have a total Period of Performance (POP) not to exceed 60 months.
- 2. This BPA does not obligate any funds.
- 3. An annual review of all BPAs will be conducted by the government to include a review of terms, conditions, and pricing.
- 4. The Government reserves the right to cancel or terminate a BPA.

Section II. MSPV Business Processes

A. Commercial Agreements

1. The Authorized Supplier awardee is required to enter into a commercial agreement with all awarded PVs, who will provide national distribution and supply management

services to facilities, in order to participate in MSPV. The commercial agreement will govern the terms and conditions of the PV and Authorized Supplier relationship and will not contradict the underlying terms and conditions established by this BPA or the underlying PV contracts. Failure to comply with the terms of this BPA, including provisions related to commercial agreements, will be considered cause for cancellation of the BPA. Authorized suppliers may also want to consider pursuing a Distribution and Pricing Agreement (DAPA) with Defense Logistics Agency (DLA) to support VAMCs supported by DLA.

- 2. If the Authorized Supplier is awarded a BPA prior to the award of the PV contracts, the Authorized Suppliers and PVs are required to form commercial agreements within 60-calendar days from the award of the PV contracts. If the Authorized Supplier is awarded a BPA after the award of the PV contracts, the supplies offered by the respective Authorized Supplier will be released on an updated MSPV Product List. An updated MSPV Product List will be released every 30-calendar days. PVs and Authorized Suppliers are required to form commercial agreements within 60-calendar days of the respective MSPV Product List release.
- 3. If Authorized Suppliers are awarded BPAs prior to the award of the PV contracts for MSPV, the government will notify Authorized Suppliers of the names of PVs as soon as possible to enable formation of commercial agreements.
- 4. Authorized Suppliers are responsible for establishing commercial agreements. Either PVs or Authorized Suppliers may initiate a commercial agreement. The terms and conditions outlined in the commercial agreement must be mutually agreed-upon by both parties. Once a commercial agreement is established between an Authorized Supplier and a PV, the Authorized Supplier will notify the VHA Office of Procurement via email to vhavamspvsupcontroff@va.gov and include the name of the Authorized Supplier and the PV. One email may contain details on multiple commercial agreements.
- 5. The commercial agreements prescribed in this section are solely between the PV and VHA Authorized Suppliers and do not involve the Government as a responsible party.

B. **Pricing**

- 1. Supply pricing established in BPAs between the Authorized Supplier and the government will be made available to PVs; PVs will use this exact price plus the distribution fees agreed upon between the PV and VA to invoice VA for PV distribution and supply management services.
- 2. The Authorized Supplier BPA-holder shall not charge the PV awardees more than the prices set forth in the BPA.
- 3. All quotes provided by the Authorized Supplier as part of the solicitation response shall remain valid for 180 calendar days after close of the solicitation.
- 4. The BPA unit of measure data field for each individual line item approved for inclusion in MSPV (case, box, each, vial, etc.) represents the shipper quantity that the BPA holder agrees to sell to any PV for the purpose of distribution to facilities. All BPA prices are Free on Board (FOB) Destination. Therefore, the BPA price shall include all attendant order processing, materiel handling, and transportation costs

incurred by the BPA holder. BPA holders are not authorized to unilaterally assess added handling and freight charges against the servicing PV unless there is an emergency request and the customer agrees to incur and pay separately the additional delivery charges.

C. **BPA Modification**

1. BPAs can be modified for Supply Recall, Policy Changes, Price Changes, Supply Additions and/or Removals. All modifications will be based on Government needs.

2. Supply Recall and Policy Changes:

- a. A BPA modification shall be made for any supply recall or policy change that applies to a supply on a BPA under this solicitation. Such instances may include, but are not limited to, a supply that is removed or recalled by the Authorized Supplier or manufacturer due to defects in the supply or potential dangers to patients, or if any required modification, removal or recall is suggested or mandated by a regulatory or official agency (e.g., FDA).
- b. BPA modifications for recall or policy change will happen on an infrequent, as needed basis.

3. Price Changes:

- a. The BPA holder or the government can additionally initiate a price increase or reduction on supplies under this BPA to result in a modification.
- b. BPA modifications for price will be made on a quarterly basis.
- c. The BPA holder may request changes to BPA pricing by contacting the respective CO for this BPA or by sending an email to vhavamspvsupcontroff@va.gov.
- 4. **Supply Addition or Removal:** BPAs may also be modified to add or remove supplies from the MSPV Product List.
 - a. New supplies may be proposed to the government at the discretion of Authorized Suppliers. Any new supplies proposed must be vetted and reviewed by the appropriate clinical Integrated Product Team (IPT) when they have availability. Any new supplies proposed must fit within the scope of the PV Program and the respective product category. The government will make the final determination as to whether a supply is within scope.
 - b. Supply additions may be initiated by sending an email to vhavamspvsupcontroff@va.gov.
 - c. If a supply is no longer available, it shall be immediately removed from the MSPV Product List.
 - d. BPA modifications reflecting supply additions and removals will occur on a quarterly basis.
- 5. The MSPV Product List will be updated to reflect changes after BPA modifications are complete.

- 6. All regulatory requirements applicable to the original BPA will apply to any change/modification.
- 7. The BPA holder may request modifications by contacting the respective CO for this BPA or by sending an email to vhavamspvsupcontroff@va.gov.
- 8. If any of the BPA holder's responses to the required representations/certifications change at any time after the BPA has been approved, the BPA holder shall immediately submit an email outlining these changes to the respective CO for this BPA or by sending an email to vhavamspvsupcontroff@va.gov.
- 9. If any supply awarded under this solicitation requires modification, is removed or recalled by the Authorized Supplier or manufacturer due to defects in the supply or potential dangers to patients, or if any required modification, removal or recall is suggested or mandated by a regulatory or official agency, the Authorized Supplier will notify the CO or by sending an email to whavamspvsupcontroff@va.gov and the MSPV Program Manager Vicky Fuller-Allen, Vicky.Fuller-Allen@va.gov, in writing, by the most expeditious manner possible. The notification shall include, but not be limited to the following:
 - a. Complete supply description and/or identification, call numbers from customers, and the BPA line item number assigned.
 - b. Reasons for modification(s), removal or recall.
 - c. Necessary instructions for return for credit, replacement or corrective action.
- 10. A copy of the modification notification described above shall additionally be provided to:

Manager, Product Recall Office National Center for Patient Safety Veterans Health Administration 24 Frank Lloyd Wright Drive, Lobby M Ann Arbor, MI 48106

11. The Authorized Supplier shall additionally provide the information above to all PVs participating in MSPV.

D. Data Transmission

- 1. The Authorized Supplier must ensure that data transmission method and format to PVs are through any system that conforms to the X12 Electronic Data Interchange (EDI) v5010 formats established by the Accredited Standards Center (ASC) and chartered by the American National Standards Institute (ANSI). The X12 EDI website http://www.x12.org) includes additional information on EDI 810 and 811 formats.
 - a. EDI is the computer-to-computer exchange of business documents in a standard electronic format between business partners. By moving from a paper-based exchange of business document to one that is electronic, VHA receives benefits such as reduced cost, increased processing speed, reduced errors and improved relationships with business partners. Electronic format

means an automated system transmitting information electronically according to accepted data transmissions using a system that conforms to the X12 EDI formats established by the ASC chartered by ANSI. For more information see the X12 EDI Web site (http://www.x12.org).

Section III. Work Requirements

A. Supply Requirements

- 1. The Authorized Supplier shall provide an uninterrupted supply and delivery of medical/surgical supplies to all PVs participating in MSPV at an enterprise/nationwide level (reference *Appendix C: Veterans Integrated Services Networks (VISNs)*).
- 2. Medical/surgical supplies are those that are involved in the diagnosis and treatment of disease and the maintenance of health (usually through nonsurgical means). They are characterized as one or more of the following:
 - a. Primarily and customarily used to serve a medical purpose
 - b. Generally, not useful to a person in the absence of illness or injury
 - c. Usually ordered and/or prescribed by a physician and/or a health care professional
 - d. Medical supplies utilized in conjunction with durable medical equipment are included if the supplies are necessary for the function of the equipment
- 3. Surgical supplies are those involved with the branch of medicine which generally treats disease or injury by operative intervention (physical means rather than drugs); i.e., operations requiring access to the inside of the body as well as manipulation from outside the body.
- 4. If the potential Authorized Supplier is not the OEM, the Authorized Supplier must provide an Authorized Distributor Letter from the OEM <u>signed within the last 90 days</u>. The Authorized Distributor Letter from the OEM shall include for each product(s) proposed authorizing the Offeror as a distributor for the proposed product(s). The letter must either state specific product(s) proposed or that the Offeror is an authorized distributor for all of the manufacturer's products. This letter must be on the manufacturer's letterhead and contain the signature of an authorized official for the manufacturer and <u>cover the duration of the BPA</u>. The Authorized Supplier shall maintain its Authorized Distributor status of all manufacturers and distributors of supplies throughout the life of this agreement as set-forth in the Authorized Distributor Letter referenced above. Failure to do so will result in cancellation of the BPA.
- 5. The Government reserves the right to request information from Authorized Suppliers related to supply descriptions, pricing, or other topics at any time and the Authorized Supplier is required to provide such information.
- 6. This language is not generated to inhibit the PV or facilities from ordering supplies already on any other designated Government contract instrument. VA's Strategic Acquisition Center (SAC) and the VHA Office of Procurement will ensure that supplies are placed on appropriate catalogs/Product Lists from which facilities may order. It is however, incumbent on the PV to honor the parameters of the contract scope of work. Where apparent conflicts arise, the CO will make the final

- determination as to whether a supply is or is not within scope. The PV must consult with the CO prior to shipping any supplies which do not clearly fall within the parameters of the above defined scope of work for PV.
- 7. The Government reserve the right to remove any supply from the MSPV Product List upon 30-calendar days' notice, resulting in modification of the BPA.

B. Gray Market

1. The Authorized Supplier shall be an OEM authorized dealer, authorized distributor, or authorized reseller for the proposed equipment/system such that the OEM warranty and service are provided and maintained by the OEM. All warranty and service associated with the equipment/system shall be in accordance with the OEM terms and conditions. The Authorized Supplier shall provide new supplies ONLY; no remanufactured or "gray market" supplies. All supplies must be covered by the manufacturer's warranty.

C. Trade Agreement Act Requirements (applicable to Large Business)

- 1. Supplies offered by the Authorized Supplier should be compliant with the Trade Agreements (TA) Certificate, found at 52.212-3. End-products offered shall be manufactured or substantially transformed either in the United States or in a designated country. The BPA holder at the supply level must certify as follows in accordance with the TA Certificate:
 - a. The Offeror certifies that each end product, except those specifically listed, is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled "Trade Agreements."
 - b. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation.

D. **Deliverv**

- 1. The Authorized Supplier shall deliver supplies in accordance with "Normal", Expedited, "Just-In-Time (JIT)", drop shipment, and consignment delivery methods as outlined in commercial agreements between the PV and the Authorized Supplier.
- 2. All BPA holder deliveries shall be FOB Destination.
- 3. The Authorized Supplier shall deliver supplies to the PV in line with established commercial agreements.

E. Orders

1. No orders are placed against the BPA. The PV places orders based on their commercial agreements with BPA holders. The sole purpose of the BPA is to identify the products, prices, and sources.

F. **Drop Shipments**

1. The Authorized Supplier can provide supplies directly to facilities through drop shipments, rather than through PV distribution. Drop shipments are ordering facility-

- authorized shipments made on supplies that a manufacturer does not normally distribute through a PV but makes available for order and delivery directly to the facility. Authorized Suppliers shall identify if supplies are available only via drop shipment as part of the solicitation response.
- 2. Requirements for drop shipment supplies will be outlined in commercial agreements, including delivery time, order accuracy, fill rate, shelf life, and others.
- 3. Supplies delivered via drop shipment to facilities shall only be delivered to facilities with at least six months shelf life remaining upon delivery to the ordering facility. For those supplies which have an initial expiration date/shelf life of six months or less, at least 75% of the original shelf life shall remain at time of delivery to the ordering facility.
- 4. Facilities will place the order through the PV. The PV will then place the order with the Authorized Supplier within one hour and provide an Order Confirmation to the facility within one hour of order placement with the Authorized Supplier.
- 5. The PV is responsible for invoicing VA for drop shipments; it is not the responsibility of the Authorized Supplier.
- 6. Once shipped, the Authorized Supplier shall provide tracking information to the PV.

G. Terms and Conditions

- 1. No purchases are made against this BPA.
- 2. A Non-Manufacturer Rule (NMR) individual waiver was obtained for this RFQ, pursuant to 13 CFR § 121.1204.
- 3. The agreement, including supplies, prices, and other terms and conditions, is public information and is releasable under the Freedom of Information Act (FOIA). Procurement related information, shall be treated as confidential and shall not be disclosed except as required by applicable laws and regulations.
- 4. All Small Business Offerors shall be certified in the System for Award Management (SAM) (www.sam.gov) as a small business under North American Industry Classification System (NAICS) code 339113.
- 5. All Offerors who wish to qualify as an SD/VOSB and/or a VOSB must be certified by the VA Center for Verification and Evaluation (CVE). Additional information and the certification process can be found on https://www.va.gov/osdbu/verification/.
- 6. The Authorized Supplier shall provide written notice to the VHA CO mail group vhavamspvsupcontroff@va.gov of any changes related to the company or the supplies offered under its BPA. Changes include, but are not limited to, change in company information, including contract administrator, company name, address and phone number.

H. Authorized Representatives

- 1. The primary CO for this Agreement is: Bradley S. Davis
- 2. The Primary Contracting Officer's Representative (COR) for projects under this Agreement will be delegated by writing by the CO if needed at a later date.

Appendix A: Acronyms

ANSI American National Standards Institute

ASC Accredited Standards Center

BPA Blanket Purchase Agreement

CO Contracting Officer

COR Contracting Officer's Representative
CVE Center for Verification and Evaluation
DAPA Distribution and Pricing Agreement

DLA Defense Logistics Agency

EDI Electronic Data Interchange

FAR Federal Acquisition Regulation

FDA Federal Drug Administration

FOB Free on Board

FOIA Freedom of Information Act

GS1 Global Standard 1

GSA General Services Administration

HIBCC Health Industry Business Communications Council

HUB Historically Under-utilized Business

IFF Industrial Funding Fee

IPT Integrated Product Team

ISBT International Society for Blood Transfusion

JIT Just-In-Time

MedPDB Medical Product Data Bank

MSPV Medical Surgical Prime Vendor

NAC National Acquisition Center

NAICS North American Industry Classification System

NMR Non-Manufacturer Rule

OEM Original Equipment Manufacturer

OGA Other Government Agency

POP Period of Performance

PV Prime Vendor

QSR Quarterly Sales Report

RFQ Request for Quote

SAC Strategic Acquisition Center

SAM System for Award Management

SDVOSB Service-Disabled Veteran-Owned Small Business

SOW Statement of Work

TAA Trade Agreement Act

VA U.S. Department of Veterans Affairs

VHA Veterans Health Administration

VISN Veterans Integrated Services Network

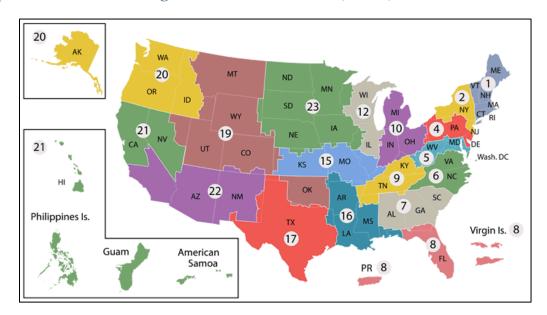
VOSB Veteran-Owned Small Business

Appendix B: Product Categories

- APPAREL/TEXTILES/GLOVES
- CENTRAL SUPPLY STERILIZATION SOLUTIONS & SUPPLIES
- DENTAL EQUIPMENT & DENTAL SUPPLIES
- DIALYSIS
- EAR/NECK/THROAT & AUDIOLOGY
- EMERGENCY MEDICAL SERVICES SUPPLIES AND EQUIPMENT
- ENDOSCOPY SUITE
- ENVIRONMENTAL SERVICES
- IMPLANTS
- IV & IRRIGATION SUPPLIES
- LABORATORY
- MEDICAL DOCUMENTATION
- MEDICAL IMAGING RADIOTHERAPY NUCLEAR MEDICINE & CATH LAB
- OCCUPATIONAL THERAPY/REHABILITATION/AIDS FOR DAILY LIVING
- OPERATING ROOM
- OPTOMETRY
- ORTHOPEDICS/PROSTHETICS & SPORTS MEDICINE
- PATIENT EXAM ROOM INSTRUMENTS AND SUPPLIES
- PATIENT MOBILITY/TRANSPORTATION/TRANSFER EQUIPMENT & AIDS

- PHYSICAL THERAPY
- PHYSIOLOGICAL & PSYCHOLOGICAL TESTING & MONITORING
- PODIATRY
- RESPIRATORY THERAPY & ANESTHESIA
- SAFETY DEVICES & SUPPLIES
- SYRINGES & NEEDLES
- UROLOGY SUPPLIES
- WOUND CARE PRODUCTS

Appendix C: Veterans Integrated Services Networks (VISNs)



- VISN 1 VA New England Healthcare System
 VISN 2 New York/New Jersey VA Health Care Network
- VISN 4 VA Healthcare
- VISN 5 VA Capitol Health Care Network
- VISN 6 VA Mid-Atlantic Health Care Network
- VISN 7 VA Southeast Network
- VISN 8 VA Sunshine Healthcare Network
- VISN 9 VA MidSouth Healthcare Network
- VISN 10 VA Healthcare System
- VISN 12 VA Great Lakes Health Care System

VISN 15	VA Heartland Network
VISN 16	South Central VA Health Care Network
VISN 17	VA Heart of Texas Health Care Network
VISN 19	Rocky Mountain Network
VISN 20	Northwest Network
VISN 21	Sierra Pacific Network
VISN 22	Desert Pacific Healthcare Network
VISN 23	VA Midwest Health Care Network

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