

Chapter VI: Other Than Full and Open Competition (OFOC) SOP  
Attachment 2: Request for Limited Sources Justification Format >\$150K

LIMITED SOURCES JUSTIFICATION

ORDER: \$150,000

FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: VA255-14-N-1918

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The item listed below in paragraph 3 is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source:

Manufacturer/Contractor: Sharps Compliance, Inc. of Texas

Manufacturer/Contractor POC & phone number: Diana Diaz, 713-660-3547

Mfr/Contractor Address: 9220 Kirby Drive, Suite 500 Houston, TX 77054

☒ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

Network Contracting Office NCO 15

3450 S. 4<sup>th</sup> Street

Leavenworth, KS 66048

VISN:

15

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

The proposed limited source action is for a firm-fixed-price (FFP) Veterans Affairs Federal Supply Schedule (FSS) delivery order for the procurement of Consumer Medication Mail-back Envelopes that meet the requirements of the Drug Enforcement Administration (DEA) final rule for return of controlled substances as published in the Federal Register Volume 79, number 174 on September 9, 2014. The required mailback envelopes shall be procured via Veterans Affairs FSS V797D-30040 under Schedule 65 II A "Medical Equipment and Supplies." The mailback envelopes are classified as a product.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

The proposed action is to purchase pre-paid envelopes to provide Veterans with a safe and responsible mechanism to return unused, unneeded medications to include legally obtained controlled substances using a secure method to a third party Drug Enforcement Agency (DEA) registered vendor with the status of "collector" for proper disposal. The following salient characteristics are required and must be in compliance with the DEA final rule:

- The package shall be nondescript and shall not include any markings or other information that might indicate that the package contains controlled substances;
- The package shall be water - and spill-proof; tamper-evident and tamper-resistant; tear-resistant and sealable;

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- The package shall be preaddressed with and delivered to the collector's registered address;
- The cost of shipping the package shall be postage paid;
- The package shall have a unique identification number that enables the package to be tracked;
- The package shall include instructions for the user that indicate the process for mailing back the package, the substances that can be sent, notice that packages may only be mailed from within the customs territory of the United States (the 50 States, the District of Columbia, and Puerto Rico), and notice that only packages provided by the collector will be accepted for destruction.

(b) ESTIMATED DOLLAR VALUE: \$6,227,706.18 (BASE YEAR) + 4 option periods = \$33,037,683.78

(c) REQUIRED DELIVERY DATE: TBD

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

☒ Specific characteristics of the material that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

Federal Acquisition Regulation (FAR) Part 8.405-6(a)(1)(i)(B): "Only one source is capable of providing the supplies required because the supplies are unique or highly specialized." Sharps TakeAway™ envelopes are the only products on the commercial marketplace that can meet the Hines VA CMOP requirement for medication return envelopes at the level of quality necessary because the supplies require specific regulations to be met by the Contractor. The regulations that need to be met by the Contractor are non-negotiable since they are required by the Veterans Health Administration (VHA) and also by the DEA. This means a qualified Contractor would have to meet all of the requirements set forth by the DEA final rule for proper return of medication/controlled substances and the regulations enforced by the VHA authority. Per the Federal Register (federalregister.gov): "With this rule, the DEA allows all pharmaceutical controlled substances collected through take-back events, mail-back programs, and collection receptacles to be comingled with non-controlled substances, although such comingling is not required. 21CFR 1317.65, 1317.70, and 1317.75. Pharmaceutical controlled substances collected by collectors may not be individually counted or inventoried. 21 CFR 1317.75. This rule also imposes various registration, security, and recordkeeping requirements."

☐ A patent, copyright or proprietary data limits competition. The proprietary data is:  
(If FAR 8.405-6(a)(2)iii before posting. Do not include specific proprietary data. Only mention the type of equipment, procedure, etc. to show that proprietary supplies or services are being procured.)

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☐ These are "direct replacements" parts/components for existing equipment.

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☐ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

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☐ The new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

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☐ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

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**(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:**

Based on market research and a Request for Information that was posted on FedBizOpps.gov on 10-1-2014, the TakeAway™ envelope patient medication return solution, manufactured by Sharps Compliance, Inc. of Texas, is the only Consumer Return Medication Envelope product that meets all of the requirements of the DEA final rule regarding mail based disposal of controlled substances (meeting these requirements is mandatory by law) and VHA regulations. Therefore, TakeAway™ envelopes are unique because they are the only product in the commercial marketplace that meet the mandatory requirement to have DEA certification. This brand name justification meets the exemption under FAR 11.105(a)(1), "Items Peculiar to One Manufacturer" because the required mailback envelopes have been determined to be essential to meeting the Government's requirement for a DEA certified mail based means for VHA patients to return unneeded pharmaceuticals, including controlled substances.

**(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:**

Market research was conducted along with a Request for Information and the results did not yield any additional sources that can meet the Government's requirements. There is no known competition for this acquisition due to the fact that Sharps Compliance, Inc. of Texas is the only Contractor who offers pharmaceutical mailback envelopes that meet the mandatory requirements set forth in the DEA final rule and VHA regulations governing the return of pharmaceuticals via mail. Maximum participation in this requirement was encouraged when an

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order for Medication Return Envelopes was awarded on March 9, 2015 for the Hines VA CMOP (Award #: VA770-15-F-0102), a Notice of Intent to Sole Source was published on March 3, 2015, and did not produce any respondents.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

N/A

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:

The Sharps Consumer Return Medication Envelope system is the only system that meets both the DEA and the VHA requirements for patient medication return and disposal. The Government will continue to conduct market research to ascertain if there are changes in the marketplace that would enable future actions to be competed.

(9) REQUIREMENTS CERTIFICATION: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

James J Hinspeter 418978

Digitally signed by James J Hinspeter, DN: cn=James J Hinspeter, o=Department of Veterans Affairs, ou=Department of Veterans Affairs, email=j.hinspeter@va.gov, c=US

James Hinspeter, Program Specialist COR  
Great Lakes CMOP #765

DATE

(10) APPROVALS IN ACCORDANCE WITH THE VHAPM, Volume 6, Chapter VI: OFOC SOP:

a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

John C. Fisher 629338

Digitally signed by John C. Fisher, DN: cn=John C. Fisher, o=Department of Veterans Affairs, ou=Department of Veterans Affairs, email=j.fisher@va.gov, c=US

John C. Fisher, Contracting Officer CMOP NCO 15

DATE

b. Director, CMOP Acquisitions/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Christine L SCENA 346512

Digitally signed by Christine L SCENA, DN: cn=Christine L SCENA, o=Department of Veterans Affairs, ou=Department of Veterans Affairs, email=c.scena@va.gov, c=US

16 April 2015

Christine L. Scena, Director CMOP Acquisitions

DATE

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c. Director of Contracting/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

**SCOTT R FISCUS 381888**

Scott R. Fiscus, Director of Contracting NCO 15

Digitally signed by SCOTT R FISCUS 381888  
DN: dc=gov, dc=va, ou=internal, ou=people, o=2342.19200300 100 1.1=scott.fiscus@va.gov, cn=SCOTT R FISCUS 381888  
Date: 2015.04.22 08:02:00 -05'00'

DATE

HIGHER LEVEL APPROVAL (Required For orders over \$650,000):

c. Director SAO Central Region: I certify the justification meets requirements for restricting consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

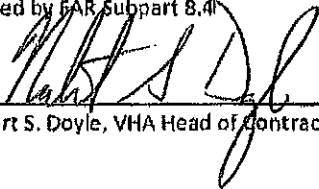
**Randy L. Hays 534204**

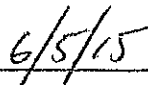
Ricky L. Lemmon, Director SAO Central Region

Digitally signed by Randy L. Hays 534204  
DN: dc=gov, dc=va, o=internal, ou=people, o=9.2342.19200300.100.1.1=randy.hays@va.gov, cn=Randy L. Hays 534204  
Date: 2015.06.04 08:54:48 -07'00'

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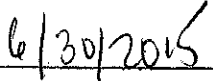
d. VHA HCA REVIEW AND APPROVAL (over \$650,000 to \$12.5 million): I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

  
Norbert S. Doyle, VHA Head of Contracting Activity

  
DATE

e. VA Deputy Senior Procurement Executive Approval (\$12.5 million not to exceed \$50 million): I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

  
for C. FORD HEARD  
Deputy Senior Procurement Executive (DSPE)

  
DATE