

JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Strategic Acquisition Center
10300 Spotsylvania Ave, Suite 400
Fredericksburg, VA 22408
2. Description of Action: The proposed sole source action is to establish a firm-fixed price (FFP) Indefinite Delivery Indefinite Quantity (IDIQ) contract with En-Vision America a Small Disadvantage Business, 825 4th St W. Palmetto Florida, 34221-5013 for Script Talk® Audible Prescription Reading Devices (APRDs) and accessory equipment. The anticipated period of performance is five years.
3. Description of Supplies: The requirement is to provide a standardized, source for APRDs. An APRD is a smart label reading system. It uses microchip technology and voice output. When a chip is implanted into a prescription container's label, a small decoder can be used to scan the container and produce a voice message for the user. The normal message includes the details of the user's prescription.

The following line items are required for this procurement:

ITEM NUMBER	DESCRIPTION	PART NO.
<u>1</u>	ScripTalk Station Prescription Reader (APRD with accessories) (HCPC: BA211)	00200-VA
<u>2</u>	ScripTalk 00220-SN 10K RFID Network Pharmacy Printer	00220-SN
<u>3</u>	Talking 2K Labels - Roll of 250 (Use only with 220-Z-Printer)	00210-0250R
<u>4</u>	Talking 10K Labels - Roll of 250 (Use only with 00220-SN)	00211-10K-250
<u>5</u>	Printer Wax Ribbon (Use only with 00220-Z-Printer)	00220-Z-RIBBON
	Misc. Accessories	

<u>6</u>	AC Power Cord (for Script Talk Station)	01-00201-E04
<u>7</u>	Carrying Case	01-00201-P26
<u>8</u>	Earphones	01-00201-P29

The total five year estimated maximum value of the proposed action is \$13,082,855.23.

4. Statutory Authority and Supporting Rationale: The statutory authority permitting other than full and open competition is 41 U.S.C. § 3304(a)(1) as implemented by 48 C.F.R, the Federal Acquisition Regulation (FAR) § subpart 6.302-1 entitled, "Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements ."

5. Rationale Supporting Use of Authority Cited Above: APRDs have been in use in the VA since 2002. Initially, use was limited to sites that had independently taken the initiative to implement these devices due to patient requests and need. A Clinical Practice Recommendation (CPR) completed in 2006 required that all eligible Veterans be provided an APRD.

Specifically, Scrip-Talk® uses text to speech capabilities which allow for uniform quality of speech output as well as speaking rate control and the option to have the information spelled out to the user. The device also offers the user volume control and additional privacy options when using the provided earphone jack.

In addition, En-Vision America ScripTalk® has the ability to integrate and is compatible with the VA's Computerized Patient Record System (CPRS). This is imperative to the success of full implementation of this initiative because the Veterans prescriptions are in CPRS. The integrated system minimizes duplication of efforts by pharmacists by directly coding the prescription label with the electronic text for computerized speech output instead of requiring the pharmacist to create a voice recording manually. This efficient automated process reduces errors and ensures uniform, complete information is provided to the patient.

The En-Vision America ScripTalk® system is the only talking prescription device which will meet the clinical needs of our patients, thereby precluding consideration of a product manufactured by another company.

Currently, VA has thousands of patients utilizing the En-Vision America ScripTalk® device at medical centers and outpatient clinics across the country.

The acquisition of the APRD will provide the following benefits to Veterans:

- Permits each patient to have immediate access to his or her detailed prescriptive medication information;
- Allows audible access with any medication container size using the RFID label;
- Increases Veteran options for privacy in regards to personal medication by utilizing the separate earphone jack;
- Decreases need for a provider/caregiver to assist the Veteran with his or her medications;
- Provides immediate information for purposes of reordering medications;
- Allows multiple language features and provides voice and speed adjustment for improved understanding;
- Allows national access without system variance from site to site; and
- Increases user safety through independent identification of medications.

6. Efforts to Obtain Competition: An Request for Information (RFI) was conducted on October 19, 2016. The two capability statements received under the RFI were reviewed and considered. The details are listed under section 8 of this document and in the market research document. This effort did not yield any additional sources that can meet the Government's requirements in an efficient and effective method. The proposed action will be synopsized on the Federal Business Opportunities in accordance with FAR 5.201. Any proposal received shall be considered and be evaluated as to the extent capable of meeting Agency needs.

7. Determination of Fair and Reasonable: The Contracting Officer will use the price analysis techniques in the FAR 15.404-1(b)(2) to determine that the proposed price is fair and reasonable. VA will independently develop, separate from the IGCE, a target price based on the lowest price in the market and discounts for VA volume and other factors, i.e., the "Target Price Range." The potential awardee will be required to justify increases over this price to satisfy Government determination that the offer price is "fair and reasonable.

8. Market Research: In accordance with Federal Acquisition Regulation (FAR) Part 10, market research was conducted to, arrive at the most suitable approach to acquiring Scrip Talk® APRDs and accessory equipment. Market research indicates the requirement is a commercial item as defined in FAR part 2.1 and readily available in the commercial market place. A review of Schedule 65II was conducted. The medical equipment listed under the schedule are not APRD's therefore they do not meet the APRD salient characteristics.

A (RFI) was posted to Federal Business Opportunities (FBO) on October 19, 2016. Two responses were received from the RFI: 1) AccessaMed, Inc. and 2) Third Evolution, Inc. Each response was reviewed and it was determined that neither response met the VA's medical requirements for the devices.

Review of Third Evolution, Inc. showed the vendor is an engineering and technology company. They have no products available to meet the requirement. The Vendor expressed they wanted to share information they received from the Foundation for Blind Children.

Review of AccessaMed, Inc. showed the device has a set volume and does not have the capabilities to adjust the voice speed and volume. Due to age related vision loss, many blind and low vision Veterans also experience hearing loss. When considering features to meet the needs of Veterans with multiple comorbidities, the APRD must allow the user options to manually adjust volume and voice speed. AccessaMed does not demonstrate these features. AccessaMed Inc. stated "there is no earphone capability on the device". They do not meet the separate earphone capability for increased privacy. The MTRs require an earphone jack to provide additional privacy options to blind Veterans. These privacy options allow for a blind Veteran to listen to his/her medication information via speaker or earphone.

In addition to the FBO posting, an internet search was conducted by the IPT. The IPT identified Talking Rx, which is a Millennium Compliance Corporation device and Digit-Eyes. Neither vendor is listed in the System for Award Management therefore a business size could not be determined during the internet search. Millennium Compliance® Corporation's Talking Rx® system would require VA pharmacists to record prescription information manually. Information would be limited by the size and shape of the containers. Manual input of prescription information would limit the pharmacists from providing uniform and complete information to the patients which does not meet the VA's needs. Talking Rx®, is fully compatible to the VA class 1 software systems.

Digit-Eyes is a software application that requires the use of an iPad and/or iPhone. Not all Veterans have access to such technology or the capacity to use an iPad or iPhone. Due to the requirement of a smart phone, this is not accessible to all our blind Veterans in need of an audible prescription reading device.

ScripTalk® is fully compatible to VA class 1 software systems. It has an integrated system that minimizes duplication of efforts by pharmacists to reduce errors and enhance outcomes. The ScripTalk® system by En-Vision America is the only product

that possesses the required features necessary to provide VA with accurate and complete pharmaceutical information electronically, is portable and has VA patient privacy features.

9. Other Facts: Scrip talk devices are approved and fully supported by the Office of Information and Technology.

10. A listing of Sources: AccessMed, Inc. and Third Evolution, Inc. has expressed interest in the requirement. Both vendors responded to the RFI but they did not meet the requirements of the request. Digit-Eyes and Millennium Compliance Corporation was reviewed by conducting an internet search. Neither companies express interest in writing.

11. Actions to Increase Competition: The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed.

12. Technical and Requirements Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.

Rodney B Hickson 588545

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Date: 2017.06.15 13:47:48 -04'00'

Rodney Hickson
Program Manager

Date

13. Contracting Officer Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.

LeShanna P
Calahan 131093

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LeShanna Calahan
Contracting Officer

Date

Approval

Based on the foregoing justification, I hereby approve the acquisition of brand name Envision America Script Talk® Audible Prescription Reading Devices and Accessory Equipment \$13,082,855.23, on other than fair and opportunity basis, pursuant to the authority cited in 38 U.S.C. on an other than full and open basis, pursuant to authority cited in 41 U.S.C. § 3304 (a) (1), 48 C.F.R., Federal Acquisition Regulation (FAR) FAR 6.302-1, Authorized by Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements, subject to the availability of funds, and provide that commodities herein described have otherwise been authorized for acquisition.

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Elegear Primus
Advocate for Competition
Strategic Acquisition Center

Date