

## JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION

Upon the basis of the following justification, I, as Contracting Agency Competition Advocate, hereby approve the use of other than full and open competition of the proposed contractual action pursuant to the authority of 41 U.S.C. 253(c)(1).

**Identification Number:** VA791-12-Q-0003

1. The Department of Veterans Affairs Denver Acquisition and Logistics Center (DALC) intends to enter into a national contract on the basis of other than full and open competition for the standardization of Audible Prescription Reading Devices (APRD) used by VA medical facilities.
2. The DALC is proposing a sole source, firm-fixed price Indefinite Delivery-Indefinite Quantity contract with En-Vision America for the Scrip Talk® audio prescriptive label reading device. These devices have previously been acquired from En-Vision under a Blanket Purchase Agreement against En-Vision's Federal Supply Schedule Contract: VA797-BP-0081, beginning April 1, 2008 and ending March 31, 2011.
3. The requirement is to provide a standardized, required 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. This type of device is needed due to the many Veterans that have difficulty reading or understanding the contents and the instructions of their prescriptions. This problem is exacerbated when patients are prescribed more than one drug and many VA patients are on multiple medications. The inability to read pill bottles can lead to dangerous conditions, e.g. taking the wrong pill at the wrong time, or taking an incorrect dosage, etc. This is particularly a problem among blind and low vision Veterans. The estimated value of this procurement is calculated at \$2,722,440.
4. The statutory authority permitting other than full and open competition is 41 U.S.C.253 (c)(1) as implemented by 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. 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. Currently, VA has thousands of patients utilizing the 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.
- Increases Veteran's privacy in regards to personal medication.
- Decreases need for a provider/caregiver to assist the Veteran with his or her medications.
- Provides immediate information for purposes of reordering information.
- Allows multiple language features.
- Allows national access without system variance from site to site.
- Increases user safety through independent identification of medications.

En-Vision America is the only company that has the features required by VA. Scrip-Talk® is the only system in which the information can be directly printed via a computer. Therefore, this is the only system available that can produce and address the variety and volume of labels necessary to meet the VA's requirements.

Another unique feature of the ScripTalk® system is that there is no requirement for a special medicine container. Pharmacies can print a label that can be affixed to any type of medical container, e.g. cough syrup or eye ointments.

In addition, ScripTalk® has the ability to integrate and is compatible with the VA's Computerized Patient Record System (CPRS); imperative to the success of full implementation of this initiative. The electronic record is the core element in an effective multi-site model which includes a multidisciplinary approaching the continuum of care. The CPRS system is covered by numerous VA regulations, bylaws and rules that recognize and control clinical privileges, scope of practice and hospital policies. The instruction of the scanning device is simple and can be done by physician and nurses in the primary care team.

Other desirable features are that the reader is portable, has an earphone jack for privacy, and has a rechargeable battery.

Given all of these reasons VA has made the medical determination that the ScripTalk® system is the only talking prescription device which will meet the clinical needs of our patients.

6. In February 2011, VA formed a multidisciplinary Integrated Product Team (IPT) including representatives from VHA Blind Rehabilitation Service, VHA Pharmacy Service, VA Denver Acquisition and Logistics Center, VHA Prosthetics and Sensory Aids Service, and a visually impaired stakeholder from the Blinded Veterans Association (BVA) to study contracting for APRDs. As the original BPA with En-Vision neared expiration, the same panel concluded that new market research needed to be conducted with all product providers to determine if advancements had been made since the original agreement with En-Vision was established. A Request For Information (RFI) was posted on Fed Biz Ops on March 10, 2011 with a closing date of March 21, 2011. The RFI informed potential interested vendors that the VA was holding an Industry Days for APRDs April 12 and 13, 2011 in Washington D.C. for the purpose of allowing vendors to give an informal presentation on their devices to the IPT. The Contracting Officer also sent an email with a questionnaire to those Federal Supply Schedule contractors that were identified as potential providers of audible prescription reading devices. This market research was conducted in April 2011. There were two responses, Millenium Compliance® Corporation and En-Vision America. Millennium Compliance® Corporation (Talking Rx®) sent in literature for review, but did not attend Industry Days. En-vision America (ScripTalk®) presented their product to the panel. As a part of the market research for APRDs, on April 13, 2011 the panel performed a more in depth review of the commercial audio devices available through FSS which appeared to be suitable for use within VA. As a result of this review the panel determined that ScripTalk® was the only product that met VA's medical requirements for this device. This determination led to preparation of a sole source request for ScripTalk® which was concurred upon by the Contracting Officer. Upon approval of this justification, the justification will be published along with the solicitation in accordance with FAR 6.302-1(c) and 5.102(a)(6).

7. The Contracting Officer determines that the anticipated price will be fair and reasonable, based on the anticipation that En-Vision will continue to provide Scrip-Talk® readers at a price representing a significant discount over their commercial and current Federal Supply Schedule contract pricing. The Program Office estimates that approximately 3,000 ScripTalk® readers will be ordered by VA medical centers annually, for an estimated annual contract value of \$680,610 per year. This procurement is planned to be a base year plus three one-year options to be exercised at the discretion of the VA. The total estimated value of the contract, including all options, is \$2,722,440. This is based on En-Vision's pricing to the VA under the previous BPA and represents a discount of approximately 17% from En-Vision's Federal Supply Schedule contract pricing.

8. Thorough market research was conducted to determine the number of potential suppliers of products that will meet the VA's needs. In addition to the FedBizOps posting, a request was submitted to Able Data, a company that provides objective information about companies that provide assistive living products. Able Data provided the Contracting Officer with the names of three other companies – E-Pill, LLC, Phillips Lifeline, and Thornsedale Software, which might have technology that could meet VA's requirements. Invitations to Industry Days sent to these companies were either declined or not responded to. In addition, an Internet search revealed another potential supplier, Wizard Software

Corporation. The Contracting Officer called this company and spoke with a representative who stated they no longer carry APRD devices and did not know of other companies who did.

9. 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. This would not meet VA's needs for pharmacy's staff to electronically input this information, and to provide uniform and complete information to the patients. Unlike Millennium Compliance® Corporation's Talking Rx®, 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. As outlined in paragraph 5, 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. In addition, ScripTalk® is the only system compatible with VA CPRS systems at this time. A new sole source agreement with En-Vision America for the continued procurement of ScripTalk® has the potential to increase the quality of life and independence of Veterans served by VA clinics nationwide.

10. No other sources have expressed an interest in this acquisition.

11. The VA will take the following actions to remove barriers to competition before a subsequent acquisition of prescription reading devices: Prior to exercising each option year, and before awarding a new contract at the expiration of this one, the VA will conduct diligent research, as was done prior to this request, to determine whether additional sources of this technology have become available.

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#### Certification

The information contained in this justification for other than full and open competition is certified accurate and complete to the best of my knowledge and belief.

#### Acquisition Initiator:

I certify that the facts and representations under my cognizance, which are included in this justification and which form a basis for this justification, are complete and accurate.



Acting BRS Director for Gale Watson

12-23-11

Signature

Date

#### Contracting Officer:

I certify that this justification is accurate and complete to the best of my knowledge and belief.



12/27/11

Signature

Date

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Reviews and Approvals

Senior Program Official (or designee):

I certify that the facts and representations under my cognizance, which are included in the justification and which form a basis for this justification, are complete and accurate.



Acting BRS Director for Gale Watson

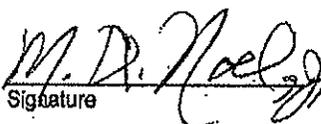
12-30-11

Signature

Date

Office of General Counsel:

I have reviewed this justification.

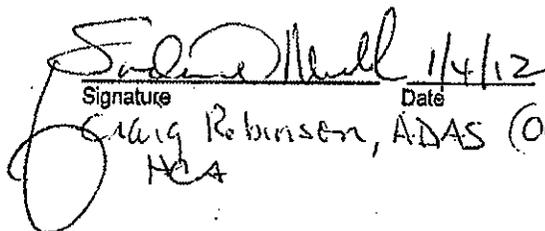
 12/30/11

Signature

Date

Activity Competition Advocate:

I have reviewed this justification and find it to be accurate and complete to the best of my knowledge and belief. Since this JOFOC does not exceed \$11.5 M, this review serves as approval.

 1/4/12

Signature

Date

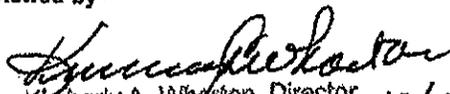
Craig Robinson, ADAS (00344)  
HCA

Justification for Other than Full and Open Competition

Audible Prescription Reading Devices

Concurrence and Summary

Reviewed by -



Kimberly A. Wherton, Director

12/22/11

Service Director's Name

Date

Title

Reviewed by -

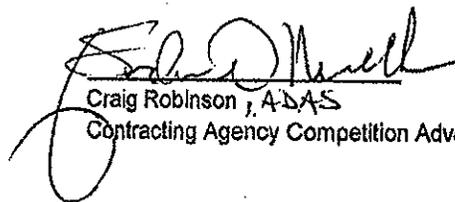


Attorney's Name

Date

Title Senior Contracts Atty.

Approved (X) Disapproved ( )



Craig Robinson, A.D.A.S.

Date

Contracting Agency Competition Advocate