

JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Technology Acquisition Center
23 Christopher Way
Eatontown, NJ 07724
2. Description of Action: This proposed action is for a firm-fixed-price contract for the procurement of a Sensitive Data Service (SDS) and associated support services.
3. Description of Supplies or Services: SDS is a Security Labeling Service (SLS) that is compliant with Health Level Seven International (HL7) standards, delivered as a cloud-based Software as a Service (SaaS). In accordance with 38 U.S. Code (USC) §7332, VA is required to obtain Veteran authorization to disclose information containing protected clinical conditions. The Office of Information & Technology (OI&T), Enterprise Project Management Office (EPMO) has a requirement for an SDS SaaS, specifically an externally hosted, commercial-off-the-shelf (COTS) service that is compliant with the HL7 Healthcare Privacy and Security Classification System (HCS). The HL7 HCS standard provides a means to categorize healthcare information by classification, sensitivity, integrity, and category, thus allowing application of proper handling instructions. HL7 is a not-for-profit, American National Standards Institute (ANSI)-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information. The HL7 standard is a clear and concise definition of VA's requirements for SDS. For this effort, the SLS Contractor shall provide an SDS as a hosted service, in addition to associated support services, which include planning, integration support, testing, and technical support that are required to facilitate VA personnel's secure integration of the EnableCare SDS SaaS into VA's Veteran's Authorization Preferences (VAP) system. The period of performance shall be a 12-month base period with two 12-month option periods. [REDACTED]
4. Statutory Authority: The statutory authority permitting other than full and open competition is 41 U.S.C.3304(a)(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. Rationale Supporting Use of Authority Cited Above: The proposed source for this action is EnableCare, 6240 135th Street, Suite 234, Overland Park, Kansas 66223. Based on extensive market research, as described in section 8 of this justification, it was determined that EnableCare's SDS is the only COTS SLS hosted solution that can meet VA's functional SLS requirements.

VA does not have an existing common mechanism in place to analyze documents based on the Consolidated Clinical Document Architecture (C-CDA) templates used

to exchange Veterans' records, automatically detect conditions protected by USC §7332, and to label those documents so that VA's existing authorization system can determine if the documents should be released. Therefore, VA must currently perform manual reviews of these documents for the protected conditions or obtain written authorization from each Veteran in advance of any disclosure. However, manual review of documents is a time-intensive process which imposes significant limits and delays on VA's ability to send Veteran health records to third parties providing direct Veteran care. VA currently receives one million requests for Veteran health records per year, but is only able to process 10% of these requests manually, resulting in significant delays in fulfilling these information requests. Veterans' ability to receive timely healthcare becomes delayed as a result of this manual review process, putting their health at risk. The proposed SDS SaaS will allow VA to achieve an approximate processing rate of 90% of submitted information requests for Veterans' health records.

EnableCare's SDS is the only hosted, COTS, HL7 compliant SLS solution currently available. The HL7 SLS standards establish a means of completing the complex task of properly classifying and handling sensitive healthcare information. As a hosted solution, it will allow VA to analyze C-CDAs, detect protected clinical conditions, and label documents from the beginning of the contract. These are all critical VA functional requirements that must be met. Only EnableCare's SDS solution is capable of meeting all of the Government's functional requirements for an existing externally hosted COTS solution that is compliant with HL7 SLS standards. Other sources do not offer existing HL7 SLS compliant solutions, which would require VA to fund development efforts. Therefore, they do not meet VA's requirement for a COTS solution that is currently available.

Additionally, only EnableCare offers an existing COTS SLS offered as a SaaS with a demonstrated capability of analyzing large numbers of documents that contain sensitive health information, thus meeting the VA functional requirement to accurately analyze clinical information. EnableCare started providing SLS to multiple non-VA clients using its proprietary SDS SaaS in 2011 and has analyzed and labeled over 50 million total transactions to date. As described in the market research paragraph below, other sources' solutions do not meet VA's requirements for an existing product, as they proposed multi-million dollar development projects to customize Business Process Management solutions achieve the same level of function as that of EnableCare's SDS.

Further, EnableCare is the only company with an existing SLS COTS tool (SDS) that is capable of being fully customized, allowing it to meet VA requirements to detect sensitive conditions in both coded (structured) and uncoded (textual and unstructured) information with real-time responses. Text and coded information includes diagnosis, medications, lab test orders and results, imaging studies and medical procedures. Codes often contain many complex terminology sets that are updated regularly and have varying usage by healthcare provider. In addition, EnableCare's SLS COTS tool (SDS) has the production ability to detect 38 USC §7332 protected conditions in both text and coded data.

Additionally the source code for SDS is proprietary to EnableCare. EnableCare is therefore the only authorized vendor that can provide the required support services associated with its SDS tool. No other source can provide the aforementioned support services, including planning, integration support, testing, and technical support-services which are required to ensure a secure integration with the VAP system.

6. Efforts to Obtain Competition: Market research was conducted, details of which are in the market research section of this document. This effort did not yield any additional sources that can meet the Government's requirements for an externally hosted, COTS SDS tool that is compliant with the HL7 HCS. There is no competition anticipated for this acquisition due to the proprietary nature of the proposed SDS solution. Additionally, the proposed action will be synopsized on the Federal Business Opportunities Page in accordance with FAR 5.201. Any proposals that are received shall be evaluated.

7. 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.

8. Market Research: A Request for Information (RFI) (VA118-17-N-1746) was issued on October 8, 2016 (revised on October 24, 2016) to the Federal Business Opportunities, General Services Administration (GSA), and Transformation Twenty-One Total Technology Next Generation websites, to ascertain if there were any other sources that could meet the Government's requirements. In each respective RFI, the Government requested capability statements from vendors that demonstrate their current ability to provide an HL7 compliant listing all of VA's functional requirements as outlined in section 5 of the Justification for Other Than Full and Open Competition document, cloud-based SLS COTS and associated support services. Furthermore, on February 13, 2017, a search was done on the Vendor Information Pages, specifically SLS under North American Industry Classification System Code 541512 as SLS is an emerging technology and the Government is requiring a COTS product that is also offered as a SaaS which means a company would have to have a mature product to be able to be implemented without development. This search yielded no results. The RFI closed on October 27, 2016; eight sources responded to the initial RFI which had been posted to FBO, GSA and T4NG. A total of 11 distinct vendors responded to the revised RFI (five responses from GSA, four responses from T4NG and two responses from FBO); however, only EnableCare's (FBO) response offered SDS, a cloud-based tool, and support services that met VA's requirements. A summary of the Government's technical experts' review of the incapable offerors is provided below.

Communication Professionals Inc. (GSA) - provided an overview of capabilities and references of previous Federal Government projects, but did not respond to the RFI questions. Therefore, the response did not provide a basis for technical review.

The proposal received from Project Managers, USA Inc. (GSA) – did not respond to RFI questions. The vendor's response also incorrectly identified the project as requiring access control and information security rather than the actual requirement for analyzing C-CDAs, detecting protected conditions and labeling the documents solution. The Government's technical experts determined that this vendor's response failed to provide a sufficient basis for technical review.

Two vendors, Favor TechConsulting, LLC. (T4NG) and Akira Technologies, Inc. (GSA), acknowledged that they currently do not have a product that can meet VA's needs. Each source separately proposed development projects to produce a new software tool to meet VA's needs. Based on technical review these responses, the Government's technical experts determined that neither vendor could meet VA's stated requirement for a currently available COTS tool.

Two vendors, Insignia Technology Services (T4NG) and Modus21, LLC. (GSA), acknowledged that they currently do not have a product that can meet VA's needs. Both proposed to implement COTS business process management (BPM) or adaptive case management (ACM) tools to deliver the SLS solution. Neither response demonstrated a current capability to implement an SLS. Based on technical review of each respective vendor's response, the Government's technical experts determined that a need for development of BPM/ACM tools did not meet VA's requirement for a SLS COTS solution that is currently available.

Goldschmidt and Associates LLC. (GSA), acknowledged that they currently do not have a product that can meet VA's needs. They proposed an analysis tool used for document indexing to improve search results that did not address the requirement to generate a Security Label. Therefore, the vendor's response failed to demonstrate an ability to meet VA's requirement for a SLS COTS solution that is currently available.

Booz Allen Hamilton, Inc. (BAH) (T4NG) acknowledged that they currently do not have a product that can meet VA's needs. They proposed a development effort with subcontractor, Jericho, based on an attribute based access control system which provides for "enterprise cybersecurity and fine-grained information sharing." Based on a technical review of this response, the Government's technical experts determined that the proposed development project did not meet VA's requirement for an available COTS SaaS HL7 compliant SLS service which analyzes C-CDA, detects protected conditions and labels the documents.

Edmond Scientific's (FBO) response proposed a software license rather than the required SaaS. Therefore, the proposal does not demonstrate that the vendor is capable of providing a currently available COTS SaaS SLS service that can meet all of VA's requirements as outlined in section 5 of the Justification for Other Than Full and Open Competition document.

Lastly, a response received from Ellumen (T4NG) proposed a prototype software requiring continued development to meet requirements. However, the proposed

prototype failed to meet requirements for analyzing clinical health information. Specifically, the prototype does not have the ability to detect uncoded (textual and unstructured) information or identify 38 USC §7332 protected conditions. Further the prototype is not offered as a service and does not meet all of VA's requirements. Based on technical review of this response, the Government's technical experts determined that the proposed development project did not meet VA's requirement for a COTS SLS offered as a SaaS that is currently available.

The Contracting Officer (CO) sent an email to each offeror on November 29, 2016 notifying them that the Government's technical experts reviewed their submissions and determined that they did not meet VA requirements. All vendors deemed incapable of meeting the Government's functional requirements for an existing externally hosted COTS SLS were afforded the opportunity to provide a response/rebuttal. Two rebuttal responses were received, one from Edmond Scientific and one from Jericho (the proposed subcontractor named in BAH's RFI response).

The Government's technical experts reviewed the supplemental response from Edmond Scientific and determined that the vendor's solution is predicated upon a security labeling service prototype which was developed under a VA contract. Edmond Scientific indicated it is currently exploring options to deploy the solution as a SaaS, highlighting the fact that they do not have an existing service. Further, the proposed solution would require an extended period of time for the vendor to operationalize the service, which fails to meet the requirement for provision of an existing and currently available COTS solution. Therefore, on December 7, 2016, the CO sent an email to Edmond Scientific notifying them that the Government's technical experts reviewed their revised submission and determined that the additional information did not meet VA requirements.

The Government's technical experts also reviewed the supplemental response from Jericho. The technical experts determined that the BAH/Jericho supplemental response failed to demonstrate that the vendor(s) possess an existing COTS product that meets the stated requirements of the PWS. The vendors' proposed solution is predicated upon the use of Jericho's Enterspace 9 and its embedded proprietary Data Labeling and Data Segmentation (DLDS) technology. The Government's experts determined that the proposed solution does not meet the requirement for providing a solution which will examine the structured and non-structured healthcare data in a C-CDA template based document and apply security labels to the document. Additionally the BAH/Jericho responses did not demonstrate the current capability of operating a required SaaS, as they were bereft of any references to providing a cloud service or addressing hardware requirements. Therefore, on January 10, 2017, the CO sent an email to BAH/Jericho notifying them that the Government's technical experts reviewed their revised submission and determined that the additional information did not meet VA requirements.

VA performed additional market research in December 2016. Specifically, research was conducted to determine if security labeling services available from either Oracle

or IBM would be capable of meeting VA's stated PWS requirements. This included internet searches and a review of each respective vendor's specifications. Based upon this research, it was determined that neither Oracle nor IBM has an HL7 compliant SLS; therefore, they were deemed not capable of meeting VA's requirements.

Based on the aforementioned market research results, the Government's technical experts determined that only EnableCare was capable of providing the required cloud-based SLS COTS tool. Additionally, only EnableCare can access the proprietary source code in order to provide the required support services and does not have any service-disabled Veteran-owned small business, Veteran-owned small business, or any other socio-economic group authorized reseller.

9. Other Facts: None.