

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID: VA260-16-AP-6874

1. **Contracting Activity:** Department of Veterans Affairs, VISN 20, Gastroenterology (GI) Program
2. **Nature and/or Description of the Action Being Processed:** This is a request for an enterprise-wide contract for the ProVation MD package which is an all-encompassing electronic procedure documentation software allowing a physician (General Surgeon, Gastroenterologist or Pulmonologist) to electronically document their procedure following the care of a patient. The cost to the government for this enterprise-wide solution will be on the order of [REDACTED]. Additionally, this software package is a Multi Care Giver where an element of the features allow for electronic nursing documentation which enables VA nurses to document pre-procedure, intra-procedure and post-procedure patient information. This enterprise-wide software system is will allow for increased quality, a reduction in time and errors, this will increase the validity and reliability of medical care in VISN 20. This project will be justified under a limited source contract action in an effort to standardize the same endoscopy reporting software at the VA and the academic affiliates, nationwide. VISN 20 affiliates such as; The University of Washington and Oregon Health and Sciences University, currently operate under this ProVation MD package and have proved to become more efficient care of Veterans, in these institutions, this improves the overall training and understanding of GI needs at the VA. The affiliate is using this for gastroenterology fellows and surgical residents rotating through the VA, having the system at the VA and our affiliates provides for systematic, reliable and standardization across VISN 20 medical centers to include affiliate partners.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for a software product in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2. This requirement will be procured as a Firm-Fixed Price contract.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** VISN 20 requires a GI clinical procedure documentation and coding system for 9 physical locations and 28 procedure rooms and emergency carts. The locations are Puget Sound (Seattle, Tacoma), Portland, Anchorage, Boise, Roseburg, Eugene, Spokane, and Walla Walla. The

number of workstations are Puget Sound (Seattle (5), Tacoma (2)), Portland (7), Anchorage (2), Boise (3), Roseburg (3), Eugene (2), Spokane (3), Walla Walla (2). The software package is a bona fide Fiscal Year 2016 requirement. Attached to this document is the Standardization of Procedural Reporting for Gastrointestinal Endoscopy across VA Work Effort Unique Identifying #20120701, Business Requirements Document. This document supports standardized reporting of Gastrointestinal (GI) endoscopic procedures in the electronic medical record and to enable the capture of standardized information about GI endoscopic procedures across the Veterans Health Administration (VHA).

This request is consistent with the Eight for Excellence goal to continuously improve the quality and safety of healthcare for Veterans, particularly in those health issues associated with military service as well as the Under Secretary's VHA Power of Performance goal to put patient care first, and improve access to care.

Colorectal cancer is the second leading cause of cancer death in North America. Screening of asymptomatic average risk individuals via colonoscopy has been recommended by the VHA Directive on Colorectal Cancer Screening (1015), the United States (US) Preventive Services Task Force, the American Cancer Society (ACS) and the Multi-Society Task Force on Colorectal Cancer (MSTF-CRC). In 2002, the MSTF-CRC identified key quality indicators that would improve the quality of colonoscopy. The Quality Assurance Task Group of the National Colorectal Cancer Round Table (NCCRT) developed a standardized Colonoscopy Reporting and Data system (CO- RADS), as the consensus data elements that should be considered when colonoscopy is performed. Implementation of a GI endoscopic application based upon CO-RADS, would help VHA to improve the quality of care provided to Veterans. See [Appendix A](#) for references.

Standardization of the language of GI endoscopy is becoming increasingly important on account of standardized documentation requirements, and computer-based reporting. The Minimal Standard Terminology (MST) for GI endoscopy is the result of continuous work by the European Society of Gastrointestinal Endoscopy (ESGE), the American Society of Gastrointestinal Endoscopy (ASGE), the World Endoscopy Organization (WEO), and other international collaborators. Incorporation of the MST into the GI endoscopy application will enable structured documentation of endoscopic results, bringing VHA into alignment with international standards.

4. Statutory Authority Permitting Other than Full and Open Competition:

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

The unique qualifications of the aforementioned software package foster an overall facility level of integration which is presently non-existent between the VISN facilities and our healthcare partners in the private sector. The two tertiary care medical centers in VISN 20 (i.e. Puget Sound and Portland) both have academic affiliates (i.e. the University of Washington and the Oregon Health and Sciences University) which have each recently acquired ProVation MD for their endoscopy units. The trainees and gastroenterologists at these academic affiliates also provide clinical services at the VA medical centers. If the VA were to acquire a different software system, it would introduce inefficiencies both in terms of training and ongoing clinical care. Moreover, it would introduce additional risk of incomplete or inaccurate documentation in the medical record. The Puget Sound VA has already experienced this as Puget Sound currently uses Clinical Outcomes Research Initiative (CORI) for endoscopy reporting. The gastroenterology fellows and University of Washington staff physicians are often unfamiliar with this software when they take call. Therefore, they are unable to enter endoscopy reports into CORI when they are on call, leading to incomplete and potentially inaccurate reporting. Endoscopy reports are typed into CPRS, but often key information is missing, this also leads to two different documentation practices and uncertainty where procedural data can be found in CPRS. Additionally, the CORI endoscopy software tracks quality measures and equipment utilization, linking each piece of equipment to the procedure and patient in the event of mechanical issues, recalls, or infection control reviews. By having two different charting programs at our academic affiliates, this introduces substantial risk to patient care in our highest volume centers.

Use of the same endoscopy reporting software at the VA and the academic affiliate, in this instance ProVation MD, will further facilitate more efficient care of Veterans since gastroenterology fellows and surgical residents rotating through the VA gastroenterology section are likely to have already been trained on ProVation MD at the academic affiliate. The Portland VA has 8 gastroenterology fellows and 1 surgical resident rotating between the academic affiliate and the VA. The Puget Sound VA currently has approximately 17 gastroenterology fellows and up to 7 surgical residents who rotate through the endoscopy units of the VA and the academic affiliates. These fellows and surgical residents rotate on a monthly basis. Considerable time would need to be invested in training these house staff upon their arrival at the VA. In addition, the Portland VA has 13 without compensation (WOC) gastroenterology staff who perform endoscopic procedures at the VA while on-call. The Puget Sound VA has approximately 28 WOC gastroenterology staff that perform

endoscopic procedures at the VA while on-call. The vast majority of these WOC staff will be using ProVation on a regular basis at their home institution. When they provide on-call care, there would be no one available to train these staff physicians in the use of the endoscopy reporting software. Therefore, they would need to have already been trained and maintain proficiency in the use of this software. Finally, the Boise VA has signed a 5 year contract with Idaho Gastroenterology Associates (IGA) to provide endoscopic services at the VA. IGA physicians use ProVation for their endoscopic reporting in their private practice. It is expected that approximately 10 IGA physicians will be rotating through the Boise VA on a regular basis.

It would be impractical to train all of these providers in the use of an alternative endoscopy reporting software system. Even if training in the alternative system were provided to these approximately 51 staff physicians and 33 trainees, it would not be possible to assure ongoing proficiency in the use of the system, exposing the VA to risk delays in documentation or incomplete and inaccurate documentation in the medical record which would jeopardize the care of Veterans. Failure to appropriately use the endoscopy software would also introduce risk as surveillance recommendation systems that are built into the software would be bypassed, increasing the risk of missed cancers or other unwanted outcomes.

Across the Pacific Northwest, [REDACTED] medical facilities outside the VA network are using ProVation MD, the stratification of this is as follows: Alaska, [REDACTED] Medical Centers, Idaho, [REDACTED] Medical Centers, Oregon, [REDACTED] Medical Centers, Washington, [REDACTED] Medical Centers. Ultimately, if the VA were to acquire a different software system, it would introduce inefficiencies both in terms of training and ongoing clinical care.

Further embracing the efficiency offered with this solution is the capturing and migration of the current and soon to be unsupportable Olympus EndoWorks imagery storage. The Olympus data migration export tool included with ProVation does not exist as a packaged solution and there is great risk of loss to the veterans care records without this capability being procured at this time. The cost for this data migration capability is [REDACTED] [REDACTED] additional fees may apply if each facility migrates individually).

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** The contracting officer conducted market research via release of a sources sought synopsis on 24 July 2016 and determined the GI software market had three respondents to the request. Due to the critical nature of the academic relationships and the continuity required under this requirement for a singular training program, none of the respondents could offer the ProVation software package to the capacity required for an enterprise-wide solution. The products [REDACTED] were not compatible with the VISN need as a result of the obvious loss of efficiency and the

impractical approach to cross-train all providers in the use of an alternative endoscopy reporting software system which were offered as solutions to this sources sought synopsis.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Commercial pricing is available for this software package and comparison between commercial off the shelf pricing and validation through other VISN pricing packages will be completed.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** The contracting officer conducted market research on 24 July 2016 and determined the GI software market had three respondents to the request. None of which could offer the ProVation software package. As this program matures and the technological advances progress, 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 offered competitively.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** This solution will strengthen the already existing affiliate agreement in the form of standardizing the same endoscopy reporting software at the VA and the academic affiliates, in this instance the University of Washington and Oregon Health and Sciences University, and in doing so delivery a more efficient care of Veterans since gastroenterology fellows and surgical residents rotating through the VA gastroenterology section will have been trained on ProVation MD at the academic affiliate.

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED] [REDACTED]	[REDACTED]	[REDACTED]

11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:** The Department of Veterans Affairs (VA) Veterans Health Administration (VHA) has executed a Business Associate Agreement (Agreement) to establish requirements with ProVation Medical, Inc. in accordance with the Health Insurance Portability and Accountability Act (HIPAA), the Health Information Technology for Economic and Clinical Health Act (HITECH) Act, and the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules ("HIPAA Rules"), 45 C.F.R. Parts 160 and 164, for the Use and Disclosure of Protected Health Information (PHI) under the terms and conditions specified below. With respect solely to the subject matter herein, the terms and conditions in this National Business Associate Agreement supersede any previous Agreement, as well as

any local Business Associate Agreement between ProVation Medical, Inc. and a component of VHA. Accordingly, this Agreement, unless otherwise provided, will control and cannot be superseded, modified, or nullified by any local Business Associate Agreement.

- 12. 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 and belief.

[REDACTED]

Sept 12, 2016

[REDACTED]

[REDACTED]

[REDACTED]

12 Sep 16

[REDACTED]

[REDACTED]

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