

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA248-16-AP-5649

1. **Contracting Activity:** Department of Veterans Affairs, VISN 08, Tallahassee Healthcare Center, Tallahassee, FL. The Ophthalmology Department. Funding under PR 573-17-1-1015-0009.
2. **Nature and/or Description of the Action Being Processed:** This procurement is for the award of a new firm-fixed priced equipment purchase. The Optical Coherence Tomography (OCT) which provides visualization of the retina and optic nerve within the eye using a scan technology as well as software to assist with analysis. This acquisition is 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.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Ophthalmology department is requesting the purchase of one (1) Optical Coherence Tomography (OCT) Equipment with the Cirrus OCT with Angioplex, two (2) VISU CAM 224 fundus camera, two (2) Humphrey Field Analyzer (HFA3) 3 Model 860 with Liquid Trial Lens, one (1) Atlas 9000 3.0 with Printer including Pathfinder II & DICOM Gateway License, one (1) Zeiss SL 130 including Tray and Pin Assembly and Binocular, two (2) HT2 Power Table, as well as one (1) SL CAM 5.0 for Slit Lamp Models SL 120/130 which includes Slit Lamp Imaging Software, Footswitch and DIGICAM Illuminator with a total estimated cost of \$283,125.00. The equipment will be delivered to the new Tallahassee Healthcare Center recently opened. These new units are needed as soon as possible to provide optical services to veterans while maintaining the high standard of care.
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;
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** This is a Brand Name Requirement. The Zeiss Cirrus HD-OCT Model 5000 equipment is compatible with existing Zeiss units, being able to communicate and transfer data from one unit to another, and are already configured and networked to our databases. Our VA population has a high prevalence of Glaucoma and retinal disease. This instrument significantly improves the ability of the clinicians to make appropriate treatment decisions involving glaucoma and retinal disease as well as the need for surgeries. The current OCT 4000 is through Carl Zeiss and has been

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used to capture patient's clinical information and images for diagnostic purposes for the past 5 years. The updated equipment has the ability to import and integrate the Cirrus Model HD 4000 'raw data', obtained over the past five years, currently being used at this medical center. The raw data must be interchangeable and compatible between the Cirrus 4000 and Cirrus 5000 unit. This allows the clinic to import the patients' data from the Cirrus 4000 and incorporate it into the Cirrus 5000, which allows for continuity and precise progression data management. If not, all data from the Cirrus 4000 becomes only a static report in PDF format that cannot be built upon. While other manufacturer's equipment can perform the same basic function, none are compatible with the previously stored data. Historical data will be useless and it will be necessary to start new baseline data. Currently, we have greater than 5 years of patient data which needs to be integrated into the new machine. Having this data and integrating onto the new machine allows providers to assess progression or resolution of disease states. Assessing progression helps to determine treatment necessity as well as aggressiveness of the treatment. The unit must be able to 'track' to prior scans and assess the same area of the nerve fiber layer and macula as previous scans. It will be necessary to upload current patient's data and images to the new OCT for continuity of care for our veterans. The Carl Zeiss machine is able to run Guided Progression Analysis of the optic nerve or Macular Change analysis utilizing the historical data from Zeiss Cirrus in a report. This unit is able to 'track' to prior scans and assess the same area of the nerve fiber layer and macula as previous scans. Maintaining the same vendor will allow a smooth transfer of patient's information, images and eliminate the potential for interface miscommunication between the old and the new equipment.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market Research shows that the manufacturer (Carl Zeiss) only authorizes one distributor (ProAim Americas, LLC.) to provide this equipment (documentation on file). There are no other interested sources other than the manufacturer that can provide the needed equipment.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost is considered fair and reasonable per FAR 13.106-3(a)(2)(ii). Purchase Order VA241-16-P-0666 was awarded at a price of \$232,251.39 for the exact same equipment in 2016. The slight escalation in price is due to technology upgrades (see section 5 above).
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Searches were conducted online to confirm the item is available on the commercial market place. A search was conducted on the VIP website using NAICS code 333314 and a total of 25 vendors were located. Of those 25 vendors there was 1 listed as a VOSB and 24 listed as SDVOSB's. All 25 vendors were contacted with an RFI via email and 0 responses were received from SDVOSB or VOSB vendors having the ability to provide the needed item. FBO and FPDS were searched for the same and similar procurements. Prior purchases found on FBO and FPDS for this exact equipment were awarded to a single small business. The Contracting Officer for the prior purchase of VA241-16-P-0666 located in VISN 1 was contacted via email and provided further information and documentation on their purchase of this exact equipment revealing there is only one authorized small business distributor able to provide the needed equipment. A sole proprietor letter from the manufacturer (Carl Zeiss), stating that the only authorized distributor of Carl Zeiss optometric equipment was received. The sole proprietor letter listed Proaim Americas, LLC (Small Business) as the only authorized distributor of the equipment. Waiver to the Non-Manufacturers rule has been received by the SBA and is on file.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None

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10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Proaim Americas, LLC 209 Bontiful Pointe Cir, Grover, MO 63040-2126.

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 only way the organization may overcome the barrier to competition is by investing in all new equipment which is not a financially sound decision or by Carl Zeiss authorizing a broader range of distributors for their products. If this need shall arise again in the future the market will be reevaluated to determine if the brand restrictions still apply.

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.